



APPENDIX 1

Written Directive NOT Required

UPTAKE, DILUTION, AND EXCRETION
IMAGING AND LOCALIZATION

NOT REQUIRING WRITTEN DIRECTIVE LESS THAN 30 MICROCURIES OF NaI-131

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654]

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

64E-5.626(1) Uptake, dilution, and excretion studies 64E-5.627(1) Imaging & Localization

64E-5.631 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 <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

- a. Provide a copy of the board certification.
- b. If using only 64E-5.631 materials, stop here. If using 64E-5.626 and 64E-5.627 materials, skip to and complete Part II Preceptor Attestation.

2. Current 64E-5.660 Authorized User Seeking Additional 64E-5.650 Authorization

- a. Authorized user on Materials License _____ meeting 64E-5.660 or equivalent NRC or Agreement State requirements seeking authorization for 64E-5.650.
- 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
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Supervisor meets the requirements below, or equivalent Agreement State requirements *(check all that apply)*.

64E-5.650 64E-5.660 64E-5.650(3)(a)(2)(g)(generators)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
 (for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] 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 <i>(not required for 64E-5.654)</i>			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 64E-5.654).
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervise Work Experience		Total Hours of Experience:	
Description of Experience	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		<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	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] continued

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

b. Supervised Work Experience. (continued)

Description of Experience	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct 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/Permit Number listing supervising individual as an authorized user
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Supervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).

64E-5.649 64E-5.650 64E-5.660 64E-5.650(3)(a)(2)(g)(generators)

c. For 64E-5.654 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

d. For 64E-5.631 uses only, stop here. For 64E-5.626 and 64E-5.627 uses, skip to and complete Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626(1), .627(1), .628 and .631) [64E-5.649, .650, and .654] 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 64E-5.654)

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

First Section

Check one of the following for each use requested:

For 64E-5.626(1)

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

64E-5.649(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 64E-5.626.

OR

Training and Experience "Non Written Directive

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 64E-5.649(3), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 64E-5.626.

For 64E-5.627(1)

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

64E-5.650(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 64E-5.626 and 64E-5.627.

OR

Training and Experience "Non Written Directive"

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 64E-5.650(3)(a), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 64E-5.626 and 64E-5.627.

Second Section

Complete the following for preceptor attestation and signature:

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

64E-5.649 64E-5.650 64E-6.660 64E-5.650(3)(a)(2)(g)(generators)

Name of Preceptor	Signature	Telephone Number	Date
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License/Permit Number/Facility Name