

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



<u>10 CFR 35.396</u> – 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); <u>OR</u>
- 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)

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	horization(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)	equiring a written direct	ive in quantities less than or equal to	
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	equiring a written direct	ive in quantities greater than 1.22	
35.300	Parenteral administration of any beta-emitte than 150 keV for which a written directive is		dionuclide with a photon energy less	
35.300	Parenteral administration of any other radio	nuclide for which a writt	en directive is required	
		NING AND EXPERIENT he three methods belo	_	
date of app training an	nd Experience, including board certification, rollication or the individual must have related of experience was completed. Provide dates related to the uses checked above.	ontinuing education and	d experience since the required	
1. Board	Certification			
a. Provide	a copy of the board certification.			
	390, provide documentation on supervised cl 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 A	Authorization	
a. Authoriz	zed User on Materials License		under the requirements below or	
equival	ent Agreement State requirements (check al	l 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.			
documenta 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) 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).

C-70/04/04/04 (41/7) (60 0049)



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 Nal-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

State or Territory Where Licensed



Name of Proposed Authorized User

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

EXPIRES: (12/31/2015)

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

Requested Authorization(s) (check all that apply):		
35,300 Use of unsealed byproduct material for which 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 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 s required	
35.300 Parenteral administration of any other radio	nuclide for which a written directive is required	
	NING AND EXPERIENCE the three methods below)	
Training and Experience, including board certification, r date of application or the individual must have related c training and experience was completed. Provide dates experience related to the uses checked above. 1. Board Certification		
a. Provide a copy of the board certification.		
 b. For 35.390, provide documentation on supervised cl be used to document this experience. 	inical case experience. The table in section 3.c. may	
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 35.300, 35.400, or 35.600 Authorized Use	r Seeking Additional Authorization	
a. Authorized User on Materials License	under the requirements below or	
equivalent Agreement State requirements (check al	I that apply):	
35.390 35.392 35.394	35.490 35.690	
b. If currently authorized for a subset of clinical uses un required supervised case experience. The table in sect experience. Also provide completed Part II Preceptor A	tion 3.c. may be used to document this	
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.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

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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued

AUTHORAGED USEN THAIRMING AND EXPENDENCE AND PRECEPTOR ATTESTATION (CONTINUES)						
3.	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		
		administering dosage				
	35.394 glgabecquere	35.392 Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
	35.396 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					
			her 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. 					
Description of Experience Number of Case Involving Person 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 glgabecquerels (33 millicuries) Oral administration of sodium lodide I-131 requiring a written directive in quantities greater than 1.22 glgabecquerels (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					

AND DOORS DADE OF TO LOD DOOR



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		
DOMESTIC CONTRACTOR OF THE PARTY OF THE PART	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);		
attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom		
		892(c)(1), and the supervised work and clinical case		
For 35.394 (Identic	al Attestation Statement Regardles	s 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 35.3 equired 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		
	Name of Proposed Authorized User			
experience re	quired in 35.390(b)(1)(II)G listed below	AC.		
	l31 requiring a written directive in quar vereis (33 millicuries)	ntitles less than or equal to 1.22		
Oral Nal-1	31 in quantities greater than 1.22 giga	abecquerels (33 millicuries)		
	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				
I attest that	Name of Proposed Authorized User	has satisfactorily achieved a level of competency to		
function indep	pendently as an authorized user for:			
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 gigabecquerels (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	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			
	R TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
Preceptor Attestation (con	tinued)			
First Section (continued	ŋ			
For 35.392 (Identical At	testation Statement Regardless of Training and Experience Pathway):			
I attest that	has satisfactorily completed the 80 hours of dissarborn			
and laboratory trail experience require	ning, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case kd in 35.392(c)(2).			
For 35.394 (Identical At	testation Statement Regardless of Training and Experience Pathway):			
I attest that	has satisfactorily completed the 80 hours of dissercom			
	Name or Proposed Authorized Laser			
and laboratory trai experience require	ning, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case and in 35.394(c)(2).			
Second Section				
I attest that	has satisfactorily completed the required clinical case Name of Proposed Authorized User			
experience require	d in 35.390(b)(1)(II)G listed below:			
	equiring a written directive in quantities less than or equal to 1.22 (33 milliouries)			
Oral Nai-131 in	quantities greater than 1.22 gigabecquerels (33 milliouries)			
	inistration of beta-emitter, or photon-emitting radionuclide with a photon in 150 keV requiring a written directive is required			
Parenteral adm	ninistration of any other radionuclide requiring a written directive			
Third Section				
I attest that	has satisfactorily achieved a level of competency to			
function independs				
	function independently as an authorized user for:			
 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 gigabecquerels (33 milliourles)				
Parenteral administration of beta-emitter, or photon-emitting radionucide with a photon energy less than 150 keV requiring a written directive is required				
Parenteral adm	ninistration 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
AUTHORIZED U	ISER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation (c	ontinued)
First Section (contin	ued)
For 35.392 (Identical	Attestation Statement Regardless of Training and Experience Pathway):
I attest that	has satisfactorily completed the 80 hours of classroom
	training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case ulred in 35.392(c)(2).
For 35.394 (Identical	Attestation Statement Regardless of Training and Experience Pathway):
I attest that	has satisfactorily completed the 80 hours of classroom
	training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case ulred in 35.394(c)(2).
Second Section	
attest that	has satisfactorily completed the required clinical case
* - 3 III	Name of Proposed Authorized User
experience req	uired in 35.390(b)(1)(II)G listed below:
	f requiring a written directive in quantities less than or equal to 1.22 reis (33 millicuries)
Oral Nai-13	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
Parenteral a energy less	dministration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
Parenteral a	dministration of any other radionuclide requiring a written directive
Third Section	
I attest that	has satisfactorily achieved a level of competency to
function indepe	ndently as an authorized user for:
	f requiring a written directive in quantities less than or equal to 1.22 rels (33 millicuries)
Oral Nal-13	1 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	dministration of beta-emitter, or photon-emitting radionuclide with a photon than 150 keV requiring a written directive is required
Parenteral a	dministration of any other radionuclide requiring a written directive

