

NRC Medical Webinar Training

MEDICAL USER AUTHORIZATIONS FOR USE OF MATERIALS UNDER 10 CFR 35.300

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November 5th, 2015



Outline

- Definition and Overview
- Types of Authorization
- Training Requirements
- Licensing Guidance
- Sample License Actions/Cases
- Questions and Answers

^{*} Note that Agreement States may have regulatory requirements that are similar or more limiting than NRC's regulatory requirements. Please review and reference your State regulations to determine if the NRC regulations referenced in this training are the same and applicable.



Definition & Overview

- 10 CFR 35.300 Use of unsealed byproduct material for which a <u>written directive</u> (WD) is required.
- Some common radiopharmaceuticals containing byproduct materials:
 - lodine-131 for treatment of hyperthyroidism and thyroid cancer.
 - Strontium-89 (Metastron) for treatment of pain caused by metastatic bone cancer
 - Samarium-153 (Quadramet) for treatment of pain caused by metastatic bone cancer
 - Radium-223 (Xofigo) for treatment of metastatic bone cancer.
 - Yttrium-90 (Zevalin) for treatment of non-Hodgkin's lymphoma.



Definition – 10 CFR 35.300

- Unsealed byproduct material may be used by a licensee for medical purposes requiring a WD if:
 - a. It is obtained from: [1] A manufacturer or preparer for commercial distribution; or [2] A PET radioactive drug producer; OR
 - b. It is prepared by (excluding production of PET radionuclides): [1] An authorized nuclear pharmacist (ANP); [2] A physician who is an authorized user (AU) and meets the requirements in 10 CFR 35.290, 35.390; or [3] An individual under the supervision of the ANP or AU; OR
 - The material is obtained from and prepared by an NRC or AS licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; OR
 - d. The material is prepared by the licensee for use in research in accordance with an IND protocol accepted by FDA.



Types of Authorization

 An AU may be authorized for one or more of the subcategories below, but not for all unsealed byproduct material. Based on the current regulations, no <u>new</u> user may be authorized for all of 10 CFR 35.300.

10 CFR 35.300 AUTHORIZATION SUBCATEGORIES [from 10 CFR 35.390(b)(1)(ii)(G)]			
Subcategory #1	Oral administration of less than or equal to 33 mCi (1.22 GBq) of sodium iodide I-131, for which a written directive is required		
Subcategory #2	Oral administration of greater than 33 mCi (1.22 GBq) of sodium iodide I-131		
Subcategory #3	Parenteral administration of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required		
Subcategory #4	Parenteral administration of any other radionuclide, for which a written directive is required **Note: There are no known clinical uses in this subcategory.		



Training Requirements:

- 10 CFR 35.390 "Training for use of unsealed byproduct material for which a written directive is required"
- 10 CFR 35.392 "Training for the oral administration of sodium iodide I-131 requiring a WD in quantities less than or equal to 33 millicuries (1.22 GBq)"
- 10 CFR 35.394 "Training for the oral administration of sodium iodide I-131 requiring a WD in quantities greater than 33 millicuries (1.22 GBq)"
- 10 CFR 35.396 "Training for the parenteral administration of unsealed byproduct material requiring a written directive"



Pathways to AU Approval

1. Is the individual currently an AU on an NRC or Agreement State license for the same use being requested?



- 2. Is the individual board certified?
- 3. Is the individual a current AU for 10 CFR 35.300 (unsealed material), 35.400 (manual brachytherapy), or 35.600 (remote afterloader, teletherapy, gamma stereotactic radiosurgery units), seeking additional authorizations?
- 4. Does the individual have any Training and Experience?



10 CFR 35.390 – Training for use of unsealed byproduct material for which a written directive is required

Except for experienced AUs under 10 CFR 35.57, an AU has to be a:

- 1. Board certified physician + AU supervised work experience + written attestation
- 2. Physician with 700 hrs T&E (including a minimum of 200 hrs of class & lab)

- Board certification process has been recognized by NRC (http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html) or an AS
- AU supervised work experience includes a minimum of 3 cases in administration of dosages in each of the following categories:
 - i. Oral administration of sodium iodide I-131≤ 33mCi (1.22GBq), for which a WD is required;
 - ii. Oral administration of sodium iodide I-131> 33mCi (1.22GBq);
 - iii. Parenteral administration of any beta emitter, or a photon-emitting radionuclide a photon energy less than 150 keV, for which a WD is required; and/or
 - iv. Parenteral administration of any other radionuclide, that requires a WD
- Written attestation signed by a preceptor AU



10 CFR 35.392 – Training for oral administration of sodium iodide I-131 requiring a WD in quantities ≤ 33 mCi (1.22 GBq)

Except for experienced AUs under 10 CFR 35.57, AU is:

- 1. Board certified physician + written attestation
- 2. A physician that is an AU (listed on a license or permit) for administrations ≤ or > than 33 mCi, or for administration of only > than 33 mCi.
- 3. Physician with 80 hrs class & lab training + AU supervised work experience + written attestation

- Board certification process:
 - (i) includes 80hrs of applicable class & lab; (ii) includes AU supervised work experience of 3 case minimum in administration of dosages for Oral administration of I-131≤ 33mCi (WD required); and (ii) has been recognized by NRC or an AS;
- Written attestation signed by a preceptor AU



10 CFR 35.394 – Training for oral administration of sodium iodide I-131 requiring a WD in quantities > 33 mCi (1.22 GBq)

Except for experienced AUs (under 10 CFR 35.57), AU is:

- 1. Board certified physician + written attestation; OR
- 2. A physician that is an AU (listed on a license or permit) for oral administrations of sodium iodide I-131 > 33 mCi; <u>OR</u>
- 3. Physician with 80 hrs of applicable class & lab training + AU supervised work experience + written attestation

- Board certification process:
 - (i) includes 80hrs of applicable class & lab; (ii) includes AU supervised work experience; and (iii) has been recognized by NRC (http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html) or an AS.
- AU supervised work experience includes a minimum of 3 cases in oral administration of dosages of I-131 > 33mCi
- Written attestation signed by a preceptor AU



10 CFR 35.396 – Training for parenteral administration of unsealed byproduct material requiring a WD

Parenteral administration of:

- i. Any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV.
- ii. Any other radionuclide for which a WD is required.

