

## Radioactive Materials Unit P.O. Box 64975 St. Paul, MN 55164-0975

Telephone: (651) 201-4400 Fax: (651) 201-4606 **AUTHORIZED USER** TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined in accordance with 4731.4450 and 4731.4463) Name of Proposed Authorized User State or Territory Where Licensed Requested Authorization(s). (Check all that apply.) 4731.4450 Manual Brachytherapy sources 4731.4463 Remote afterloader unit(s) 4731.4450 Ophthalmic use of Strontium-90 4731.4463 Teletherapy unit(s) 4731.4463 Gamma stereotactic radiosurgery unit(s) PART I – TRAINING AND EXPERIENCE (Select one of the three methods below) \* Training and Experience, including board certification, must have been obtained within seven 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. Provides 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 For 4731.4463, go to the table in section 3.e. and describe the training provider and dates of training for each type of use for which authorization is being requested. Skip to and complete Part II Preceptor Attestation 2. Current 4731.4463 Authorized User Requesting Additional Authorization for 4731.4463 Use(s) Checked **Above** Go to the table in section 3.e. to document training for new device. a. Skip to and complete Part II Preceptor Attestation 3. **Training and Experience for Proposed Authorized User** Classroom and Laboratory Training 4731.4458 4731.4459 4731.4479 Clock Dates of **Description of Training** Location of Training Hours 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)

Training and Experience for Proposed Authorized User (continued)
b. Supervised Work and Clinical Experience for 4731.4458. (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience	Total Hours of Experience:		
Description of Experience	Location of Experience and License or Permit Number of Facility	Confirm	Dates of Work Experience*
Ordering, receiving, and unpacking radioactive material 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 and conducting inventories of radioactive material on hand		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of radioactive material		☐ Yes ☐ No	
Using emergency procedures to control radioactive material		☐ Yes ☐ No	
Clinical Experience in radiation oncology as part of an approved formal training program	Location of Experience and License or Permit Number of Facility		Dates of Work 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			

Training and Experience for Prop c. Supervised Work Experience for Prop c.			
Clinical Experience in radiation oncology as part of an approved formal training program	Location of Experience and License or Permit Number of Facility	Clock Hours	Dates of Wo
Use of Strontuim-90 for ophthalmic treatment, including: examination for 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 or Permit Num individual as an Author		supervising
Remote afterloader unit(s)  Description of Experience	Location of Experience and	Clock	Dates of W
Description of Experience  Reviewing full calibration			
Description of Experience	Location of Experience and	Clock	Dates of W
Description of Experience  Reviewing full calibration measurements and periodic spot checks  Preparing treatment plans and calculating treatment doses and times	Location of Experience and	Clock	Dates of W
Description of Experience  Reviewing full calibration measurements and periodic spot checks  Preparing treatment plans and calculating treatment doses and times  Using administrative controls to prevent a medical event involving the use of radioactive material	Location of Experience and	Clock	Dates of W
Description of Experience  Reviewing full calibration measurements and periodic spot checks  Preparing treatment plans and calculating treatment doses and times  Using administrative controls to prevent a medical event involving the use of radioactive	Location of Experience and	Clock	Dates of W
Reviewing full calibration measurements and periodic spot checks  Preparing treatment plans and calculating treatment doses and times  Using administrative controls to prevent a medical event involving the use of radioactive material  Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or	Location of Experience and	Clock	Dates of W

Training and Evner	ionoo for Drone	and Author	الممدن	oor (continued)	•	•
Training and Experd. Supervised Wo				.4479 (continued)		
Clinical Experience oncology as pa approved forma	art of an			n of Experience and Permit Number of Facili	ty	Dates of Wo Experience
progran Approved by:	n					
Residency Revidence Committee for Revidence Oncology of the	Radiation					
Royal College o						
Committee on P Training of the A Osteopathic Ass	American					
Supervising Individe	ual			License or Permit Nur individual as an Autho		supervising
e. For 4731.4463, authorization is  Description of Training				dates of training for each	s Gar	se for which  nma Stereotacti Radiosurgery
Device operation						
Safety procedures						
Clinical use of the device						
Supervising Individuals (individual is necessary to experience, provide multiple superience)	If more than one sup o document supervis	pervising sed work	indi	ense or Permit Number vidual as an Authorized rsicist		

f. Provide completed Part II Preceptor Attestation

Authorized for the following types of use:

