

STATE OF FLORIDA DEPARTMENT OF HEALTH BUREAU OF RADIATION CONTROL



REGULATORY GUIDE

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General Instructions and Guidance for documenting Training and Experience for **Proposed Authorized Users**

Preceptor Attestation for Medical Authorized Users

Regulatory guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Chapter 64E-5, Florida Administrative Code ("State of Florida Control of Radiation Hazard Regulations") to delineate techniques used by the staff in evaluating specific problems or postulating accidents, or to provide guidance to applicants or licensees. Regulatory guides are not a substitute for regulations and compliance with them is not required unless specifically referenced in a radioactive materials license. Methods or solutions different from those set forth in the guides will be acceptable if they provide a basis for the Bureau of Radiation Control to make necessary determinations to issue, renew, amend, or terminate a license, or to establish standards of protection.

Guides are issued in the following six broad categories: 1) License Application Guides 4) Radioactive Waste 2) Inspection and Enforcement 3) General Health Physics

5) Transportation 6) General

Written comments and suggestions for improvements to regulatory guides are encouraged at all times. Guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments, or requests for single copies or issued guides (which may be reproduced) should be sent to: Department of Health, Bureau of Radiation Control, Radioactive Materials Section, 4052 Bald Cypress Way, Bin C21, Tallahassee, FL 32399-1741.

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I. INTRODUCTION

A. PURPOSE OF GUIDE

This guide is intended for applicants who are requesting to be listed on a radioactive materials license as an authorized user of radioactive materials for medical purposes. It contains instructions to select and prepare the appropriate application form(s) for the authorized use(s) being requested. These forms document the applicants training and experience and must include the preceptor's attestation of this training.

B. APPLICABLE REGULATIONS

The following medical sections of Chapter 64E-5, Florida Administrative Code (F.A.C.), should be used in conjunction with these instructions:

- Uptake, Dilution, and Excretion "64E-5.649, Florida Administrative Code"
- Imaging and Localization "64E-5.650, Florida Administrative Code"
- Radiopharmaceuticals for Therapy "64E-5.651, Florida Administrative Code"
- Remote Afterloader "64E-5.655, Florida Administrative Code"
- Gamma Stereotactic Radiosurgery "64E-5.655, Florida Administrative Code"
- Manual Brachytherapy "64E-5.652, Florida Administrative Code"
- Ophthalmic use of Strontium-90 "64E-5.653, Florida Administrative Code"
- Teletherapy Unit "64E-5.655, Florida Administrative Code"
- Radiation Safety Officer "64E-5.648, Florida Administrative Code"
- Authorized Medical Physicist "64E-5.656, Florida Administrative Code"

Each of these medical uses requires specific training and this guide provides multiple pathways for documenting the required training and experience for each type of use. This guide represents the minimum documentation necessary to comply with the regulatory requirements which can be found in the above referenced rule.

C. PURPOSE OF APPENDICES

Each appendix consists of two parts: 1) the instructions and 2) the form. The instructions contain guidance for completing each item on the form. All relevant items on the form must be completed and appropriately signed where indicated. Incomplete items will delay the approval of the application. Depending on the type and number of authorized uses being requested, it may be necessary to complete and submit several of the forms to be granted the requested authorized uses.

II. GENERAL INSTRUCTIONS

Name of individual

Provide the individual's complete name so that The State of Florida can distinguish the training and experience received from that received by others with a similar name.

Note: Do <u>not</u> include personal or private information (e.g., date of birth, social security number, home address, personal phone number) as part of your qualification documentation.

Professional Licensure

The State of Florida requires physicians, dentists, podiatrists, and pharmacists to be licensed by Florida to prescribe drugs in the practice of medicine, practice dentistry, practice podiatry, or practice pharmacy, respectively (see definitions of "physician," "dentist," "podiatrist," and "pharmacist"). Please see Florida Department of Health, Division of Medical Quality Assurance - http://www.doh.state.fl.us/mqa/

Requested Authorization(s).

Check all authorizations that apply to you and fill in the blanks as provided.

PART I. TRAINING AND EXPIRENCE

There are always multiple pathways provided for each training and experience section. Select the applicable one.

A. ITEM 1. Board Certification

The applicant may use this pathway if the individual is certified by a board recognized by the State of Florida and the NRC (to confirm that the board is recognized, see NRC's web page http://www.nrc.gov/materials/miau/med-usetoolkit.html.

Note: An individual that is board eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will not be considered for this pathway.

The applicant will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework as indicated on the applicable preceptor attachment.

All applicants under this pathway (except for 64E-5.631 Sealed Sources for Diagnosis) must submit a completed Part II Preceptor Attestation.

B. ITEM 2. Currently Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific preceptor attachment. (*Note:* This section does not include individuals who are authorized only on foreign licenses.)

All applicants under this pathway must submit a completed Part II Preceptor Attestation.

C. ITEM 3. Alternate Pathway for Training and Experience for Proposed Applicant

This pathway is used by those individuals not listed on a license as an authorized individual, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised clinical experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (a) classroom and laboratory training, or (b) supervised work experience. Please note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities: therefore, space is provided to identify each location and dates of training or experience. Dates should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the "classroom and laboratory training," provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The applicant may obtain the required "classroom and laboratory training" in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the State of Florida will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

C. ITEM 3. <u>Alternate Pathway for Training and Experience for Proposed</u> <u>Applicant (Continued)</u>

Under the "supervised work experience" sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements, to confirm that the listed subject areas were included in the supervised work experience.

The "supervised work experience" for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The State of Florida recognizes that physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the State of Florida, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

Note: If the applicant had more than one supervisor, provide the information requested for each supervising individual.