NOTE:

Currently no known clinical uses in 10 CFR 35.300 subcategory #4 –
parenteral administration of any other radionuclide, for which a WD is
required.



10 CFR 35.396 – Training for parenteral administration of unsealed byproduct material requiring a WD

Except for experienced AUs (under § 35.57), AU is:

- 1. Physician AU (on a license or permit) under 10 CFR 35.390 for parenteral administration (i) or (ii); OR
- 2. Physician AU (on a license or permit) under 10 CFR 35.490 or 35.690 or equivalent AS requirements, + 80 hrs of class & lab training + AU supervised work experience + written attestation; OR
- 3. Board certified physician under 10 CFR 35.490 or 35.690 + has completed 80 hrs of class and lab training + supervised work experience + written attestation.

- AU supervised work experience in the parenteral administration of (i) and/or (ii), for which a
 WD is required.
- Written attestation signed by a preceptor AU



Licensing Guidance

NUREG-1556, Volume 9, Rev. 2: Consolidated Guidance About Materials Licensees – Program-Specific Guidance About Medical Use Licenses (http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/)

- Provides guidance to:
 - NRC and AS licensees and MML permittees for preparation of applications
 - NRC, AS, and MML staff for review of applications
- NRC Forms in Appendices to document training and experience
 - NRC Form 313A (AUT), "AU Training and Experience and Preceptor Attestation (for uses defined under 10 CFR 35.300)
 - NRC Form 313, "Application for Materials License"
 - NRC Form 313A (RSO), "RSO Medical Use Training & Experience & Preceptor Attestation"
 - NRC Forms 313A (AMP), (ANP), (AUD), (AUS)



Licensing Guidance

NRC FORM 313A (AUT)

Part I – Training & Experience NRC FORM 313A (AUT) (10-2015) U.S. NUCLEAR REGULATORY COMMISSION



AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (12/31/2015)

Name of Propose	ed Authorized User	State or Territory Where Licensed			
Requested Aut	Requested Authorization(s) (check all that apply):				
35.300	35.300 Use of unsealed byproduct material for which a written directive is required				
OR					
35.300	35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	equiring a written directive in quantities greater than 1.22			
35.300	Parenteral administration of any beta-emitte than 150 keV for which a written directive is	er, or photon-emitting radionuclide with a photon energy less required			
35.300	Parenteral administration of any other radio	nuclide for which a written directive is required			
		NING AND EXPERIENCE he three methods below)			
date of app training an	* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have 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. Provide a copy of the board certification.				
	390, provide documentation on supervised cl o document this experience.	inical case experience. The table in section 3.c. may			
and super	c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.				
d. Skip to	and complete Part II Preceptor Attestation.				
2. Current	t 35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional Authorization			
a. Authoriz	zed User on Materials License	under the requirements below or			
equival	lent Agreement State requirements (check al	I that apply):			
35.	390 35.392 35.394	35.490 35.690			
required su	b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.				
c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.					

NRC FORM 313A (AUT) (10-2015) PAGE 1



Licensing Guidance

NRC FORM 313A (AUT)

 Part II – Preceptor Attestation NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) Training and Experience for Proposed Authorized User (continued) Supervised Clinical Case Experience (continued) Supervising Individual License/Permit Number listing supervising individual as an authorized user. ets the requirements below, or equivalent Agreement State requirements (check all that apply)": With experience administering dosages of: 35,390 Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22. 35,392 gigabecquereis (33 millicuries) 35.394 Oral Nai-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) 35,396 Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV regulring a written directive is regulred. Parenteral administration of any other radionuclide requiring a written directive requesting authorized user status. Provide completed Part II Preceptor Attestation. PART II - PRECEPTOR ATTESTATION 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 35,390: Board Certification has satisfactorily completed the training and experience I attest that Name of Proposed Authorized User requirements in 35,390(a)(1). OR Training and Experience has satisfactorily completed the 700 hours of training I attest that Name of Proposed Authorized User and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).

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Licensing Actions – Case Examples



REMEMBER!!!

Pathways to AU Approval

- Current AU on an NRC or Agreement State license for the same use being requested
- 2. Board Certification
- 3. Current AU for 35.300 (unsealed material), 35.400 (manual brachytherapy), or 35.600 (remote afterloader, teletherapy, gamma stereotactic radiosurgery units) seeking additional authorizations
- 4. Training and Experience





Current AU for same uses requested

Case 1:

Dr. Goodfellow has been employed by South Hospital as a nuclear medicine physician since 1989. He is listed on their NRC license for use of unsealed byproduct materials under 10 CFR 35.300. He has been offered a position at North Hospital across town.

 May he be authorized for 10 CFR 35.300 on the new license?







Current AU for same uses requested

Case 1:

Yes, Dr. Goodfellow may be listed on the new license for uses under 10 CFR 35.300 because he is currently listed on an NRC license for the same uses.

At this point, this is the only way a physician may be authorized for all of 10 CFR 35.300.



Current AU for same uses requested

Case 2:

A licensee requests that Dr. Kupec be added to their NRC license for Oral administration of sodium iodide I-131 in quantities less than or equal to 33 mCi. As evidence of his experience, the licensee provides a copy of a current Agreement State license listing Dr. Kupec for the identical use.

May Dr. Kupec be listed for this use on the NRC license?







Current AU for same uses requested Case 1:

Yes, Dr. Kupec may be listed for the use of sodium iodide I-131 based on his current listing of the use on the Agreement State license.*

*Note that often, Agreement State licenses reference their State Regulations and you may have to review these to determine if the category of use is the same.



Three pieces of information are normally necessary to approve a proposed AU by the board certification pathway:

- Specialty board certification recognized by NRC under 10 CFR 35.300 (The current list and certification dates allowing approval are found on the NRC's website: http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html)
- 2. Clinical case experience
- 3. Preceptor Attestation

Note: NRC Form 313A (AUT) may be used to document Items 2 and 3



Case:

ABC Hospital has requested that Dr. Smith be added to their license for the use of sodium iodide I-131. Dr. Smith is a board certified Nuclear Medicine physician.

