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U. S. NUCLEAR REGULATORY COMMISSION

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AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION

(for uses defined under 35.100, 35.200, and 35.500)
[10 CFR 35.57, 35.190, 35.290, and 35.590]

Name of Proposed Authorized User	State or Territory Where Licensed

Requested Authorization(s) *(check all that apply)*

☐ 35.100 Uptake, dilution, and excretion studies ☐ 35.200 Imaging and localization studies

☐ 35.500 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 the 7 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. Provide 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. For a board certification issued on or before October 24, 2005 that is listed in 10 CFR 35.57(b)(2)(i), provide the following:

(i) Documentation that the individual performed each use checked above on or before October 24, 2005.

(ii) Dates, duration, and description of continuing education and experience within the past seven years for each use checked above.

c. Stop here.

☐ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

a. Authorized user on Materials License _____ meeting 10 CFR 35.390, 10 CFR 35.57 for 35.300 uses, or equivalent Agreement State requirements seeking authorization for 35.290.

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/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 reagent kits to prepare labeled radioactive drugs			
Total Hours of Experience: ☐			
Supervising Individual	License/Permit Number listing supervising individual as an authorized user or authorized nuclear pharmacist		

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply).*

☐ 35.290 ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G) ☐ 35.55 ☐ 35.57 for 35.200 uses

c. If board certified, provide a copy of the certificate and stop here. If not board certified, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use *(not required for 35.590)*			
Radiation biology			
Total Hours of Training: ☐			

b. Supervised Work Experience (completion of this table is not required for 35.590).
(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 Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		☐ Yes ☐ No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		☐ Yes ☐ No	

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

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

b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		☐ Yes ☐ No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		☐ Yes ☐ No	
Administering dosages of radioactive drugs to patients or human research subjects		☐ Yes ☐ No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		☐ Yes ☐ No*	

Supervising Individual	License/Permit Number listing supervising individual as an authorized user or an authorized nuclear pharmacist for generator training

Supervisor meets the requirements below, or equivalent Agreement State requirements *(check one).*

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

☐ 35.55 ☐ 35.57 for 35.200 uses

*Not required for 10 CFR 35.100 use.

c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING, EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.57, 35.190, 35.290, and 35.590](continued)

PART II – PRECEPTOR ATTESTATION

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is not attesting to the individual's "general clinical competency."

First Section
Check one of the following for each use requested:

For 35.190

☐ I attest that _____ has satisfactorily completed the 60 hours of training and
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

☐ 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 10 CFR 35.290(c)(1), and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses under 10 CFR 35.100 and 35.200.

Second Section
Complete one of the following for attestation and signature:

☐ Authorized User:

☐ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience ☐ 35.57 for 35.200 uses

OR

☐ Residency Program Director:

☐ I affirm that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements below or equivalent Agreement State requirements for:

☐ 35.190 ☐ 35.290 ☐ 35.390 ☐ 35.390 + generator experience ☐ 35.57 for 35.200 uses

☐ I affirm that this facility member concurs with the attestation I am providing as program director.

☐ I affirm that the residency training program is approved by the:

☐ Residency Review Committee of the Accreditation Council for Graduate Medical Education

☐ Royal College of Physicians and Surgeons of Canada

☐ Council on Post-Graduate Training of the American Osteopathic Association

☐ I affirm that the residency training program includes training and experience specified in:

☐ 35.190 ☐ 35.290

Name of Facility:	License/Permit Number:	
Name of Preceptor or Residency Program Director (Typed or Printed)	Telephone Number	Date
Signature		