PART II. PRECEPTOR ATTESTATION

The State of Florida defines the term "preceptor" in 64E-5.6011, F.A.C. "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer." While the supervising individual for the clinical experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the required training and experience. The preceptor must attest in writing regarding the training and experience of the applicant to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience criteria and has achieved a level of competency or a level of radiation safety knowledge sufficient to function independently. Preceptors must meet specific requirements.

The State of Florida allows for supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various types of licensed facilities, from teaching university hospital to a small private practice.

The Preceptor Attachments Part II - Preceptor Attestation has multiple sections. The preceptor must complete and sign the attestation of the applicants training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each Preceptor Attachment.

Appendix 1

"Written Directive NOT Required" [Uptake, Dilution, and Excretion], [Imaging and Localization] [Sealed Sources for Diagnosis]

Note: Preceptor Attestation for uses defined under 64E-5.626(1), .627(1), .628 and .631 and training and experience under 64E-5.649, .650, and .654

PART I. Training and Experience - select one of the three methods below:

ITEM 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

ITEM 2. Current 64E-5.660 Authorized User Seeking Additional 64E-5.650 Authorization

- (a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.
- (b) Provide a description of the proposed user's experience that meets the requirements of

64E-5.650(3)(a)(2)(g)(generators) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an authorized user.

ITEM 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

Note: Providing the training and experience information required under 64E-5.650 (Imaging and Localization non written directive) will allow the individual to be authorized to use materials permitted by both 64E-5.626(1) and 64E-5.627(1).

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 64E-5.631 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 64E-5.631 uses.

Submit a completed Preceptor Attestation, except for 64E-5.631 uses.

PART II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The attestations for training and experience requirements in 64E-5.649 and 64E-5.650 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

The preceptor must fill out both sections.

Note: The attestation to the proposed user's training and competency to function independently under 64E-5.649 covers the use of material permitted by 64E-5.626(1) only. The attestation to the proposed user's training and competency to function independently under 64E-5.650 training will allow the individual to be authorized to use material permitted by both 64E-5.626(1) and 64E-5.627(1).

APPENDIX 1 Written Directive NOT Required UPTAKE, DILUTION, AND EXCRETION IMAGIND AND LOCALIZATION NOT REQUIRING WRITTEN DIRECTIVE LESS THAN 30 MICROCURIES OF NaI-131				
	ERIENCE AND PRECEPTOR ATTESTATION (1), .628 and .631) [64E-5.649, .650, and .654]			
Name of Proposed Authorized User	State or Territory Where Licensed			
Requested Authorization(s) (check all that apply)				
□64E-5.626(1)Uptake, dilution, and excretion studies	64E-5.627(1) Imaging & Localization			
□64E-5.631 Sealed sources for diagnosis (specify de	evice)			
PART I TRAININ	G AND EXPERIENCE			
	three methods below)			
* Training and Experience, including board certification, mu the date of application or the individual must have obtained the required training and experience was completed. Pro- education and experience related to the uses checked ab	ed related continuing education and experience since ovide dates, duration, and description of continuing			
1. Board Certification http://www.nrc.gov/materials/miau/m	ed-use-toolkit/spec-board-cert.html			
a. Provide a copy of the board certification.				
 b. If using only 64E-5.631 materials, stop here. If using complete Part II Preceptor Attestation. 	g 64E-5.626 and 64E-5.627 materials, skip to and			
2. Current 64E-5.660 Authorized User Seeking Addit	ional 64E-5.650 Authorization			
a. Authorized user on Materials License meeting 64E-5.660 or equivalent NRC or Agreement				
State requirements seeking authorization for 64E-5.				
 b. Supervised Work Experience. (If more than one supervising individual is necessar, copies of this section.) 	y to document supervised work experience, provide multiple			
	berience/License or Clock Dates of Experience			
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs				
Total Hours of Experience:				
Supervising Individual				
Supervisor meets the requirements below, or equivalent Agreement State requirements <i>(check all that apply).</i> 64E-5.650 64E-5.660 64E-5.650(3)(a)(2)(g)(generators)				

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] continued

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

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			
Chemistry of byproduct material for medical use <i>(not required for 64E-5.654)</i>			
Radiation biology			
	Total House of Training.	1	

Total Hours of Training:

b. Supervised Work Experience (completion of this table is not required for 64E-5.654). (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervise Work Experience	Total Hours of Experience:		
Description of Experience	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		□Yes □No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		□Yes □No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] continued

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

b. Supervised Work Experience. (continued)

Description of Experience		of Experience/License or nit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages			□Yes □No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material			□Yes □No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures			□Yes □No	
Administering dosages of radioactive drugs to patients or human research subjects			□Yes □No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			□Yes □No	
Supervising Individual		License/Permit Number listing as an authorized user	supervising ir	ndividual
Supervisor meets the requirements below, or equivalent Agreement State requirements (check one).				
□64E-5.649 □64E-5.650	□64E-5.660	□64E-5.650(3)(a)(2)(g)(gene	rators)	

c. For 64E-5.654 only, provide documentation of training on use of the device.

Type of Training	Location and Dates
	Type of Training

d. For 64E-5.631 uses only, stop here. For 64E-5.626 and 64E-5.627 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] 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. (Not required to meet training requirements in 64E-5.654)				
	By checking the boxes below of the position sought and ne				ill the duties
First So Check	ection one of the following for eac	h use requested:			
For	64E-5.626(1)				
	Board Certification				
	I attest that		has satisfactorily co	mpleted the requiremen	ts in
	Name of F	roposed Authorized User			
	64E-5.649(1) and has ac authorized user for the m			nction independently as	an
			OR		
	Training and Experience "No	n Written Directive			
	I attest that		has satisfactorily co	mpleted the 60 hours of	training and
	experience, including a n	roposed Authorized User	classroom and laborat	tory training required by	
	64E-5.649(3), and has a authorized user for the m	hieved a level of com	petency sufficient to fu		
For	64E-5.627(1)				
	Board Certification				
	I attest that has satisfactorily completed the requirements in			ts in	
	Name of Proposed Authorized User				
	64E-5.650(1) and has ac authorized user for the m				an
			OR		
	Training and Experience "No	n Written Directive"			
	I attest that		has satisfactorily co	mpleted the 700 hours o	of training
	Name of F	roposed Authorized User			
	and experience, including a minimum of 80 hours of classroom and laboratory training, required by 64E-5.650(3)(a), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 64E-5.626 and 64E-5.627.				
Second	Second Section				
Comple	ete the following for precep		-	amonto en en dest	d upon fam
	I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:				
	□64E-5.649 □64E-5.650 □64E-6.660 □64E-5.650(3)(a)(2)(g)(generators)				
Name of	f Preceptor	Signature		Telephone Number	Date
License/Permit Number/Facility Name					