 What do you look for in the supporting information submitted?



Approved Boards

http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html

American Board of Radiology certificate (Diagnostic Radiology) dated from June 2011 forward with "AU eligible" appearing above the ABR seal

OR

Certification Board of Nuclear Endocrinology certification process from 2013 to present for all physicians issued a CBNE Nuclear Endocrinology- High Dose certificate.

OR

American Osteopathic Board of Radiology certificate (Diagnostic Radiology) dated from May 17, 2015 forward with the words "AU Eligible" appearing above the D.O. symbol



Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed:
 - Part I, Section 1 indicating the Board Certification pathway
 - Part I, Section 3.c. documenting at least 3 cases each of oral administration of sodium iodide I-131 in quantities less than or equal to and greater than 33 mCi under the supervision of an AU*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU Status



Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed (contd.):
 - Part II Preceptor Attestation
 - First Section indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework
 - Second Section confirming that the proposed AU has completed the required clinical casework for Oral NaI-131 in quantities greater than and less than 33 mCi
 - Third Section confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for oral administration of sodium iodide I-131



Preferred Documentation (10 CFR 35.392 & 35.394)

- NRC Form 313 (AUT) with the following sections completed (contd.):
 - Fifth Section Preceptor signature and confirmation of their training and experience*
 - *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.



NRC Form 313 (AUT) with the following sections completed:

 Part I, Section 1 indicating the Board Certification pathway NRC FORM 313A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION



AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-012 EXPIRES: (12/31/2015)

Name of Propose	ed Authorized User	State or Territory Where	Licensed	
Requested Authorization(s) (check all that apply):				
35.300	35.300 Use of unsealed byproduct material for which a written directive is required			
OR				
35.300	35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	equiring a written direc	tive in quantities greater than 1.22	
35.300	Parenteral administration of any beta-emitte than 150 keV for which a written directive is		adionuclide with a photon energy less	
35.300	Parenteral administration of any other radio	nuclide for which a writ	tten directive is required	
		NING AND EXPERIEN		
Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have 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. Provide a copy of the board certification.			
	b. For 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.			
c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.				
d. Skip to	and complete Part II Preceptor Attestation.			
2. Current	t 35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional	Authorization	
a. Authoriz	zed User on Materials License		under the requirements below or	
equivalent Agreement State requirements (check all that apply):				
35.	390 35.392 35.394	35.490	35.690	
b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.				
c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.				

NRC FORM 313A (AUT) (10-2015) PAGE 1



NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3.c. documenting at least 3 cases each of oral administration of sodium iodide I-131 in quantities ≤ and > 33 mCi under the supervision of an AU*
- * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

	AUTHORIZED USER TRAIL	NING AND EXPENSE	NCE AND PRECEPTOR ATTESTATION (CO	nunuea)		
3.	Training and Experience for Proposed Authorized User (continued)					
	b. Supervised Work Experience (continued)					
	Supervising Individual		License/Permit Number listing supervising indi- authorized user	License/Permit Number listing supervising individual as an authorized user		
	Supervising individual meets the apply) ":	e requirements below,	or equivalent Agreement State requirements	(check all that		
		e administering dosages of:				
35.392 Crai Nai-131 requiring a written directive in quantities less than or equal to 1.22 glgabecquereis (33 millicuries)						
	35.396 Parenteral ad	ministration of beta-e	han 1.22 gigabecquerels (33 millicuries) mitter, or photon-emitting radionuciide with a p a written directive is required	photon		
	Parenteral ad	iministration of any ot	her radionuclide requiring a written directive			
			tering dosages in the same dosage category or categorie	s as the individual		
	Supervised Clinical Case Experience More than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.					
Description of Experience Number of Car Involving Perso Participation			Location of Experience/License or Permit Number of Facility	Dates of Experience*		
	Oral administration of sodium lodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)					
	Oral administration of sodium lodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquereis (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					



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- First Section indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION		
The Section Control of the Control o	USER TRAINING AND EXPERIENC	E AND PRECEPTOR ATTESTATION (continued)		
Preceptor Attestation	(continued)			
First Section (conti	nued)			
For 35.392 (Identic	al Attestation Statement Regardles	s of Training and Experience Pathway):		
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom		
	y training, as required by 10 CFR 35.3 quired in 35.392(c)(2).	892(c)(1), and the supervised work and clinical case		
For 35.394 (Identic	al Attestation Statement Regardles	s of Training and Experience Pathway):		
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	AND THE RESERVE AND A STATE OF THE PARTY OF	994 (c)(1), and the supervised work and clinical case		
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	Name of Proposed Authorized User			
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	l administration of beta-emitter, or pho ss than 150 keV requiring a written dire	oton-emitting radionuclide with a photon ective is required		
Parenteral	administration of any other radionucli	lde requiring a written directive		
Third Section				
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I attest that	Name of Proposed Authorized User	has satisfactorily achieved a level of competency to		
function indep	pendently as an authorized user for:			
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Oral Nal-1	31 In quantities greater than 1.22 giga	abecquerels (33 milliouries)		
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				

NRC FORM (III.A (III.) (III.) (III.)



