



APPENDIX 2

Written Directive Required

UPTAKE, DILUTION, AND EXCRETION
IMAGING AND LOCALIZATION
RADIOPHARMACEUTICALS FOR THERAPY

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and.663]

Name of Proposed Authorized User | State or Territory Where Licensed

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

Grid of checkboxes for authorization categories: 64E-5.626, 64E-5.627, 64E-5.630 (1-4), 64E-5.630 (4) other radionuclide.

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...

- 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. For 64E-5.660, provide documentation on supervised clinical case experience.
c. For 64E-5.663, provide documentation on classroom and laboratory training...
d. Skip to and complete Part II Preceptor Attestation.
2. Current 64E-5.630, 64E-5.632, or 64E-5.634 Authorized User Seeking Additional Authorization
a. Authorized User on Materials License _____ under the requirements below or equivalent Agreement State requirements (check all that apply):
64E-5.660 64E-5.661 64E-5.662 64E-5.652 64E-5.655
b. If currently authorized for a subset of clinical uses under 64E-5.630, provide documentation on additional required supervised case experience.
c. If currently authorized under 64E-5.652 or 64E-5.655 and requesting authorization for 64E-5.663, provide documentation on classroom and laboratory training...

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .633]

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 64E-5.660 64E-5.661 64E-5.662 64E-5.663

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			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience 64E-5.660 64E-5.661 64E-5.662 64E-5.663

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

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	
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	
Total Hours of Supervised Work Experience:			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
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3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements <i>(check all that apply)**:</i>	
<input type="checkbox"/> 64E-5.660 <input type="checkbox"/> 64E-5.661 <input type="checkbox"/> 64E-5.662 <input type="checkbox"/> 64E-5.663	With experience administering dosages of: <input type="checkbox"/> Only for oral administration of sodium iodide I-131 less than or equal to 33 millicuries <input type="checkbox"/> Only for oral administration of sodium iodide I-131 greater than or equal to 33 millicuries <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive

** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

c. 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/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			
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			
<hr style="width: 20%; margin-left: 0;"/> (List radionuclides)			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
 (for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .663]

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

c. Supervised Clinical Case Experience (continued)

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)**:	
<input type="checkbox"/> 64E-5.660 <input type="checkbox"/> 64E-5.661 <input type="checkbox"/> 64E-5.662 <input type="checkbox"/> 64E-5.663	With experience administering dosages of: <input type="checkbox"/> Only for oral administration of sodium iodide I-131 less than or equal to 33 millicuries <input type="checkbox"/> Only for oral administration of sodium iodide I-131 greater than or equal to 33 millicuries <input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive <input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

d. Provide completed Part II Preceptor Attestation.

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.

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 requested authorization:

For 64E-5.660:

Board Certification

I attest that _____ has satisfactorily completed the training and experience requirements in 64E-5.660(1)(a).
Name of Proposed Authorized User

OR

Training and Experience

I attest that _____ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 64E-5.660(2)(a).
Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION
(for uses defined under 64E-5.626, .627, .630) [64E-5.660, .661, .662 and .663]

Preceptor Attestation (continued)

First Section (continued)

For 64E-5.661 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 64E-5.661(3)(a), and the supervised work and clinical case experience required in 64E-5.661(3)(b).

For 64E-5.662 (Identical Attestation Statement Regardless of Training and Experience Pathway):

I attest that _____ has satisfactorily completed the 80 hours of classroom
Name of Proposed Authorized User

and laboratory training, as required by 64E-5.662(3)(a), and the supervised work and clinical case experience required in 64E-5(3)(b).

Second Section

I attest that _____ has satisfactorily completed the required clinical case
Name of Proposed Authorized User

experience required in 64E-5.660(2)(g) listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Third Section

I attest that _____ has satisfactorily achieved a level of competency to
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

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Fourth Section

For 64E-5.663:

Current 64E-5.652 or .64E-5.655 authorized user:

I attest that _____ is an authorized user under 64E-5.652 or .64E-5.655
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 64E-5.663(4)(a), and the supervised work and clinical case experience required by 64E-5.663(4)(b), and has achieved a level of competency sufficient to function independently as an authorized user for:

- 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

OR

Board Certification:

I attest that _____ has satisfactorily completed the board certification
Name of Proposed Authorized User

requirements of 64E-5.663(3), has satisfactorily completed the 80 hours of classroom and laboratory training required by 64E-5.663(4)(a) and the supervised work and clinical case experience required by 64E-5.663(4)(b), and has achieved a level of competency sufficient to function independently as an authorized user for:

- 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

Fifth 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-5.660 64E-5.661 64E-5.662 64E-5.663

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

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