Appendix 2

"Written Directive Required" [Uptake, Dilution, and Excretion], [Imaging and Localization] [Radiopharmceuticals for Therapy]

Note: Preceptor Attestation for uses defined under 64E-5.626, .627, .630 and training and experience under 64E-5.660, .661, .662 and .663

Part I. Training and Experience - select one of the three methods below:

ITEM 1. Board Certification

If the applicant is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 35.300 on NRC's website, provide the requested information (i.e., a copy of the board certification, documentation of supervised clinical experience (complete the table in section 3.c), and completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or supervised clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

If the applicant is a radiation oncologist whose board certification is not listed under10 CFR 35.300 on NRC's website, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's website, documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training and supervised work experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

ITEM 2. Current 64E-5.630, 64E-5.632, or 64E-.634 Authorized User Seeking Additional Authorization

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the applicant is currently authorized for a subset of clinical uses under 64E-5.630, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

If the applicant is currently authorized under 64E-5.652 or 64E-5.655 and meets the requirements in 64E-5.663, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b); documentation of supervised clinical experience (complete the table in Section 3.c); and completed Preceptor Attestation)). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an authorized user.

Appendix 2 "continued"

ITEM 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the degree, training and/or work experience was completed more than 7 years ago.

Submit a completed section 3.a.

Submit a completed section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an authorized user.

Submit a completed section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an authorized user.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The attestations for training and experience requirements in 64E-5.660, 64E-5.661, and 64E-.662 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for competency to function independently as an authorized user for specific uses is in the third section.

The attestation for training and experience requirements and competency to function independently for a radiation oncologist meeting the requirements in 64E-5.663 is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

There are seven possible categories of individuals seeking authorized user status under this form. Follow the instructions for the applicable category.

The preceptor for a proposed authorized user who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on NRC's website must complete the first, second, third, and fifth sections of this part.

The preceptor for a proposed authorized user for all the uses listed in 64E-5.660(2)(g) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on NRC's website must complete the first, second, third, and fifth sections of this part.

The preceptor for a proposed authorized user for 64E-5.630(2) and .630(3) uses who is a radiation oncologist with a board certification listed under 10 CFR 35.490 or 10 CFR 35.690 on NRC's website must complete the fourth and fifth sections of this part.

The preceptor for an authorized user who is currently authorized for a subset of clinical uses under 64E-5.630 must complete the second, third, and fifth sections of this part, except for an authorized user meeting the criteria in 64E-5.661 seeking to meet the training and experience requirements under 64E-5.662.

The preceptor for an authorized user meeting the criteria in 64E-5.661 seeking to meet the training and experience requirements under 64E-5.662 must complete the first, second, third, and fifth sections of this part.

The preceptor for an authorized user currently authorized under 64E-5.652 or 64E-5.655 and meeting the requirements in 64E-5.663 must complete the fourth, and fifth sections of this part.

The preceptor for a proposed new authorized user must complete the first, second, third and fifth sections of this part.

APPENDIX 2 Written Directive Required			
UPTAKE, DILUTION, AND EXCRETION IMAGING AND LOCALIZATION			
RADIOPHARMCEUTICALS FOR THERAPY AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and.663]			
Name of Proposed Authorized User State or Territory Where Licensed			
Requested Authorization(s) (check all that apply):			
64E-5.626 Uptake, dilution, and excretion studies 64E-5.627 Imaging & Localization			
64E-5.630 (1)Unsealed radiopharmaceuticals including parenteral use and sodium iodide I-131			
64E-5.630 (2)Only for oral administration of sodium iodide I-131 less than or equal to 33 millicuries			
64E-5.630 (3)Only for oral administration of sodium iodide I-131 greater than or equal to 33 millicuries			
64E-5.630 (4)Only Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
64E-5.630 (4)Only Parenteral administration of any other radionuclide for which a written directive is required			
PART I TRAINING AND EXPERIENCE			
<i>(Select one of the three methods below)</i> Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have 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 http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html			
a. Provide a copy of the board certification.			
 b. For 64E-5.660, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience. 			
c. For 64E-5.663, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.			
d. Skip to and complete Part II Preceptor Attestation.			
2. Current 64E-5.630. 64E-5.632. or 64E-5.634 Authorized User Seeking Additional Authorization			
a. Authorized User on Materials License under the requirements below or			
equivalent Agreement State requirements (check all that apply):			
64E-5.660 64E-5.661 64E-5.662 64E-5.652 64E-5.655			
b. If currently authorized for a subset of clinical uses under 64E-5.630, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.			
c. If currently authorized under 64E-5.652 or 64E-5.655 and requesting authorization for 64E-5.663, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .633]				
3. <u>Training and Experience for Proposed Authorized User</u> a. Classroom and Laboratory Training 64E-5.660 64E-5.661 64E-5.662 64E-5.663				
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				
Chemistry of byproduct material for medical use				
Radiation biology				
	Total Hours of Training:			
 b. Supervised Work Experience If more than one supervising of this page. Description of Experience 	64E-5.660 64E-5.661 64E individual is necessary to document supervised train Location of Experience/License or Permit Number of Facility		64E-5.663 Iltiple copies Dates of Experience*	
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		□Yes □No	Experience	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		□Yes □No		
Calculating, measuring, and safely preparing patient or human research subject dosages		□Yes □No		
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		□Yes □No		
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		□Yes □No		
Total Hours of Supervised Work Experience:				