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Second Section –
 confirming that the
 proposed AU has
 completed the required
 clinical casework for Oral
 Nal-131 in quantities
 greater than and less
 than 33 mCi

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION				
AUTHORIZED U	SER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)				
Preceptor Attestation (co	ontinued)					
First Section (continu	ed)					
For 35.392 (Identical	Attestation Statement Regardle	ss of Training and Experience Pathway):				
I attest that	I attest that has satisfactorily completed the 80 hours of classroom					
	Name of Proposed Authorized User					
	raining, as required by 10 CFR 35. Ired in 35.392(c)(2).	392(c)(1), and the supervised work and clinical case				
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	Name of Proposed Authorized User					
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	requiring a written directive in qua els (33 millicuries)	antities less than or equal to 1.22				
Oral Nai-131	In quantities greater than 1.22 gig	gabecquerels (33 millicuries)				
Parenteral a energy less t	dministration of beta-emitter, or ph than 150 keV requiring a written di	oton-emitting radionuclide with a photon rective is required				
Parenteral a	dministration of any other radionuc	elide requiring a written directive				
Third Section						
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_	Name of Proposed Authorized User	_				
function indeper	function independently as an authorized user for:					
	requiring a written directive in qua els (33 millicuries)	antities less than or equal to 1.22				
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 a	Parenteral administration of any other radionuclide requiring a written directive					

NRC FORM 313A (AUT) (10-3015)



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Third Section –
 confirming the proposed
 AU has achieved a level
 of competency necessary
 to function independently
 as an AU for Oral
 administration of sodium
 iodide I-131

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
The second secon	USER TRAINING AND EXPERIENCE	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (c	continued)	
First Section (contin	ued)	
For 35.392 (Identica	Attestation Statement Regardles	ss of Training and Experience Pathway);
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
	training, as required by 10 CFR 35.3 ulred in 35.392(c)(2).	392(c)(1), and the supervised work and clinical case
For 35.394 (Identical	i Attestation Statement Regardles	ss of Training and Experience Pathway):
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	training, as required by 10 CFR 35. uired in 35.394(c)(2).	394 (c)(1), and the supervised work and clinical case
Second Section		
I attest that		has satisfactorily completed the required clinical case
es.	Name of Proposed Authorized User	
experience req	uired in 35.390(b)(1)(II)G listed belo	W.
	f requiring a written directive in qua rels (33 millicuries)	antities less than or equal to 1.22
Oral Nai-13	11 in quantities greater than 1.22 gig	abecquerels (33 millicuries)
	administration of beta-emitter, or phy than 150 keV requiring a written dir	oton-emitting radionuclide with a photon rective is required
Parenteral :	administration of any other radionuc	lide requiring a written directive
Third Section		
I attest that		has satisfactorily achieved a level of competency to
function indepe	Name of Proposed Authorized User endently as an authorized user for:	
Oral Nal-13	if requiring a written directive in qua	antities less than or equal to 1.22
	rels (33 millicuries)	
	if in quantities greater than 1.22 gig administration of beta-emitter, or ob-	abecquereis (33 milliounes) oton-emitting radionucide with a photon
	than 150 keV requiring a written dir	
Parenteral :	administration of any other radionuc	lide requiring a written directive

NRC FORM 310A (AUT) (10-0015)



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Fifth Section Preceptor signature and confirmation of their training and experience*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.

RC FORM 313A (AUT)						
AUTHORIZED	USER TRAININ	IG AND EXPERIEN	CE AND PRECEPTO	OR ATTESTATION (cor	ntinued)	
ourth Section						
For 35.396:						
Current 35,490 o	r 35.690 author	ized user:				
attest that	Maria of Dece	osed Authorized User	is an authorized us	ser under 10 CFR 35.49	0 or 35.690	
or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:						
		of any beta-emitter, o vritten directive is rec		dionucilde with a photon	energy less	
Parenteral	administration o	of any other radionuo	lide for which a writt	en directive is required		
		OF	l (
Board Certificati	on:					
 I attest that 			has satisfactorily of	completed the board cert	trication	
35.396(d)(2), authorized use	required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), 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 o	of any other radionuo	lide for which a writt	en directive is required		
Fifth Section Complete the following	g for preceptor	attestation and sig	nature:			
I meet the require	ements below, o	r equivalent Agreem	ent State requiremen	nts, as an authorized us	er for.	
35.390	35.392	35.394	35.396			
 I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization. 						
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						
ame of Preceptor		Signature		Telephone Number	Date	
cense/Permit Number/Facility Name						



Current 10 CFR 35.300, 35.400, or 35.600 AU seeking additional authorizations

REMINDER!

To approve a proposed AU by this pathway:

- 1. AU under a subset of 10 CFR 35.390 or 35.490 or 35.690, and
- Successful completion of 80 hours of classroom and lab training applicable to parenteral administrations, for which a written directive is required, and
- 3. Work experience under an AU who is authorized for 10 CFR 35.390 or 35.396, and
- Documented casework (at least 3), and
- Preceptor attestation



Case 1:

Dr. Stewart is listed as an AU at Main Line Hospital, a medical broad scope licensee, for oral administration of sodium iodide I-131 in quantities less than or equal to 33 mCi. The licensee has requested that Dr. Stewart's authorization be expanded to include all uses of sodium iodide I-131.







A copy of the broad scope permit authorizing him for the use of sodium iodide I-131 in quantities less than or equal to 33 mCi

- NRC Form 313 (AUT) with the following sections completed:
 - Part I, Section 2 indicating current status as an AU for 10 CFR35.392
 - Part I, Section 3 documentation of casework (including the name and authorization of the supervising AU*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



- NRC Form 313 (AUT) with the following sections completed (contd.):
 - Part II Preceptor Attestation
 - First Section indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework, as required by 10 CFR 35.394
 - Third Section confirming the proposed AU has achieved a level of competency necessary to function independently as an AU for oral administration of sodium iodide I-131
 - Fifth Section-Preceptor signature and confirmation of their training and experience*
 - *Confirm that preceptor is an AU by obtaining the NRC or Agreement State license or permit issued by a broad scope licensee that lists the preceptor as an AU.



