



Colorado Department of Public Health and Environment

Colorado Department of Public Health and Environment
Radiation Management Unit
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

Telephone: (303) 692-3319 or (303) 692-3300
FAX: (303) 759-5355

AUTHORIZED USER
TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined in accordance with 7.30, 7.32, and 7.40)

Name of Proposed Authorized User Colorado Medical License No. and Expiration Date

Requested Authorization(s). (Check all that apply.)

- 7.30 Uptake, dilution, and excretion studies
7.32 Imaging and localization studies
7.40 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.

-> For all pathways, each applicant must provide a copy of their license to practice medicine in Colorado

- 1. Board Certification
a. Provide a copy of the proposed authorized user's board certification
If requesting only 7.40 materials (sealed sources for diagnosis) -> STOP HERE
If requesting 7.30 (uptake, dilution, and excretion) and 7.32 (imaging and localization) materials, -> GO TO Part II Preceptor Attestation
2. Current 7.36.2 Authorized User seeking Additional Authorization for 7.32 uses (Imaging & Localization)
a. Applicant is an Authorized User on Radioactive Materials License Number and meets Appendix 7F or equivalent NRC or Agreement State requirements and is seeking authorization for 7.32 uses.
b. Supervised Work Experience
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Table with 4 columns: Description of Experience, Location of Experience and License or Permit Number of Facility, Clock Hours, Dates of Experience\*. Row 1: 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

Supervising individual meets the requirements below, or equivalent NRC or Agreement State requirements. (Check all that apply.)

- Appendix 7E (7.32 uses) Appendix 7F (7.36.2 uses) AND generator experience in Appendix 7E2.1(2)(g)

**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  |                      |             |                    |
| <b>Total Hours of Training:</b>                                    |                      |             |                    |

b. Supervised Work Experience (*Completion of below table is not required for 7.40 uses.*)  
(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<br><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<br><input type="checkbox"/> No |                           |
| Calculating, measuring, and safely preparing patient or human research subject dosages   |   | <input type="checkbox"/> Yes<br><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<br><input type="checkbox"/> No |                      |
| Using procedures to contain spilled radioactive material safely and using proper decontamination procedures  |  | <input type="checkbox"/> Yes<br><input type="checkbox"/> No |                      |
| Administering dosages of radioactive drugs to patients or human research subjects  |  | <input type="checkbox"/> Yes<br><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<br><input type="checkbox"/> No |                      |

|                        |  |
|------------------------|--|
| Supervising Individual | License or Permit Number that lists the supervising individual as an Authorized User |
|------------------------|--|

Supervising individual is an Authorized User named on a license and meets the requirements below, or equivalent NRC or Agreement State requirements. (Check one.)

Appendix 7D (7.30 uses)       Appendix 7E (7.32 uses)  
 App 7F (7.36.2 uses)     Appendix 7F (7.36.2 uses) **AND** generator experience in Appendix 7E2.1(2)(g)

c. For 7.40 uses (Appendix 7J) only, provide documentation of training below on the use of the device.

| Device | Type of Training | Location and Dates |
|--------|------------------|--------------------|
|        |                  |                    |
|        |                  |                    |

d. For 7.40 uses only, → **STOP HERE**.  
For 7.30 and 7.32 uses, → **GO 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. *(NOTE: A preceptor attestation is **not** required to meet the training requirements of Appendix 7J for 7.40 uses)*

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

**First Section**

Check **one** of the following for each use requested:

**For 7.30 uses (Uptake, Dilution and Excretions studies):**

**Board Certification pathway**

I attest that \_\_\_\_\_ has satisfactorily completed the requirements of  
Name of Proposed Authorized User  
 Appendix 7D1 and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 7.30.

-OR-

**Training and Experience pathway**

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 Appendix 7D2 and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in 7.30.

**For 7.32 uses (Imaging and Localization studies):**

**Board Certification pathway**

I attest that \_\_\_\_\_ has satisfactorily completed the requirements of  
Name of Proposed Authorized User  
 Appendix 7E1 and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in accordance with 7.30 and 7.32.