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .663]

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

b. Supervised Work Experience (continued)

Supervising Individual		License/Permit Number listing supervising individual as an authorized user
Supervising in (check all that		r equivalent Agreement State requirements
□64E-5.660 □64E-5.661 □64E-5.662 □64E-5.663	Only for oral administration of sodium Parenteral administration of beta-emi less than 150 keV requiring a written	n iodide I-131 less than or equal to 33 millicuries n iodide I-131 greater than or equal to 33 millicuries itter, or photon-emitting radionuclide with a photon energy directive or radionuclide requiring a written directive

* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. Supervised Clinical Case Experience If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral adminstration of any other radionuclide for which a written directive is required			

	AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .663]					
3.	3. Training and Experience for Proposed Authorized User (continued)					
	c. Supervised	Clinical Case Experience	(continued)			
	Supervising Individual License/Permit Number listing supervising individual as an authorized user					
	Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:					
	□64E-5.660	With experience administeri	ing dosages of:			
	□64E-5.661	Only for oral adminis	tration of sodium iodide I-131 less than or equal to 33 millicuries			
			tration of sodium iodide I-131 greater than or equal to 33 millicuries			
	□64E-5.662	Parenteral administra	ation of beta-emitter, or photon-emitting radionuclide with a photon energy quiring a written directive			
	□64E-5.663	_	ation of any other radionuclide requiring a written directive			
		thorized User must have exper horized user status.	ience in administering dosages in the same dosage category or categories as the individual			
	d. Provide com	npleted Part II Preceptor A	Attestation.			
		PAR	T II – PRECEPTOR ATTESTATION			
Not	individual as	s long as the preceptor pi	ndividual's preceptor. The preceptor does not have to be the supervising rovides, directs, or verifies training and experience required. If more than tent experience, obtain a separate preceptor statement from each.			
			receptor is attesting that the individual has knowledge to fulfill the duties ng to the individual's "general clinical competency."			
	st Section eck one of the fo	ollowing for each reque	sted authorization:			
	For 64E-5.660:					
	Board Cert	ification				
	I attest that has satisfactorily completed the training and experience					
	Name of Proposed Authorized User requirements in 64E-5.660(1)(a).					
	OR					
	<u>Training an</u>	d Experience				
	I attest t		has satisfactorily completed the 700 hours of training			
	Name of Proposed Authorized User and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 64E-5.660(2)(a).					

(for use	es defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .663]
Preceptor Attes	station (continued)
First Section (continu	Jed)
For 64E-5.661 (Identi	cal Attestation Statement Regardless of Training and Experience Pathway):
I attest that	has satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User
	training, as required by 64E-5.661(3)(a), and the supervised work and clinical case uired in 64E-6.661(3)(b).
For 64E-5.662 (Identin	cal Attestation Statement Regardless of Training and Experience Pathway):
I attest that	has satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User
	training, as required by 64E-5.662(3)(a), and the supervised work and clinical case uired in 64E-5(3)(b).
Second Section	
I attest that	has satisfactorily completed the required clinical case
	Name of Proposed Authorized User
experience requ	uired in 64E-5.660(2)(g) listed below:
	1 requiring a written directive in quantities less than or equal to 1.22 rels (33 millicuries)
Oral Nal-13	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	administration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
Parenteral a	administration of any other radionuclide requiring a written directive
,	
Third Section	
I attest that	has satisfactorily achieved a level of competency to
	Name of Proposed Authorized User
function indepe	ndently as an authorized user for:
	1 requiring a written directive in quantities less than or equal to 1.22 rels (33 millicuries)
Oral Nal-13 [,]	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
Parenteral a	administration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
ee.g)ee	than too key requiring a written areotive is required

	AINING AND EXPERIENCE AND PR nder 64E-5.626, .627, .630) [64E-5.6		-		
Fourth Section			_		
<u>For 64E-5.663:</u>					
Current 64E-5.652 or .64E-5.655	authorized user:				
I attest that	is an authorized us	er under 64E-5.652 or .6	64E-5.655		
or equivalent Agreement Stat laboratory training, as require	or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 64E-5.663(4)(a), and the supervised work and clinical case experience required by 64E-5.663(4)(b), and has achieved a level of competency sufficient to function independently				
	of any beta-emitter, or photon-emitting rac written directive is required	lionuclide with a photon e	energy less		
Parenteral adminstration	of any other radionuclide for which a writte	en directive is required			
	OR				
Board Certification:					
I attest that		ompleted the board certif	fication		
requirements of 64E-5.663(3) training required by 64E-5.66	Name of Proposed Authorized User requirements of 64E-5.663(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 64E-5.663(4)(a) and the supervised work and clinical case experience required by 64E-5.663(4)(b), and has achieved a level of competency sufficient to function independently as an authorized user for:				
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required					
Parenteral adminstration of any other radionuclide for which a written directive is required					
Fifth Section Complete the following for preceptor	attestation and signature:				
I meet the requirements below, c	or equivalent Agreement State requiremen	its, as an authorized user	for:		
64E-5.660 64E-5.661	64E-5.662 64E-5.663				
I have experience administering requesting authorization.	I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.				
Oral Nal-131 requiring a writt millicuries)	Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
Oral Nal-131 in quantities gre	Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)				
	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required				
Parenteral administration of a	ny other radionuclide requiring a written d	lirective			
Name of Preceptor	Signature	Telephone Number	Date		
License/Permit Number/Facility Name					