NRC Form 313 (AUT) with the following sections completed:

Part I, Section 2 indicating current status as an AU for 10 CFR35.392

NRC FORM 313A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION

State or Territory Where Licensed



Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300)

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (12/31/2015)

[10 CFR 35.390, 35.392, 35.394, and 35.396]

Requested Aut	thorization(s) (check all that apply):			
35.300	Use of unsealed byproduct material for which	ch a written directive is	required	
OR				
35.300	Oral administration of sodium iodide I-131 r 1.22 gigabecquerels (33 millicuries)	requiring a written direct	tive in quantities less than or equal to	
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	requiring a written direct	tive in quantities greater than 1.22	
35.300	Parenteral administration of any beta-emitte than 150 keV for which a written directive is		idionuclide with a photon energy less	
35.300	Parenteral administration of any other radio	nuclide for which a writ	ten directive is required	
		NING AND EXPERIEN		
date of app training an experience	nd Experience, including board certification, replication or the individual must have related of dexperience was completed. Provide dates are related to the uses checked above. Certification	ontinuing education an	d experience since the required	
a. Provide	a copy of the board certification.			
	390, provide documentation on supervised cl o document this experience.	linical case experience.	The table in section 3.c. may	
and super	396, provide documentation on classroom an vised clinical case experience. The tables in this experience.			
d. Skip to	and complete Part II Preceptor Attestation.			
2. Current	t 35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional	Authorization	
a. Authoriz	zed User on Materials License		under the requirements below or	
equival	lent Agreement State requirements (check al	ll that apply):		
35.	390 35.392 35.394	35.490	35.690	
required su	ntly authorized for a subset of clinical uses un upervised case experience. The table in sect e. Also provide completed Part II Preceptor A	tion 3.c. may be used to		
c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.				

NRC FORM 313A (AUT) (10-2015)



NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 –
 documentation of
 casework (including the
 name and authorization
 of the supervising AU*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU Status

NRC FORM 313A (AUT)
U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

b. Supervised Work Experience	(continued)				
Supervising Individual		License/Permit Number listing supervising Indi- authorized user	vidual as an		
Supervising Individual meets the apply) ":	Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that				
35,390 With experience administering dosages of: 35,392 Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquereis (33 millicuries) Oral Nai-131 in quantities greater than 1.22 gigabecquereis (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					
		tering dosages in the same dosage category or categorie			
c. Supervised Clinical Case Exp if more than one supervising multiple copies of this page.		ny to document supervised work experience, p	orovide		
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 lodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)					
Oral administration of sodium lodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquereis (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					



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- First Section indicating the proposed AU has completed 80 hours of classroom and laboratory training, supervised work experience, and clinical casework, as required by 10 CFR 35.394

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
AUTHORIZED	USER TRAINING AND EXPERIENCE	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation	(continued)	
First Section (conti	nued)	
For 35.392 (Identic	al Attestation Statement Regardles	s of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
		392(c)(1), and the supervised work and clinical case
For 35.394 (Identic	al Attestation Statement Regardles	ss of Training and Experience Pathway):
attest that		has satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User y training, as required by 10 CFR 35. quired in 35.394(c)(2).	394 (c)(1), and the supervised work and clinical case
Second Section		
I attest that	Name of Proposed Authorized User	has satisfactorily completed the required clinical case
Oral Nal-1 glgabecqu	quired in 35.390(b)(1)(ll)G listed belo 31 requiring a written directive in qua sereis (33 millicuries)	antities less than or equal to 1.22
A CONTRACTOR OF THE PARTY OF TH	31 in quantities greater than 1.22 gig	Service and the service of the servi
	l administration of beta-emitter, or phy is than 150 keV requiring a written dir	oton-emitting radionuclide with a photon ective is required
Parentera	l administration of any other radionuc	ilde requiring a written directive
Third Section		
I attest that		has satisfactorily achieved a level of competency to
function indep	Name of Proposed Authorized User bendently as an authorized user for:	
	31 requiring a written directive in qua verels (33 millicuries)	intities less than or equal to 1.22
	31 In quantities greater than 1.22 glg	A CONTRACTOR OF THE PROPERTY O
	l administration of beta-emitter, or phy is than 150 keV requiring a written dir	oton-emitting radionuclide with a photon rective is required
Parenteral	administration of any other radionuc	lide requiring a written directive

NRC FORM (III.A (III.) (III.) (III.)



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Third Section –
 confirming the proposed
 AU has achieved a level
 of competency necessary
 to function independently
 as an AU for Oral
 administration of sodium
 iodide I-131

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
NAME AND ADDRESS OF THE OWNER, TH	USER TRAINING AND EXPERIENCE A	ID PRECEPTOR ATTESTATION (continued)
Preceptor Attestation	(continued)	
First Section (cont	Inued)	
For 35,392 (Identic	cal Attestation Statement Regardless of	Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	satisfactorily completed the 80 hours of classroom
	THE PERSON NAMED IN COLUMN TWO IS NOT THE PERSON NAMED IN COLUMN TWO IS NAM	(1), and the supervised work and clinical case
For 35.394 (Identic	cal Attestation Statement Regardless of	Training and Experience Pathway):
I attest that		satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User	
	y training, as required by 10 CFR 35.394 (equired in 35.394(c)(2).	c)(1), and the supervised work and clinical case
Second Section		
I attest that	Name of the state	satisfactorily completed the required clinical case
	Name of Proposed Authorized User	
experience re	equired in 35.390(b)(1)(II)G listed below:	
	131 requiring a written directive in quantitie uereis (33 millicuries)	s less than or equal to 1.22
Oral Nai-	131 in quantities greater than 1.22 gigabed	querels (33 millicuries)
	il administration of beta-emitter, or photon- ss than 150 keV requiring a written directiv	
Parentera	il administration of any other radionuclide r	equiring a written directive
Third Section		
I attest that	A STATE OF THE STA	satisfactorily achieved a level of competency to
	Name of Proposed Authorized User	
function inde	pendently as an authorized user for:	
	131 requiring a written directive in quantitle uereis (33 millicuries)	s less than or equal to 1.22
Oral Nai-	131 In quantities greater than 1.22 gigabed	quereis (33 millicuries)
	il administration of beta-emitter, or photon- ss than 150 keV requiring a written directiv	
E-	il administration of any other radionuclide r	

NRC FORM 310A (AUT) (10-3015)



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Fifth Section Preceptor signature and confirmation of their training and experience*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit issued by a broad scope licensee which lists the preceptor as an AU.

