



Radioactive Materials Unit
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**AUTHORIZED USER
 TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
 (for uses defined in accordance with 4731.4432, 4731.4434, and 4731.4460)**

Name of Proposed Authorized User	State or Territory Where Licensed
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Requested Authorization(s). *(Check all that apply.)*

4731.4432 Uptake, dilution, and excretion studies

4731.4434 Imaging and localization studies

4731.4460 Sealed sources for diagnosis (specify device: _____)

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
- b. If using only 4731.4460 materials, stop here. If using 4731.4432 and 4731.4434 materials, skip to Part II Preceptor Attestation
- 2. Current 4731.4443 Authorized User seeking Additional 4731.4436 Authorization**
- a. Authorized User on Materials License Number _____ meeting 4731.4443 or equivalent NRC or Agreement State requirements seeking authorization for 4731.4436.
- b. Supervised Work 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 Experience and License or Permit Number of Facility	Clock Hours	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 reagents kits to prepare labeled radioactive drugs			

Total Hours of Experience:

Supervising Individual	License or Permit Number that lists the supervising individual as an Authorized User
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Supervising individual meets the requirements below, or equivalent NRC or Agreement State requirements. *(Check all that apply.)*

- 4731.4436 4731.4443 and generator experience in 4731.4436 Subpart 1. Item C(1)(b)vii.

**AUTHORIZED USER
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (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 radioactive material for medical use			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (*Completion of this table is not required for 4731.4461.*)
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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

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

Description of Training/Experience	Location of Experience, License or Permit Number of Facility	Confirm	Dates of Experience*
Using administrative controls to prevent a medical event involving the use of unsealed radioactive material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled radioactive material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> 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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Supervising Individual		License or Permit Number that lists the supervising individual as an Authorized User	
Supervising individual meets the requirements below, or equivalent NRC or Agreement State requirements. (Check one.)			
<input type="checkbox"/> 4731.4433 <input type="checkbox"/> 4731.4436 <input type="checkbox"/> 4731.4443 <input type="checkbox"/> 4731.4443 and generator experience in 4731.4436 Subpart 1. Item C(1)(b)vii.			

c. For 4731.4461 only, provide documentation of training on the use of the device.

Device	Type of Training	Location and Dates

d. For 4731.4460 uses only, stop here. For 4731.4432 and 4731.4434 uses, skip to and complete Part II Preceptor Attestation.

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

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies the 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 the training requirements for 4731.4461.)

First Section

Check one of the following for each use requested:

For 4731.4433

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
 4731.4433 Subpart 1 Item A and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 4731.4432.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 60 hours of training
Name of Proposed Authorized User
 And experience, including a minimum of 8 hours of classroom and laboratory training, required by 4731.4433 Subpart 1 Item C, and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 4731.4432.

For 4731.4436

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User
 4731.4436 Subpart 1 Item A and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 4731.4432 and 4731.4434.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training
Name of Proposed Authorized User
 And experience, including a minimum of 80 hours of classroom and laboratory training, required by 4731.4436 Subpart 1 Item C, and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 4731.4432 and 4731.4434.

Second Section

Complete the following for preceptor attestation and signature:

- I meet the requirements below, or equivalent NRC or Agreement State requirements, as an Authorized User for:
- 4731.4433 4731.4436 4731.4443
 4731.4443 and generator experience in 4731.4436 Subpart 1. Item C(1)(b)vii.

Name of Preceptor	Signature	Date
Telephone Number	License or Permit Number and Facility Name	

4731.4731.4432, 4731.4434, AND 4731.4460 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;
3. 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 313D (AUD)

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 was greater than seven years ago.

Item 2. Current 4731.4443 Authorized User Seeking Additional 4731.4436 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 4731.4436 Subpart 1. Item C(1)(b)vii as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more 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 training and/or work experience was completed more than seven years ago.

Note: Providing the training and experience information required in accordance with 4731.4436 will allow the individual to be authorized to use materials permitted by both 4731.4432 and 4731.4434.

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

Submit a completed section 3.b, except for 4731.4460 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 4731.4460 uses.

Submit a completed preceptor attestation, except for 4731.4460 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The attestations for training and experience requirements in 4731.4433 and 4731.4436 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 in accordance with 4731.4433 covers the use of material permitted by 4731.4432 only. The attestation to the proposed user's training and competency to function independently in accordance with 4731.4436 training will allow the individual to be authorized to use material permitted by both 4731.4432 and 4731.4434.