Appendix 3

[Remote Afterloader], [Gamma Stereotactic Radiosurgery], [Manual Brachytherapy], [Ophthalmic Use of Strontium-90], [Teletherapy Unit]

Note: Preceptor Attestation for uses defined under 64E-5.632, .634 and training and experience under 64E-5.652, .653, and .655

PART I. Training and Experience - select one of the three methods below:

ITEM 1. Board Certification

Provide the requested information (i.e., a copy of the board certification) for 64E-5.634 uses documentation of device-specific training in the table in 3.e, and for all uses, a completed Preceptor Attestation. As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users, or either a supervising authorized user or an authorized medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.e

if the training was provided by an authorized user or authorized medical physicist. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 2. Current 64E-5.634 Authorized User Requesting Additional Authorization for 10 CFR 35.64E-5.634 Use(s) Checked Above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.e)) and completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising authorized user, or an authorized medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.e if the training was provided by an authorized user or authorized medical physicist. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 3. Training and Experience for Proposed Authorized User

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience was completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 64E-5.632 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising authorized user provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising authorized user provided the supervised clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.d for each requested 64E-5.634 use. If more than one supervising authorized user provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.e for each specific 64E-5.634 device for which the applicant is requesting authorization.

Appendix 3 "continued"

Device-specific training may be provided by the vendor, a supervising authorized user or an authorized medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.e if the training was provided by an authorized user or authorized medical physicist. If more than one supervising individual provided the training, identify each supervising individual by name and provide their qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The attestation to the training and individual's competency for 64E-5.632 uses or strontium-90 eye applicator use is in the first section.

The attestation to the training for the proposed authorized user for 64E-5.634 uses is in second section.

The attestation for the 64E-5.634 device-specific training is in the third section.

The attestation of the individual's competency to function independently as an authorized user for the specific, 64E-5.634 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, in addition to the preceptor's signature.

The preceptor for a 64E-5.632 proposed authorized user must fill out the first and fifth sections of this Part.

The preceptor for a 64E-5.634 proposed authorized user must fill out the second, third, fourth and fifth sections.

The preceptor for an authorized user seeking additional 64E-5.634 authorizations must complete the third, fourth, and fifth sections.

APPENDIX 3 HEALTH REMOTE AFTERLOADER, GAMMA STEREOTACTIC RADIOSURGERY MANUAL BRACHYTHERAPY, OPHTHALMIC USE OF STRONTIUM-90, TELETHERAPY UNIT				
AUTHORIZED USER TI (for uses defined und				TATION
Name of Proposed Authorized User		State or Territory Whe	ere Licensed	
Authorization(s)632(2) Op (check all that apply)	ual brachytherapy sour ohthalmic use of stron amma stereotactic rad	tium-90 .634(3)	Remote afterloader un Teletherapy unit(s)	it(s)
	PART I TRAINING (Select one of the t	G AND EXPERIENC		
*Training and Experience, including Bo of application or the individual must have training and experience was complete experience related to the uses checke	ave obtained related co d. Provide dates, dura d above.	ontinuing education a ation, and descriptior	and experience since the of continuing education of continuing education of continuing education of the other second s	ne required
□ 1. <u>Board Certification http://www</u>		ned-use-toolkit/spec-boa	ard-cert.html	
 a. Provide a copy of the board of b. For 64E-5.634, go to the table for which authorization is sough 	in 3.e. and describe t	raining provider and	dates of training for ea	ch type of use
c. Skip to and complete Part II P	-			
2. <u>Current 64E-5.634 Authorized</u>	User Requesting Add	ditional Authorization	on for 64E-6.634 Use(<u>s) Checked Above</u>
a. Go to the table in section 3.e.	to document training f	or new device.		
b. Skip to and complete Part II P	receptor Attestation.			
3. <u>Training and Experience for</u>	Proposed Authorize	d User		
a. Classroom and Laboratory Tra	aining 64E-5.652	64E-5.653	64E-5.655	
Description of Training	Locat	ion 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</u> (continued)

b. Supervised Work and Clinical Experience for 64E-5.652 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Description of Experience	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		□Yes □No	
Checking survey meters for proper operation		□Yes □No	
Preparing, implanting, and safely removing brachytherapy sources		□Yes □No	
Maintaining running inventories of material on hand		□Yes □No	
Using administrative controls to prevent a medical event involving the use of byproduct material		□Yes □No	
Using emergency procedures to control byproduct material		□Yes □No	
1	Total Hours of Work Experience		l
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 Authorized User	supervising indi	vidual as an

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

c. Supervised Clinical Experience for 64E.653

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 Authorized User	supervising indi	vidual as an

d. Supervised Work and Clinical Experience for 64E-5.655

.634(1) Gamma stereotactic radiosurgery unit(s)

.634(2)Remote afterloader unit(s)

.634(3) Teletherapy unit(s)

Description of Experience	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	
т	otal Hours of Work Experience		

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

d. Supervised Work and Clinical Experience for 64E-5.655 (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 supervising indi Authorized User	vidual as an

e. For 64E-5.634, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training		Training Provider and Dates	
	Gamma Stereotactic Radiosurgery .634(1)	Remote Afterloader .634(2)	Teletherapy .634(3)
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
	ollowing 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.		