RC FORM 313A (AUT)				U.S. NUCLEAR REGULA	ATORY COMMISSION
AUTHORIZED	D USER TRAINI	NG AND EXPERIE	NCE AND PRECEPT	OR ATTESTATION (C	ontinued)
ourth Section					
For 35.396:					
Current 35,490	or 35.690 autho	rized user:			
I attest that	Name of Dec	posed Authorized User	is an authorized u	user under 10 CFR 35.4	490 or 35.690
laboratory tra experience re	t Agreement Stat aining, as require	te requirements, ha ed by 10 CFR 35.39 96(d)(2), and has ac	96 (d)(1), and the supe	eted the 80 hours of cla ervised work and clinica petency sufficient to fu	al case
		of any beta-emitter written directive is r		adionuclide with a phot	on energy less
Parenter	al administration	of any other radion	uclide for which a writ	tten directive is require	d
Board Certificat	diam.	C	OR		
	mon.				
I attest that		posed Authorized User	has satisfactorily	completed the board o	ertification
than 150	al administration keV for which a al administration	written directive is r of any other radion	required nuclide for which a writ	adionuclide with a phot tten directive is required	24
I meet the requi	irements below, (or equivalent Agree	ment State requireme	ents, as an authorized (user for:
35.390	35.392	35.394	35.396		
I have experient requesting author		dosages in the folk	owing categories for w	which the proposed Aut	thorized User is
Oral Nai-131 millicuries)	l requiring a writt	en directive in quar	ntities less than or equ	ual to 1.22 glgabecquer	rels (33
Oral Nai-131	I in quantities gre	eater than 1.22 glga	abecquerels (33 millio	urles)	
150 keV requ	uiring a written d	frective is required		ilde with a photon ener	gy less than
ame of Preceptor		Signature	-	Telephone Number	Date
THE TAX I TO SERVE YOUR				12 12 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
cense/Permit Number/F	acilty Name				
on proper series payers associated.					0.000



Dr. Miller is a Radiation Oncologist at Suburban Hospital (AS licensee). She is listed on their license for the use of high dose rate remote afterloader (35.600). The hospital intends to use Xofigo (parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV) in the near future and would like her to be the AU.

What would Dr. Miller need to provide?



A copy of the AS license listing her as an AU for 10 CFR 35.600.

- NRC Form 313 (AUT) with the following sections completed:
 - Part I, Section 2 indicating the current AU pathway
 - Part I, Section 3 documentation of 80 hrs of classwork and lab training; supervised work experience (including the name and authorization of the supervising AU); and casework*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status



- NRC Form 313 (AUT) with the following sections completed (contd.):
 - Part II Preceptor Attestation
 - Fourth Section confirming current AU status; 80 hrs of classroom and lab training; supervised work experience; and casework
 - Fifth Section-Preceptor signature and confirmation of their T&E*
 - *Confirm that preceptor is an AU by obtaining the NRC or Agreement State license or permit that lists the preceptor as an AU.

NOTE: In addition, 10 CFR 35.396 T&E requirements are only for 35.400 and 35.600 users. If an individual is authorized under 35.400 or 35.600, then that individual would only need an additional 80 hours of T&E, specifically in parenteral administrations and three cases of parenteral administration.



NRC Form 313 (AUT) with the following sections completed:

Part I, Section 2 indicating the current AU pathway

NRC FORM 313A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION

State or Territory Where Licensed



Name of Proposed Authorized User

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]

APPROVED BY OMB: NO. 3150-0120 EXPIRES: (12/31/2015)

Requested Aut	Requested Authorization(s) (check all that apply):					
35.300	Use of unsealed byproduct material for which	ich a written directive is required				
OR						
35.300	Oral administration of sodium iodide I-131 r 1.22 gigabecquerels (33 millicuries)	requiring a written directive in quantities less than	or equal to			
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	requiring a written directive in quantities greater th	nan 1.22			
35.300	Parenteral administration of any beta-emitte than 150 keV for which a written directive is	er, or photon-emitting radionuclide with a photon e s required	energy less			
35.300	Parenteral administration of any other radio	onuclide for which a written directive is required				
		INING AND EXPERIENCE the three methods below)				
date of app training an experience	plication or the individual must have related c	must have been obtained within the 7 years prece continuing education and experience since the red s, duration, and description of continuing education	quired			
	e a copy of the board certification.					
b. For 35.		linical case experience. The table in section 3.c.	may			
and super	396, provide documentation on classroom an rvised clinical case experience. The tables in this experience.	nd laboratory training, supervised work experience in sections 3.a., 3.b., and 3.c. may be used to	; ,			
d. Skip to	and complete Part II Preceptor Attestation.					
2. Curren	t 35.300, 35.400, or 35.600 Authorized Use	er Seeking Additional Authorization				
a. Authori	zed User on Materials License	under the requirements b	elow or			
equivalent Agreement State requirements (check all that apply):						
35.	35.390 35.392 35.394 35.490 35.690					
required si	b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.					
document case expe	c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.					

NRC FORM 313A (AUT) (10-2015)



NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 –
 documentation of 80 hrs
 of classroom and lab
 training; supervised work
 experience (including the
 name and authorization
 of the supervising AU);
 and casework*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

IC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION 3010)				
AUTHORIZED USER TRAI	NING AND EXPERIENCE AND PRECEPTOR ATT	ESTATION (co	intinued)	
3. Training and Experience fo	r Proposed Authorized User			
a. Classroom and Laboratory Tr	alning 35.390 35.392 35.3	394	35.396	
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 blology				
	Total Hours of Training:			
 Supervised Work Experience if more than one supervising of this page. 	e 35.390 35.392 35.3 Individual is necessary to document supervised trail	_	35.396 nultiple copies	
Supervised Wo	ork Experience Total Hours of Expe	rience:		
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		
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		

or programme management of the control of the contr



NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3 –
 documentation of 80 hrs
 of classroom and lab
 training; supervised work
 experience (including the
 name and authorization
 of the supervising AU);
 and casework*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

NRC FORM 313A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued

ĸ,	. Training and Experience for Proposed Authorized User (continued)				
	b. Supervised Work Experience	(continued)			
	Supervising Individual		License/Permit Number listing supervising indi- authorized user	License/Permit Number listing supervising individual as an authorized user	
	Supervising Individual meets the apply) ":	e requirements below,	, or equivalent Agreement State requirements	(check all that	
	35,390 With experience	administering dosage	s of:		
	digabecquere	requiring a written din ss (33 millicuries)	ective in quantities less than or equal to 1.22		
	35.394 Oral Nal-131	In quantities greater t	han 1.22 gigabecquerels (33 millicuries)		
	Parenteral ad		mitter, or photon-emitting radionuclide with a p pa written directive is required	ohoton	
		•	her radionuclide requiring a written directive		
			tering dosages in the same dosage category or categorie		
	c. Supervised Clinical Case Ex If more than one supervising multiple copies of this page.		ry to document supervised work experience, p	orovide	
	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 lodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
	Oral administration of sodium lodide 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				



