

### Radioactive Materials PO 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 4731.4440) Name of Proposed Authorized User State or Territory Where Licensed Requested Authorization(s). (Check all that apply.) Use of unsealed radioactive material for which a written directive is required **4731.4440** OR **4731.4440** Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels) Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than ☐ 4731.4440 33 millicuries (1.22 gigabecquerels) **4731.4440** 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 administration of any other radionuclide for which a written directive is required 731.4440 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 4731.4443, provide documentation on supervised clinical case experience. The table in 3.c. may be used to document this experience. For 4731.4446, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. Tables in 3.a., 3.b., and 3.c. may be used to document this experience. Skip to and complete Part II Preceptor Attestation Current 4731.4440, 4731.4450, 4731.4463 Authorized User Seeking Additional Authorization 2. Authorized User on Radioactive Materials License in accordance with the requirements below or equivalent NRC or Agreement State requirements. (Check all that apply.) ☐ 4731.4443 ☐ 4731.4444 ☐ 4731.4445 731.4458 ☐ 4731.4479 If currently authorized for a subset of clinical uses in accordance with 4731.4440, provide documentation on additional required supervised case experience. The table in 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation. If currently authorized in accordance with 4731.4458 or 4731.4479 and requesting authorization for 4731.4446, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. Tables in 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

TRAINING AND EXP		D PRECEPTO	OR ATTESTAT	ION (continue	ed)			
☐ 3. Training, and Experience for Pro a. Classroom and Laboratory Tr ☐ 4731.4443 ☐ 4731.4	aining	rized User 731.4445	☐ 4731.4446					
Description of Training	L	ocation of Tra	aining	Clock Hours	Dates of Training*			
Radiation physics and instrumentation								
Radiation Protection								
Mathematics pertaining to the use and measurement of radioactivity								
Chemistry of radioactive material for medical use								
Radiation biology								
	Total Hours of Training:							
b. Supervised Work Experience  4731.4443 4731.4  If more than one supervising multiple copies of this page.	1444 🔲 47	731.4445 cessary to do	4731.4446 ument superv		erience, provide			
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				
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 radioactive material				☐ Yes ☐ No				
Using procedures to contain spilled radioactive material safely and proper decontamination procedures				☐ Yes ☐ No				

AUTHORIZED USER	
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION	(continued)

# 3. Training and Experience for Proposed Authorized User (continued)b. Supervised Work Experience (continued)

Supervising Individ	License or Permit Number listing supervising individual as an authorized user			
	ual meets the requirements below or equivalent NRC or Agreement State requirements.			
(Check all that app	$\left\langle y_{\cdot} \right\rangle^{7}$			
	With experience administering dosages of:			
☐ 4731.4443	Oral Nal-131 requiring a written directive in quantities less than or equal to 33			
	millicuries (1.22 gigabecquerels)			
☐ 4731.4444	☐ Oral Nal-131 requiring a written directive in quantities greater than 33			
	millicuries (1.22 gigabecquerels)			
☐ 4731.4445	☐ Parenteral administration of beta-emitter or photon-emitting radionuclide with a			
	photon energy less than 150 keV requiring a written directive			
☐ 4731.4446	Parenteral administration of any other radionuclide requiring a written directive			
<sup>1</sup> Supervising Authorized User must have experience in administering dosages in the same dosage category				
or categories as the individual requesting authorized user status.				

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 and License or Permit Number of Facility	Dates of Work Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels)			
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 administration of any other radionuclide for which a written directive is required			
(List radionuclides)			

TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)						
3.	<b>Tra</b> i			pposed Authorized Uperience (continued)	Jser (continued)	
	Supervising Individual				License or Permit Number listing supervising individual as an authorized user	
	Supervising individual meets the requirements below (Check all that apply.) <sup>1</sup>					
	With experience administering dosages of:  Oral Nal-131 requiring a written directive in quantities less than or to 33 millicuries (1.22 gigabecquerels)			ring a written directive in quantities less than or equal		
		4731.4444		Oral Nal-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels)  Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive		
		4731.4445 4731.4446				
	1 S	upervising Auth	Parenteral administration of any other radionuclide requiring a written directive sing Authorized User must have experience in administering dosages in the same dosage category			
	<u>o</u> d.	-		equesting authorized	user status.	
	u.	Frovide Compi	eleu Fall II Fle	eceptor Attestation		
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 preceptor is necessary to document experience, obtain a separate preceptor statement from each.					
First Sec Check or			r each request	ed authorization:		
For 4731.4443 Board Certification						
		I attest that	Name of Pro	oposed Authorized User	has satisfactorily completed the requirements	
	in 4731.4443 Subpart 2. Item A.					
OR						
Training, and Experience						
		I attest that	Name of Pr	oposed Authorized User	has satisfactorily completed 700 hours of	
	training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 4731.4443 Subpart 1. Item B.					