		PART II – PRECEPTOR ATTESTATION
Note:	individual as long as the one preceptor is neces	pleted by the individual's preceptor. The preceptor does not have to be the supervising the preceptor provides, directs, or verifies training and experience required. If more than assary to document experience, obtain a separate preceptor statement from each.
		s below, the preceptor is attesting that the individual has knowledge to fulfill the duties and not attesting to the individual's "general clinical competency."
	Section a one of the following for	or each requested authorization:
<u>For 6</u>	<u>64E-5.652:</u>	
<u>Boar</u>	d Certification	
	I attest that	has satisfactorily completed the requirements in
	-	Name of Proposed Authorized User
		nd has achieved a level of competency sufficient to function independently as an manual brachytherapy sources for the medical uses authorized under 64E-5.632.
-		OR
L	raining and Experience	
	I attest that	has satisfactorily completed the 200 hours of Name of Proposed Authorized User
	clinical experience of competency suf	boratory training, 500 hours of supervised work experience, and 3 years of supervised in radiation oncology, as required by 64E-5.652(2)(a) and (2)(b), and has achieved a level ficient to function independently as an authorized user of manual brachytherapy sources as authorized under 64E-5.632.
For 6	64E-5.653:	
	I attest that	has satisfactorily completed the 24 hours of
		Name of Proposed Authorized User
	has used strontium	pratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, n-90 for ophthalmic treatment of 5 individuals, as required by 64E-5.653(2), and has competency sufficient to function independently as an authorized user of strontium-90 for
Seco	ond Section	
<u>For (</u>	64E-5.655:	
E	Board Certification	
	I attest that	has satisfactorily completed the requirements in
	64E-5.655(1)(a).	
		OR
	Training and Experien	
	I attest that	has satisfactorily completed 200 hours of classroom
		Name of Proposed Authorized User
		aining, 500 hours of supervised work experience, and 3 years of supervised clinical liation therapy, as required by 64E-5.655(2)(1) and (2)(2).
		AND

	AINING AND EXPERIENCE AND PR der 64E-5.632 and .634) [64E-5.652		-
Preceptor Attestation (continued)			
Third Section			
<u>For 64E-5.655:</u> (continued)			
I attest that		ning required in 64E-5.65	55(3) for device
	oposed Authorized User s, and clinical use for the type(s) of use fo	r which authorization is s	ought, as
Remote afterloader unit(s) 🗌 Teletherapy unit(s) 🗌 Gamm	a stereotactic radiosurge	ery unit(s)
	AND		
Fourth Section			
I attest that	has achieved a le	evel of competency suffic	cient to
	cy sufficient to function independently as	an authorized user for:	
Remote afterloader unit(s) 🗌 Teletherapy unit(s) 📃 Gamm	a stereotactic radiosurge	ery unit(s)
Fifth Section			
Complete the following for precepto	r attestation and signature.		
	4E-5.652, .653, .655, or equivalent Agree	ment State requirements	, as an
64E-5.632(1) Manual brachy sources	therapy 64E-5.634(1) Gamma	a stereotactic radiosurge	ry unit(s)
64E-5.632(2) Ophthalmic us strontium-90	e of 64E-5.634(2) Remote	e afterloader unit(s)	
64E-5.634(3) Teletherapy ur	nit(s)		
Name of Preceptor	Signature	Telephone Number	Date
License/Permit Number/Facility Name			

Appendix 4 Radiation Safety Officer

Note: Preceptor Attestation for training and experience under 64E-5.648

Part I. Training and Experience - select one of four methods below:

ITEM 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of specific radiation safety training for all types of use on the license, and completed preceptor attestation). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in 3.c) and completed preceptor attestation in Part II). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, an authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.c if the training was provided by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 3. Structured Educational Program for Proposed New Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience, and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of a Radiation Safety Officer. This is documented in 3.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.c if the training was provided by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising

individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Appendix 4 "continued"

ITEM 4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on the Licensee's License

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 3.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.c if the training was provided by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

PART II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the new proposed Radiation Safety Officer's training or identification on the license as an authorized user, authorized medical physicist, or authorized nuclear pharmacist is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation of the individual's competency to function independently as a Radiation Safety

Officer for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as a Radiation Safety Officer on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed Radiation Safety Officer must fill out all four sections of this page.

The preceptor for a Radiation Safety Officer seeking authorization to be recognized as a Radiation Safety Officer for the additional medical use(s) must fill out the second, third, and fourth sections.

APPENDIX 4 IEALTH RADIATION SAFETY OFFICER		
TRAINING AND EXPIRENCE AND PRECEPTOR ATTESTATION Training and Experience[64E-5.648]		
lame of Proposed Radiation Safety Officer		
Requested Authorization(s) The license authorizes the following medical uses (check all that apply):		
64E-5.626 64E-5.627 64E-5.630 64E-5.632 64E-5.631 64E-5.634(2)(remote after	erloader)	
64E-5.634(3)(teletherapy) 64E-5.634(1)(gamma stereotactic radiosurgery) 64E-5.664()	
PART I TRAINING AND EXPERIENCE (Select one of the four methods below)		
*Training and Experience, including board certification, must have been obtained within the 7 years preceding the application or the individual must have obtained related continuing education and experience since the required t and experience was completed. Provide dates, duration, and description of continuing education and experience to the uses checked above.	training	
1. Board Certification http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html		
a. Provide a copy of the board certification.		
 b. Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license. 		
c. Skip to and complete Part II Preceptor Attestation.		
OR 2. <u>Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety</u> <u>Officer for the Additional Medical Uses Checked Above</u>		
a. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.		
 b. Skip to and complete Part II Preceptor Attestation. OR 		
3. <u>Structured Educational Program for Proposed Radiation Safety Officer</u>		
a. Classroom and Laboratory Training	sof	
Description of Training Location of Training Hours Training		
Radiation physics and instrumentation		
Radiation protection		
Mathematics pertaining to the use and measurement of radioactivity		
Chemistry of byproduct material for medical use		
Radiation biology		
Total Hours of Training:		

RADIATION SAFETY OFFICER TRAINING AND EXPIRENCE AND PRECEPTOR ATTESTATION Training and Experience[64E-5.648] continued

3. <u>Structured Educational Program for Proposed Radiation Safety Officer</u> (continued)

b. Supervised Radiation Safety Experience (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 64E-5.626, 64E-5.627, etc <u>.)+</u>		
+ Choose all applicable sections of 64E-5 Part 6 to describe	e radioisotopes and quantities used: 64E-5.626, 64E-5.627	