NRC Form 313 (AUT) with the following sections completed:

- Part II Preceptor Attestation
- Fourth Section –
 confirming current AU
 status; 80 hrs of
 classroom and lab
 training; supervised work
 experience; and
 casework
- Fifth Section Preceptor signature & confirmation of their T&E

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) Forth Section For 35.395: Current 35.490 or 35.690 authorized user:	NRC FORM 313A (AUT)					
For 35.396: Current 35.490 or 35.690 authorized user: lattest that Name of Proposes Authorized User Is an authorized user under 10 CFR 35.490 or 35.690 lattest that Name of Proposes Authorized User Is an authorized user under 10 CFR 35.490 or 35.690 lattest that Name of Proposes Authorized User Is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactority completed the 80 hours of classroom and laboratory training, as required by 35.396 (2)(2), 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 Parenteral administration of any other proposed Authorized User Requirements of 35.396 (3)(1) and the supervised work and clinical case experience required by 35.396(d)(2), 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 Parenteral administration of any other radionuclide for which a written directive is required I have experience administration directive in quantities less than or equal to 1.22 gigabecquereis (33 millicuries) I have experience administration of directive in quantities less than or equal to 1.22 gigabecquereis (33 millicuries) Oral Nai-131 in quantities greater than 1.22 gigabecquereis (33 millicuries) Parenteral administration of any other radionuclide requiring a written directive is required Parenteral administration of any other radionuclide requiring a written directive	AUTHORIZED USER TRAINI	NG AND EXPERIENC	E AND PRECEPTO	OR ATTESTATION (con	ntinued)	
Current 35.490 or 35.690 authorized user:	Fourth Section					
lattest that Share of Proposed Authorized User Is an authorized user under 10 CFR 35.490 or 35.690 or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), 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 Parenteral administration of any other radionuclide for which a written directive is required Parenteral administration of any other radionuclide for which a written directive board certification Parenteral administration of any other supervised work and clinical case experience required by 35.395(d)(2), 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 Parenteral administration of any other radionuclide for which a written directive is required I have experience administration of any other radionuclide for which a written directive user for: I have experience administration of any other radionuclide is set than or equal to 1.22 gigabecquereis (33 millicuries) Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive in required Parenteral administration of any other radionuclide requiring a written directive is required Parenteral administration of any other radionuclide requiring a written directive Par	The second of the second					
or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.996 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), 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 Parenteral administration of any other radionuclide for which a written directive is required OR Board Cartifloation:	Current 35.490 or 35.690 author	orized user:				
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than 150 keV for which a written directive is required Parenteral administration of any other radionuclide for which a written directive is required Roard Cartification:	or equivalent Agreement Sta laboratory training, as require experience required by 35.33	te requirements, has s ed by 10 CFR 35.396 (96(d)(2), and has achie	d)(1), and the super	rvised work and clinical o	case	
Date				dionuclide with a photon	energy less	
lattest that	Parenteral administration	of any other radionucl	ide for which a writt	en directive is required		
I attest that National of Proposed Authorized User requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), 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 I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390		OR				
requirements of 35.396(c), has satisfactorized the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), 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 Parenteral administration of any other radionuclide for which a written directive is required I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390	Board Certification:					
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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: 35.390				diolidande wiet a priotori	energy less	
I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390	Parenteral administration	of any other radionuc	ide for which a writt	en directive is required		
35.390 35.392 35.394 35.396 I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization. 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 Name of Preceptor Signature Telephone Number Date	Fifth Section Complete the following for precepto	r attestation and sign	nature:			
I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization. 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 Name of Preceptor Signature Telephone Number Date	I meet the requirements below,	or equivalent Agreeme	ent State requiremen	nts, <mark>as an authorized use</mark>	er for:	
requesting authorization. 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 Name of Preceptor Signature Telephone Number Date	35.390 35.392	35.394	35.396			
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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						
150 keV requiring a written directive is required Parenteral administration of any other radionuclide requiring a written directive Signature Telephone Number Date	Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 milliouries)					
Name of Preceptor Signature Telephone Number Date						
	Parenteral administration of any other radionuclide requiring a written directive					
Jcense/Fermit Number/Facility Name	Name of Preceptor	Signature		Telephone Number	Date	
	License/Permit Number/Facility Name					



Training & Experience

Case:

Dr. Jones just completed her residency and has been hired by Metro Hospital. She is a nuclear medicine physician that has not completed her boards. Metro Hospital has requested that Dr. Jones be added to the license as an AU for the use of sodium iodide I-131 in quantities greater than 33 mCi (10 CFR 35.394). She has completed 4 clinical cases.

 What evidence of training and experience would you expect to see?



NRC Form 313 (AUT) with the following sections completed:

- Part I, Section 3a.,b.,c. documentation of 80 hrs of class and lab training applicable to administration of I-131; supervised work experience (including the name and authorization of the supervising AU); and casework*
 - * the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

C FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION 2015) AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)						
Training and Experience for Classroom and Laboratory Tr.	3. Training and Experience for Proposed Authorized User a. Classroom and Laboratory Training 35.390 35.392 35.394 35.396					
Description of Training	alning 35.390 35.392 35. Location of Training	394 35.396 Clock Dates of Hours Training*				
Radiation physics and Instrumentation	-	Training Training				
Radiation protection						
Mathematics pertaining to the use and measurement of radioactivity						
Chemistry of byproduct material for medical use						
Radiation blology						
	Total Hours of Training:					
 Supervised Work Experience If more than one supervising of this page. 	e 35.390 35.392 35. Individual is necessary to document supervised train	394 35.396 Ining, provide multiple copies				
Supervised Wo	ork Experience Total Hours of Expe	erlence:				
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				
Calculating, measuring, and safely preparing patient or human research subject dosages		Yes				
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				
C POPM 1419 (NUT), HARRING		54050				