☐ Remote afterloader unit(s)

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

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

Note:	PART II - PRECEPTOR ATTESTATION  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 the training and experience required. If more than one supervising individual is necessary to document supervised work experience, provide a separate preceptor statement from each.						
First Se	ction eck one of the following for each requested authorization:						
For	4731.4458:						
	Board Certification						
	I attest that has satisfactorily completed the requirements     Name of Proposed Authorized User						
	in 4731.4458 Subpart 2. Item A. and has achieved a level of competency sufficient to function independently as an Authorized User of manual brachytherapy sources for medical uses authorized in accordance with 4731.4450.						
	OR						
	Training and Experience						
	I attest that has satisfactorily completed 200 hours of Name of Proposed Authorized User						
	classroom and laboratory training, 500 hours of supervised work experience, and three years of supervised clinical experience in radiation oncology as required by 4731.4458 Subpart B. Item (1) and (2) and has achieved a level of competency sufficient to function independently as an Authorized User of manual brachytherapy sources for medical uses authorized in accordance with 4731.4450.						
For	4731.4459:						
	I attest that has satisfactorily completed 24 hours of  Name of Proposed Authorized User  Name of Proposed Authorized User						
	classroom and laboratory training applicable to the medical use of Strontium-90 for ophthalmic radiotherapy, has used Strontium-90 for ophthalmic treatment of five individuals, as required by 4731.4459 Subpart B. and has achieved a level of competency sufficient to function independently as an Authorized User for Strontium-90 for ophthalmic use.						
Second	Section						
For	4731.4479:						
Воа	ard Certification						
	I attest that has satisfactorily completed the requirements in Name of Proposed Authorized User						
	Name of Proposed Authorized User 4731.4479 Subpart 2. Item A.						
_							
ıra	ining and Experience						
	I attest that has satisfactorily completed 200 hours of Name of Proposed Authorized User						
	classroom and laboratory training, 500 hours of supervised work experience, and three years of supervised clinical experience in radiation therapy as required by 4731.4479 Subpart 1 Item B(1) and (2).						

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)				
AND				
Preceptor Attestation (continued)				
Third Section				
For 4731.4479 (continued)				
I attest that has received the training required in 4731.4479  Name of Proposed Authorized User  Name of Proposed Authorized User				
Subpart 1. Item B.(4) for device 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 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 4731.4458, 4731.4459, 4731.4479, or equivalent NRC or Agreement State requirements, as an Authorized User for:				
☐ 4731.4450 Manual Brachytherapy sources ☐ 4731.4463 Remote afterloader unit(s) ☐ 4731.4463 Teletherapy unit(s) ☐ 4731.4463 Gamma stereotactic radiosurgery unit(s)				
Name of Preceptor Signature Date				
Telephone Number License or Permit Number Facility Name				

#### 4731.4450 AND 4731.4463 AUTHORIZED USERS

#### General Instructions and Guidance for Completing MDH Form 313 Series

#### **Recentness of Training**

The required training and experience, including board certification, must be obtained within the seven years preceding the date of the application, or the individual must document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience include the following:

- 1. Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use;
- 2. Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization;
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization; and
- 4. For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple MDH Form 313 series forms or fill out some sections more than once. Also, if the applicant requests a physician be authorized for both high dose rate remote afterloading and gamma stereotactic radiosurgery in accordance with 4731.4463, only one form, MDH Form 313 (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

If you need to identify a license and it is an NRC or Agreement State license not issued by MDH, provide a copy of the license. If you need to identify an NRC Master Materials License permit, provide a copy of the permit.

If you need to identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad scope license or broad scope permit, provide a copy of the permit issued by the broad scope licensee/permittee.