RADIATION SAFETY OFFICER TRAINING AND EXPIRENCE AND PRECEPTOR ATTESTATION Training and Experience[64E-5.648] continued

3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (continued)

(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer
This license authorizes the following medical uses:	
64E-5.626 64E-5.627 64E-5.630	64E-5.632
64E-5.631 64E-5.634(2)(remote afterloader)	64E-5.634(3)(teletherapy)
64E-5.634(1)(gamma stereotactic radiosurgery)	64E-5.664()

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 64E-5.626, 64E-5.627, and 64E-5.631 uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.630 uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.632 uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.634(3) - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.634(2) - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.634(1) - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 64E-5.664, specify use(s):		

RADIATION SAFETY OFFICER TRAINING AND EXPIRENCE AND PRECEPTOR ATTESTATION Training and Experience[64E-5.648] continued

3.	Str	uctured Educational Program for Pr	oposed Radiat	ion Safety Officer (continued)
	c.	Training in radiation safety, regulatory license (continued)	issues, and emo	ergency procedures for all types of medical use on the
	RS nec	pervising Individual If training was provide O, AU, AMP, or ANP. (If more than one supervi sessary to document supervised training, provide page.)	sing individual is	License/Permit Number listing supervising individual
-	Lic	ense/Permit lists supervising individua	al as:	
		Radiation Safety Officer	Authorized Use	r Authorized Nuclear Pharmacist
		Authorized Medical Physicist		
		Authorized as RSO, AU, ANP, or AMF	P for the followin	a medical uses.
		64E-5.626 64E-5.627	64E-5.630	64E-5.632
		64E-5.631 64E-5.634(2) (ren		
		64E-5.634(1) (gamma stereotactio		64E-5.664 ()
	d.	Skip to and complete Part II Precepto		
			OR	
4	•	Authorized User. Authorized Medic the licensee's license	al Physicist. or	Authorized Nuclear Pharmacist identified on
		a. Provide license number.		
			cribe training in	radiation safety, regulatory issues, and emergency
		procedures for all types of medical		
		c. Skip to and complete Part II Prece	ptor Attestation.	
		PAR	T II – PRECEPT	OR ATTESTATION
Note	:	individual as long as the preceptor pre-	ovides, directs, o	ptor. 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.
		ection one of the following:		
•	۱. ,	Board Certification		
		I attest that	h	as satisfactorily completed the requirements in
		Name of Proposed Radiation	n Safety Officer	
		64E-5.648(1)(a)(1) and (1)(a)(2); or 6	4E-5.648(1)(b)(1	1) and (1)(b)(2); or 64E-5.648(2)(b).
			OR	2
	2. <u>S</u>	Structured Educational Program for	Proposed Radi	ation Safety Officers
		I attest that	h	as satisfactorily completed a structural educational
		Name of Proposed Radiation	n Safety Officer	
		program consisting of both 200 hours radiation safety experience as require		nd laboratory training and one year of full-time (2)(a).
			ÓR	

RADIATION SA	AFETY OFFICER TRAINING AND E Training and Experience	XPIRENCE AND PRECEPTOR ATTESTATION
Preceptor Attesta		
First Section (continu Check one of the foll		
3. Additional A	uthorization as Radiation Safety Office	er
I attest that	isa	an
	Name of Proposed Radiation Safety Officer	
Author	ized User Aut	horized Nuclear Pharmacist
Author	ized Medical Physicist	
aspects of	on the Licensees license and has experie f similar type of use of byproduct materia Safety Officer responsibilities	ence with the radiation safety I for which the individual has
Second Section	AND	
Complete for all (che	eck all that apply):	
I attest that	has tra	aining in the radiation safety, regulatory issues, and
emergency proce	edures for the following types of use:	
64E-5.626		
64E-5.627		
64E-5.630(2)	oral administration of less than or eq 131, for which a written directive is re	ual to 33 millicuries of sodium iodide I- equired
64E-5.630(3)	oral administration of greater than 33	3 millicuries of sodium iodide I-131
64E-5.630(4)	parenteral administration of any beta less than 150 keV for which a written	a-emitter, or a photon-emitting radionuclide with a photon energy
64E-5.630(4)	parenteral administration of any othe	er radionuclide for which a written directive is required
64E-5.631		
64E-5.632		
64E-5.634(2)	remote afterloader units	
64E-5.634(3)	teletherapy units	
64E-5.634(1)	gamma stereotactic radiosurgery units	
64E-5.664	emerging technologies, including:	

RADIATION SAFETY OFFICER TRAINING AND EXPIRENCE AND PRECEPTOR ATTESTATION Training and Experience[64E-5.648] continued								
AND								
Third Section Complete for ALL	AND							
I attest that has achieved a level of radiation safety knowledge Name of Proposed Radiation Safety Officer								
sufficient to function independently	as a Radiation Safety Officer for a medica	al use licensee.						
Fourth Section Complete the following for Preceptor	-							
I am the Radiation Safety Officer for	Name of Facil	ity						
License/Permit Number:								
Name of Preceptor	Signature	Telephone Number	Date					
	oignature							

Appendix 5 Authorized Medical Physicist

PART I. Training and Experience - select one of the three methods below:

ITEM 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, documentation of

device specific training in the table in 3.c, and completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification or device specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.c if the training was provided by an authorized medical physicists. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in Table 3.c if the training was provided by an authorized medical physicist. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

ITEM 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience which cannot be concurrent. This is documented in 3.b by providing the ranges of dates for training and work experience.

If the proposed authorized medical physicist had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an authorized medical physicist, the applicant must provide documentation that the supervising individual meets the requirements in 64E-5.656 and 64E-5.658.