NRC FORM INDA (NUT) (16-0015) PAGE 1



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.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) Fourth Section For 35.395: Current 35.490 or 35.690 authorized user: lattest that	NRC FORM 313A (AUT)					
For 35.396: Current 35.490 or 35.690 authorized user: lattest that	AUTHORIZED USER TRAIN	NING AND EXPERIENCE	E AND PRECEPTO	OR ATTESTATION (con	ntinued)	
Current 35.490 or 35.690 authorized user:	Fourth Section					
lattest that	The second of th					
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 auti	norized user:				
or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CPR 35.396 (d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for. Parentleral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required Parentleral administration of any other radionuclide for which a written directive is required OR Roard Cartifloation: I attest that Name of Proposed Authorized User requirements of 35.396(g); has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CPR 35.395 (d)(1); and the 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: Parentleral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required Parentleral administration of any other radionuclide for which a written directive is required Parentleral 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 35.392 35.394 35.394 15.395 I have experience administration of any other radionuclide isses than or equal to 1.22 gigabecquereis (33 milliouries) Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquereis (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 is required		Innovant & Shortest User	is an authorized us	ser under 10 CFR 35.49	0 or 35.690	
than 150 keV for which a written directive is required Parenteral administration of any other radionuclide for which a written directive is required Roard Certification:	or equivalent Agreement St laboratory training, as requi experience required by 35.3	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				
Date Date				dionuclide with a photon	energy less	
lattest that	Parenteral administratio	n of any other radionuc	lide for which a writt	en directive is required		
I attest that Name 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 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	i i			
requirements of \$3.56(c), has satisfatorized their requirements of \$3.56(c), has satisfatorized work and clinical case experience 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:					
requirements of 35.396(g), 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 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			has satisfactorily o	completed the board cert	tfication	
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 is requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390	required by 10 CFR 35.396 35.396(d)(2), and has achie authorized user for:	(d)(1) and the supervis eved a level of compete	ed work and clinical ncy sufficient to fund	case experience require tion independently as a	ed by	
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				diological will a prictor	chegy ico	
I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390	Parenteral administratio	n of any other radionuc	lide 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 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 Name of Preceptor Signature Telephone Number Date	Fifth Section Complete the following for precept	or 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 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 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			
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						
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 Signature Telephone Number Date						
150 keV requiring a written directive is required Parenteral administration of any other radionuclide requiring a written directive Vame of Preceptor Signature Telephone Number Date	Oral Nai-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)					
Name of Preceptor Signature Telephone Number Date						
	Parenteral administration of any other radionuclide requiring a written directive					
Icense/Permit Number/Facility Name	Name of Preceptor	Signature		Telephone Number	Date	



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



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	horization(s) (check all that apply):				
35.300	Use of unsealed byproduct material for whi	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 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 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 s required			
35.300	Parenteral administration of any other radio	nuclide for which a written directive is required			
		NING AND EXPERIENCE			
	(Select one of t	the three methods below)			
date of app training an	olication or the individual must have related o	must have been obtained within the 7 years preceding the continuing education and experience since the required , duration, and description of continuing education and			
	Certification				
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	• •	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. Authoria	zed User on Materials License	under the requirements below or			
equival	lent Agreement State requirements (check a	Il that apply):			
35.	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 –
 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)

 Supervised Work Experience 	(continued)			
Supervising Individual		License/Permit Number listing supervising indi- authorized user	vidual as an	
		or equivalent Agreement State requirements	(check all that	
35.392	ls (33 millicuries)	s of: ective in quantities less than or equal to 1.22 han 1.22 gigabecquerels (33 millicuries)		
35.396 Parenteral ad energy less th	ministration of beta-e ian 150 keV requiring	mitter, or photon-emitting radionuclide with a a written directive is required	photon	
	· · · · · · · · · · · · · · · · · · ·	her radionuclide requiring a written directive tering dosages in the same dosage category or categorie		
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 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				

AND DESCRIPTION OF THE PARTY OF THE PARTY.