-OR-

**Training and Experience pathway**

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 Appendix 7E2, and has achieved a level of competency sufficient to function independently as an Authorized User for medical uses authorized in 7.30 and 7.32.

**Second Section**

Complete the following for preceptor attestation and signature:

- I have read and understand the responsibilities of a preceptor as described in the instructions that accompany this form; **and**
- I meet the requirements as an Authorized User for:
  - 7.30 uses     7.32 uses     7.36.2 uses (= "broad" 7.36 authorization)
  - 7.36.2 uses **AND** I have the generator experience required by Appendix 7E2.1(2)(g).

|                           |                     |      |
|---------------------------|---------------------|------|
| Printed Name of Preceptor | Preceptor Signature | Date |
|---------------------------|---------------------|------|

|                  |  |
|------------------|--|
| Telephone Number | Facility Name and Radioactive Materials License Number |
|------------------|--|

## AUTHORIZED USERS FOR 7.30, 7.32, AND 7.40 USES

### General Instructions and Guidance for Completing Colorado Department of Public Health and Environment (CDPHE) Form 313 Series

**NOTE:** The CDPHE series 313 forms are based on the content and format of the NRC form 313 series.

#### **Responsibilities of Preceptors**

*A board certificate issued to an individual by a certification board that is recognized by the NRC (or Department) indicates that an applicant is qualified to be designated by the Department as an authorized individual on the license. The certificate is relied upon by the Department in making a regulatory decision. It, along with other documentation is a representation to the Department that the individual has completed training and supervised work experience that includes all of the hours, in all of the topics, specified by Department regulations. Such statements must be complete and accurate in all material respects.*

*Additionally, the Department relies on the truthful and accurate attestations of the preceptors for individuals seeking authorization under all pathways. Each preceptor who verifies the training and experience for a proposed authorized individual must, to the best of his or her professional ability and judgment, determine that the candidate has actually received the training and supervised work experience claimed. Preceptors are expected to take reasonable measures to ensure that proposed authorized individuals have completed all of the required training and supervised work experience (e.g., contacting individuals providing the training and supervised work experience). Further, proposed authorized individuals must provide complete and accurate documentation of their own training and experience, and should cooperate in the attestation process so that the preceptor will have a thorough understanding of the specific training and experience that the proposed authorized individual has received. Cognizant persons should notify the Department if they become aware of any proposed authorized individual who is misrepresenting his or her own training and supervised work experience, or of any other individual who is making inaccurate attestations about the completion of training and supervised work experience. False attestations and misrepresentations may cause a violation of the Regulations and/or the individual may not be granted authorized individual status.*

#### **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 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 CDPHE 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 Section 7.48 (Appendix 7M), only one form, CDPHE Form 313 (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

When using any radioactive materials license not issued by the Department as a basis for prior experience or authorization, please provide a copy of that NRC, Agreement State, or NRC Master Materials License/Permit with the application.

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 CDPHE 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 the State of Colorado 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 CDPHE. To confirm that CDPHE 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 CDPHE Form 313 series.

All applicants under this pathway (except for 7.40 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 CDPHE 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.

CDPHE 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. CDPHE 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 CDPHE, may be counted toward the supervised work experience to obtain the required total hours of training.

Similarly, the CDPHE 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 CDPHE 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**

The term “preceptor” is defined 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.

CDPHE 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.

CDPHE 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 CDPHE 313 series form.

### **Specific Instructions and Guidance for Completing CDPHE 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 7.36 Authorized User Seeking Additional Appendix 7E 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 Appendix 7E2.1(2)(g) 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 Appendix 7E will allow the individual to be authorized to use materials permitted by both 7.30 and 7.32.

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

Submit a completed section 3.b, except for 7.40 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 7.40 uses.

Submit a completed preceptor attestation, except for 7.40 uses.

#### **Part II. Preceptor Attestation**

The Preceptor Attestation page has two sections.

The attestations for training and experience requirements in Appendix 7D and Appendix 7E 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 as an AU for 7.30 uses covers the use of material permitted by 7.30 only. The attestation to the proposed user's training and competency to function independently in accordance with Appendix 7E training will allow the individual to be authorized to use material permitted by both 7.30 and 7.32.