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)								
Preceptor Attestation (continued)								
Firs	st Section (continue	ed)						
	For 4731.4444 (Id	dentical Attestation Statement Regardless of Training and Experience Pathway)						
	I attest that has satisfactorily completed 80 hours of Name of Proposed Authorized User							
	Name of Proposed Authorized User Classroom and laboratory training as required by 4731.4444 Subpart C. Item (1) and the supervised work and clinical case experience in 4731.4444 Subpart C. Item (2).							
	For 4731.4445 (Id	dentical Attestation Statement Regardless of Training and Experience Pathway)						
	☐ I attest that _	has satisfactorily completed 80 hours of Name of Proposed Authorized User						
		boratory training as required by 4731.4445 Subpart C. Item (1) and the supervised work and rience in 4731.4445 Subpart C. Item (2).						
Second	Section							
	I attest that	has satisfactorily completed the required clinical case  Name of Proposed Authorized User						
	experience require	ed in 4731.4443 Subpart 1. Item B.(1).vi. listed below:						
	☐ 4731.4440	Oral Nal-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels)						
	4731.4440	Oral Nal-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels)						
	4731.4440	Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive						
	☐ 4731.4440	Parenteral administration of any other radionuclide requiring a written directive						
Third Se	ection							
	I attest that	Name of Proposed Authorized User has satisfactorily achieved a level of competency						
	sufficient to function independently as an Authorized User for:							
	4731.4440	Oral Nal-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels)						
	☐ 4731.4440	Oral Nal-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels)						
	☐ 4731.4440 Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive							
	4731.4440	Parenteral administration of any other radionuclide requiring a written directive						

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)								
Preceptor Attestation (continued)								
Fou	ırth Section							
	For 4731.4458	3 or 4731.4479 Authoriz	ed User:					
	I attest that is an Authorized User in accordance with  Name of Proposed Authorized User  4731.4458 or 4731.4479 or equivalent NRC or Agreement State requirements, has satisfactorily completed 80							
	hours of classroom and laboratory training as required by 4731.4446 Subpart B Item 1 and the supervised work and clinical case experience required by 4731.4446 Subpart B Item 2, and has achieved a level of competency sufficient to function independently as an Authorized User for:							
	☐ 4731.4440 ☐ 4731.4440	Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive Parenteral administration of any other radionuclide requiring a written directive						
	□ 4/31.4440	raienterai auminist	OR	iuciide requiring a writtei	Tallective			
	Board Certific	cation						
	☐ I attest the	at		has satisfactorily comple	eted the board			
	□ I attest that has satisfactorily completed the board  Name of Proposed Authorized User  Certification requirements in 4731.4446 Subpart A Item (3). has satisfactorily completed 80 hours of classroom and laboratory training as required by 4731.4446 Subpart B Item 1 and the supervised work and clinical case experience required by 4731.4446 Subpart B. Item 2, and has achieved a level of competency sufficient to function independently as an Authorized User for:							
	☐ 4731.4440 ☐ 4731.4440	energy less than 15	Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive Parenteral administration of any other radionuclide requiring a written directive					
Fifth Sec		or preceptor attestation a	and signature					
	I meet the requ	uirements below or equiv	alent NRC or Agreement	State requirements as a	an Authorized User for:			
	<b>4731.4443</b>	<b>4731.4444</b>	☐ 4731.4445 ☐ 47	731.4446				
	I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.							
	<ul> <li>Oral Nal-131 requiring a written directive in quantities less than or equal to 33 millicuries (1.22 gigabecquerels)</li> <li>Oral Nal-131 requiring a written directive in quantities greater than 33 millicuries (1.22 gigabecquerels)</li> <li>Parenteral administration of beta-emitter or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive</li> </ul>							
		enteral administration of a		quiring a written directive				
Name of	Preceptor		Signature		Date			
Telephor	ne Number	License or Permit Numb	рег	Facility Name				

#### 4731,4440 AUTHORIZED USER

#### 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 313T (AUT)

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

#### **Item 1. Board Certification**

If you are a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 35.300 [4731.4440] on NRC's website, which is located at <a href="http://www.nrc.gov/materials/miau/med-use-toolkit.html">http://www.nrc.gov/materials/miau/med-use-toolkit.html</a>, 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 was greater than seven years ago.

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

If you are a radiation oncologist whose board certification is not listed under 35.300 [4731.4440] on NRC's website, provide the requested information (i.e., a copy of the board certification listed under either 35.400 [4731.4450] or 35.600 [4731.4463] 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 or clinical experience was greater than seven years ago.

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

# Item 2. Current 4731.4440, 4731.4450, or 4731.4463 Authorized User Seeking Additional Authorization

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

If you are currently authorized for a subset of clinical uses in accordance with 4731.4440, submit the requested information, i.e., complete the table in section 3.c to document your new supervised clinical case experience and the completed preceptor attestation. As indicated on the form, additional information is needed if the clinical case experience was greater than seven years ago.

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

If you are currently authorized in accordance with 4731.4458 or 4731.4479 and meet the requirements in 4731.4446, 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 was greater than seven 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 degree, training and/or work experience was completed more than seven 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 35.390, 4731.4444, and 4731.4445 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 radiation oncologist meeting the requirements in 4731.4446 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 in accordance with 35.390 [4731.4443] 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 4731.4443 Subpart 1. Item B(1)(b)vi who is a radiation oncologist with a board certification that is not listed in accordance with 35.390 [4731.4443] on NRC's website must complete the first, second, third, and fifth sections of this part.

The preceptor for a proposed authorized user for 4731.4443 Subpart 1. Item B(1)(b)vi uses who is a radiation oncologist with a board certification listed under 35.490 [4731.4458] or 36.690 [4731.4479] 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 in accordance with 4731.4440 must complete the second, third, and fifth sections of this part, except for an authorized user meeting the criteria in 4731.4444 seeking to meet the training and experience requirements in accordance with 4731.4445.

The preceptor for an authorized user meeting the criteria in 4731.4444 seeking to meet the training and experience requirements in accordance with 4731.4445 must complete the first, second, third, and fifth sections of this part.

The preceptor for an authorized user currently authorized in accordance with 4731.4458 or 4731.4479 and meeting the requirements in 4731.4446 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.