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. The applicant only has to identify the supervising medical physicist in the table in 3.c and his/her qualifications if this was the source of training. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Appendix 5 "continued"

PART II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the proposed authorized medical physicist's training is in the first section. The attestation for the device-specific training is in the second section.

The attestation of the individual's competency to function independently as an authorized medical physicist for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new authorized medical physicist must fill out all four sections of this page. The preceptor for an authorized medical physicist seeking additional authorizations must complete the last three sections.

APPEN HEALTH AUTHORIZED MEI	
	AINING AND EXPERIENCE AND PRECEPTOR TON [64E-5.656]
Name of Proposed Authorized Medical Physicist	
Requested Authorization(s) (check all that apply).632(2) Ophthalmic use of stron .634(2) Remote afterloader unit	
	G AND EXPERIENCE three methods below)
*Training and Experience, including Board Certification, must date of application or the individual must have obtained rela- required training and experience was completed. Provide da and experience related to the uses checked above.	st have been obtained within the 7 years preceding the ted continuing education and experience since the
1. Board Certification	
a. Provide a copy of the board certification.	
 Go to the table in 3.c. and describe training provider authorization is sought. 	r and dates of training for each type of use for which
c. Skip to and complete Part II Preceptor Attestation.	
2. <u>Current Authorized Medical Physicist Seeking Ac</u>	Iditional Authorization for use(s) checked above
a. Go to the table in section 3.c. to document training f	or new device.
b. Skip to and complete Part II Preceptor Attestation	
3. Education. Training. and Experience for Propose	d Authorized Medical Physicist
a. Education: Document master's or doctor's degree in engineering, or applied mathematics from an accred	
Degree	Major Field
College or University	
	Work Experience in clinical radiation facilities that provide ectrons with energies greater than or equal to 1 million
Yes. Completed 1 year of full-time training in m	edical physics (for areas identified below) under the
supervision of	who meets the requirements for an
Authorized Medical Physicist.	
A	ND
Yes. Completed 1 year of full-time work experies	ence in medical physics (for areas identified below)
	who meets the requirements for
an Authorized Medical Physicist.	

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [64E-5.656] (continued)

3. Education. Training. and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience		icense or Permit Number /Iedical Devices Used+	Dates of Training*	Dates of Work Experience*				
Medical Physics								
Performing sealed source leak tests and inventories								
Performing decay corrections								
Performing full calibration and periodic spot checks of external beam treatment unit(s)								
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)								
Performing full calibration and periodic spot checks of remote afterloading unit(s)								
Conducting radiation surveys around external beam treatment unit(s), sterotactic radiosurgery unit(s), remote after loading unit(s)								
Supervising Individual** License/Permit Number listing supervising individual a an authorized Medical Physicist								
for the following types of use:								
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)								
 Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services. 								
* 1 year of Full-time medical physics traini	•		nt.					
** If the supervising medical physicist is no physicist meets the training and experier authorization.	t an authorized medical physi	cist, the licensee must submit ev	idence that the su					

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [64E-5.656] (continued)

3. Education. Training. and Experience for Proposed Authorized Medical Physicist (continued)

c. Describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates						
	Re	mote Afterloader		Telether	ару	G	amma Stereotactic Radiosurgery
Hands-on device operation							
Safety procedures for the device use							
Clinical use of the device							
Treatment planning system operation							
Supervising Individual If training is provided by Supervising Medidcal Physicist, (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)				License/Permit Number listing supervising individual as an authorized Medical Physicist			
for the following typ	es of use						
Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)						ic radiosurgery unit(s)	
If Applicable:	If Applicable:						
Authorization Sought Device			Training Provided By			Dates of Training	
35.400 Ophthalmic of strontium-90	Use						

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [64E-5.656] (continued)

PART	PART II – PRECEPTOR ATTESTATION								
	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. First Section								
Check	one of t		-						
	1. <u>Boa</u>	rd Certi	<u>ification</u>						
	I att	test that				atisfactorily	completed the require	ments in	
	64F	-5 6560	Name of Proposed 1)(a) and (1)(b).	d Authorized Medical P	Physicist				
	012		r)(u) unu (1)(b).		OR				
	2. <u>Edu</u>	cation.	Training, and Ex	<u> (perience</u>	UI				
	I att	test that				atisfactorily	completed the 1-year	of full-time	
	4		•	d Authorized Medical P			anian an an an incal ba		
		-5.656		nd an additional	year of full-til	me work exp	perience as required by	/	
					AND				
Second	d Sectio	n			AND				
Comple	ete the f	followin	g:						
	I att	test that				raining for th	e types of use for whic	ch authorization	
	io o		-	d Authorized Medical P	-	*****		anation of a	
			at include hands- lanning system.	on device opera	ation, safety p	rocedures, o	clinical use, and the op	eration of a	
Third S					AND				
	ete the f	followin	g:						
_	I att	test that	-		has a	ichieved a le	vel of competency suf	ficient to	
			-	d Authorized Medical P	-				
	func	ction ind	ependently as an	Authorized Me	dical Physicis	t for the follo	owing:		
		.632(2)	Ophthalmic use	of strontium-90	.634(3)	Teletherapy	vunit(s)		
		.634(2)	Remote afterload	der unit(s)	.634(1)	Gamma ste	reotactic radiosurgery un	iit(s)	
Fourth	Section	า			AND				
Comple	ete the f	followin	g for preceptor	attestation and	l signature:				
	I meet the requirements in 64E-5.656, or equivalent NRC or Agreement State requirements for Authorized Medical Physicist for the following:								
	.632(2) Ophthalmic use of strontium-90 .634(3) Teletherapy unit(s)								
	634(2) Remote afterloader unit(s) 634(1) Gamma stereotactic radiosurgery unit(s)								
Name of	f Precept	or		Signature			Telephone Number	Date	
inaitie O	recept			Signature				Dale	
License/	/Permit N	lumber/F	acility Name						
1									