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NRC Form 313 (AUT) with the following sections completed:

Part I, Section 3a.,b.,c. – documentation of 80 hrs of class and lab training applicable to administration of I-131; supervised work experience (including the name and authorization of the supervising AU); and casework*

* the supervising AU must have experience in administering dosages in the same categories as the individual requesting AU status

NRC FORM 313A (AUT)

U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) 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 (check all that 35,390 Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22 35,392 digabecquerels (33 millicuries) 35,394 Oral Nat-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) 35,396 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 Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status. Supervised Clinical Case Experience If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page. Number of Cases Location of Experience/License or Permit Dates of Description of Experience Involving Personal Number of Facility Experience^{*} Participation | Oral administration of sodium odide I-131 requiring a written directive in quantities less than or equal to 1.22 glgabecquerek (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

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 (Lat radionuclides)		
period from the base of the control of the same		BACK A



NRC Form 313 (AUT) with the following sections completed – <u>Part II</u> – Preceptor Attestation:

- First Section indicating proposed AU for 35.394, has completed 80 hrs of class & lab; supervised work experience; and clinical casework.
- Second Sectionconfirming that the proposed AU has completed the required clinical casework for administrations > 33 mCi

NRC FORM 313A (AUT)		U.S. NUCLEAR REGULATORY COMMISSION
THE RESERVE OF THE PARTY OF THE	ISER TRAINING AND EXPERIENCE	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (c	ontinued)	
First Section (continu	ued)	
For 35.392 (Identical	Attestation Statement Regardles	s of Training and Experience Pathway):
I attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
		392(c)(1), and the supervised work and clinical case
For 35.394 (Identical	Attestation Statement Regardles	s of Training and Experience Pathway):
attest that		has satisfactorily completed the 80 hours of classroom
	Name of Proposed Authorized User raining, as required by 10 CFR 35.3 lined in 35.394(c)(2).	394 (c)(1), and the supervised work and clinical case
Second Section		
attest that	Name of Proposed Authorized User	has satisfactorily completed the required clinical case
Oral Nai-13	uired in 35.390(b)(1)(li)G listed belo I requiring a written directive in qua reis (33 millicuries)	
Oral Nal-13	I in quantities greater than 1.22 gig	abecquerels (33 millicuries)
	dministration of beta-emitter, or phy than 150 keV requiring a written dir	oton-emitting radionuclide with a photon ective is required
	dministration of any other radionuc	CONTRACTOR CONTRACTOR STOCKERS
Third Section		
I attest that		has satisfactorily achieved a level of competency to
	Name of Proposed Authorized User	
function indeper	ndently as an authorized user for:	
	l requiring a written directive in qua reis (33 millicuries)	intities less than or equal to 1.22
Oral Nai-13	I in quantities greater than 1.22 gig	abecquerels (33 millicuries)
	dministration of beta-emitter, or phy than 150 keV requiring a written dir	oton-emitting radionuciide with a photon rective is required
Parenteral a	dministration of any other radionuc	lide requiring a written directive

NRC FORM (IDA NUT) (10-0015)



NRC Form 313 (AUT) with the following sections completed – <u>Part II</u> – Preceptor Attestation:

- Third Section —
 confirming the proposed
 AU has achieved a level
 of competency necessary
 to function independently
 as an AU for
 administration of I-131
- <u>Fifth Section</u> Preceptor signature & confirmation of their T&E*
- *Confirm the preceptor is an AU by obtaining the NRC or Agreement State license or permit, which lists the preceptor as an AU.

NRC FORM 313A (AUT)				U.S. NUCLEAR REGULATORY COMMISSION		
AUTHORIZED	USER TRAINII	NG AND EXPERIE	NCE AND PRECEPT	OR ATTESTATION (co	ontinued)	
Fourth Section						
For 35.396:						
Current 35,490 d	or 35.690 autho	rized user:				
attest that	Name of Proposed Authoritied User		is an authorized u	d user under 10 CFR 35.490 or 35.690		
laboratory tra experience re	Agreement Stati Ining, as require	e requirements, had d by 10 CFR 35.39 6(d)(2), and has ac	6 (d)(1), and the supe	eted the 80 hours of cla ervised work and clinica petency sufficient to fur	case	
		of any beta-emitter, written directive is r		idionuclide with a photo	n energy less	
Parenteral	administration	of any other radioni	clide for which a writ	ten directive is required	i	
		0	R			
Board Certificat	ion:					
I attest that			has satisfactorily completed the board certification			
required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), 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 followin	V 10 10 10 10 10 10 10 10 10 10 10 10 10		The state of the s			
i meet the requir	ements below, o	or equivalent Agree	ment State requireme	nts, as an authorized u	ser for.	
35.390	35.392	35.394	35,396			
I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.						
Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)						
Oral Nal-131	In quantities gre	eater than 1.22 glga	becquerels (33 millio	uries)		
		eta-emitter, or phot rective is required	on-emitting radionuc	ide with a photon energ	y less than	
Parenteral ad	ministration of a	any other radionucli	de requiring a written	directive		
Name of Preceptor		Signature		Telephone Number	Date	
License/Permit Number/Facility Name						



Training & Experience

NOTE:

10 CFR 35.392 (b) states that if a physician is authorized for the use of 35.394 materials, they may be authorized for 35.392.

Therefore, Dr. Jones could be approved for the use of sodium iodide I-131 for both less than and greater than 33 mCi.



Training & Experience

Case (contd.):

What if Dr. Jones had documented 5 cases of sodium iodide I-131 less than or equal to 33 mCi and 2 cases of sodium iodide I-131 greater than 33 mCi?

 35.394(c)(2)(vi) requires that the proposed AU have experience administering dosages in <u>at least 3</u> <u>cases</u> involving the oral administration of greater than 33 mCi of sodium iodide I-131.

Therefore, Dr. Jones would be authorized for sodium iodide I-131 less than or equal to 33 mCi only.

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QUESTIONS?