#### Name of individual

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

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

#### State or territory where licensed

Physicians, dentists, podiatrists, and pharmacists are required to be licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, practice of dentistry, practice of podiatry, or practice of pharmacy, respectively.

### Requested Authorization(s)

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

#### Part I. Training and Experience

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

#### Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by MDH. To confirm that MDH recognizes that boards certifications see NRC's web page http://www.nrc.gov/materials/miau/med-use-toolkit.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 also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other training, experience, or clinical casework as indicated on the specific form of the MDH Form 313 series.

All applicants under this pathway (except for 4731.4460 uses) must submit a completed Part II Preceptor Attestation.

### Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the MDH Form 313 series. (*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.

#### Item 3. Training and Experience for Proposed New Authorized Individuals

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

The proposed authorized individual is not required to receive the classroom and laboratory training, supervised work experience, or clinical casework at any one location or at one time, therefore space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year format. The clock hours must be indicated for those individuals that must meet a minimum number of training and work experience hours. The specific number of hours needed for each training element will depend upon the type of approval sought.

**Note**: Classroom and Laboratory Training or Didactic Training may be provided at medical teaching/university institutions. In some cases, a course may be provided for that particular need and taught in consecutive days; in others, the period may be a semester or quarter as part of the formal curriculum. The required "structural educational programs" or "training" may be obtained in any number of settings, locations, and educational situations.

MDH expects that clinical laboratory hours credited toward meeting the requirements for classroom and laboratory training will involve training in radiation safety aspects of the medical use of byproduct material. MDH recognizes, for example, that physicians in training may not dedicate all of their clinical laboratory time specifically to the subject areas covered in these subparts and will be attending to other clinical matters involving the medical use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). However, those hours spent on other duties, not related to radiation safety, should not be counted toward the minimum number of hours of required classroom and laboratory training in radiation safety.

This type of supervised work experience, even though not specifically required by the MDH, may be counted toward the supervised work experience to obtain the required total hours of training.

Similarly, the MDH recognizes that clinicians will not dedicate all of their time in training specifically to the subject areas described and will be attending to other clinical matters. The MDH will broadly interpret "classroom training" to include various types of instruction received by candidates for approval, including online training, as long as the subject matter relates to radiation safety and safe handling of byproduct material.

**Note:** If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

#### Part II. Preceptor Attestation

MDH defines the term "preceptor" 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 work 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 training and experience required. The preceptor must attest in writing regarding the training and experience of any individual 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. This preceptor also has to meet specific requirements.

MDH may require 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 licensed facilities, from a large teaching university hospital to a small private practice.

MDH Form 313 series Part II - Preceptor Attestation pages have multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and competency to function independently, as well as provide information concerning his/her own qualifications and sign the attestation. 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 MDH 313 series form.

#### Specific Instructions and Guidance for Completing MDH Form 313S (AUS)

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 4731.4463 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 greater than seven years ago.

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

# Item 2. Current 4731.4463 Authorized User requesting Additional Authorization for 4731.4463 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 greater than seven years ago.

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

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

Submit a completed section 3.b if applying for 4731.4450 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 their 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 their qualifications.

Submit a completed section 3.d for each requested 4731.4463 use. If more than one supervising authorized user provided the supervised work and clinical experience, identify each supervising individual by name and provide their qualifications.

Submit a completed section 3.e for each specific 4731.4463 device for which the applicant is requesting authorization.

Device specific training may be provided by the vendor, or a supervising authorized user or authorized medical physicist authorized for the requested type of use. The applicant only has to identify the supervising authorized user or authorized medical physicist in the table in 3.e and his/her qualifications if this was the source of training. 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 individuals competency for 4731.4450 uses or Strontium-90 eye applicator use is in the first section.
- The attestation to the training for the proposed authorized user for 4731.4463 uses is in second section.
- The attestation for the 4731.4463 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 4731.4463 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 4731.4450 proposed authorized user must fill out the first and fifth sections of this Part.

The preceptor for a 4731.4463 proposed authorized user must fill out the second, third, fourth and fifth sections.

third, fourth, and fifth sections.	