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
THE RESERVE OF THE PARTY OF THE	USER TRAINING AND EXPERIENCE	CE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation	(continued)	
First Section (conti	nued)	
For 35,392 (Identic	al Attestation Statement Regardles	ss of Training and Experience Pathwayi;
attest that	Name of Proposed Authorized User	has satisfactorily completed the 80 hours of classroom
and laboratory experience re	y training, as required by 10 CFR 35.3 quired in 35.392(c)(2).	392(c)(1), and the supervised work and clinical case
For 35.394 (Identic	al 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
	to Management of the state of t	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	quired in 35.390(b)(1)(ll)G listed belo 31 requiring a written directive in qua ereis (33 millicuries)	
Oral Nal-1	31 in quantities greater than 1.22 gig	abecquerels (33 milliouries)
	administration of beta-emitter, or phy s 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		
attest that	Name of Proposed Authorized User	has satisfactorily achieved a level of competency to
function indep	endently as an authorized user for:	
	31 requiring a written directive in qua ereis (33 millicuries)	intities less than or equal to 1.22
Oral Nal-1	31 In quantities greater than 1.22 glg	abecquerels (33 millicuries)
	administration of beta-emitter, or phy s 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 313A (AUT) (10-0015)



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 AN	ID PRECEPTOR ATTESTATION (continued)					
Preceptor Attestation	(continued)						
First Section (cont	Inued)						
For 35,392 (Identic	cal Attestation Statement Regardless of	Training and Experience Pathwayi;					
I attest that	Name of Proposed Authorized User	satisfactorily completed the 80 hours of classroom					
		(1), and the supervised work and clinical case					
For 35.394 (Identic	cal Attestation Statement Regardless of	Training and Experience Pathway):					
attest that		satisfactorily completed the 80 hours of classroom					
	Name of Proposed Authoritied User	The second secon					
	y training, as required by 10 CFR 35.394 (c equired in 35.394(c)(2).	s)(1), and the supervised work and clinical case					
Second Section							
I attest that	1 A A A A A A A A A A A A A A A A A A A	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 quantities uereis (33 millicuries)	s less than or equal to 1.22					
Oral Nai-	131 in quantities greater than 1.22 gigabeco	querels (33 milliouries)					
	il administration of beta-emitter, or photon-e ss than 150 keV requiring a written directive						
Parentera	il administration of any other radionuclide re	equiring a written directive					
Third Section							
attest that	a Marine	satisfactorily achieved a level of competency to					
	Name of Proposed Authorized User						
function inde	pendently 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 Nal-	131 In quantities greater than 1.22 glgabeco	quereis (33 millicuries)					
	al administration of beta-emitter, or photon- ss than 150 keV requiring a written directive						
Parentera	il administration of any other radionuclide re	equiring a written directive					

NRC FORM 313A (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		
AUTHORIZE	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 Day	ocead 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 require			
I meet the requi	rements below,	or equivalent Agree	ment State requireme	ents, <mark>as an authorized</mark> (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)	Oral Nai-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 milliouries)						
Oral Nai-131	I in quantities gr	eater than 1.22 glga	abecquerels (33 millio	urles)			
150 keV requ	uiring a written d	frective is required		dide with a photon ener	gy less than		
ame of Preceptor		Signature	-	Telephone Number	Date		
THE THE STREET				A TROY I IV I MAN IN THE			
cense/Permit Number/F	acilty Name						
on proper seda, raciffy concess.					George George		



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	thorization(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 e	qual to			
35.300	Oral administration of sodium iodide I-131 r gigabecquerels (33 millicuries)	requiring a written directive in quantities greater than '	1.22			
35.300	Parenteral administration of any beta-emitted than 150 keV for which a written directive is	ter, or photon-emitting radionuclide with a photon ener s required	gy 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 o	must have been obtained within the 7 years preceding continuing education and experience since the require s, duration, and description of continuing education an	d			
	e a copy of the board certification.					
b. For 35.		linical case experience. The table in section 3.c. may				
and super	• •	nd laboratory training, supervised work experience, n 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 below	v or			
equiva	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

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued) 3. Training and Experience for Proposed Authorized User a. Claseroom and Laboratory Training 35.390 35.392 35.394 35.396 Description of Training Location of Training Clock Dates of Training' Radiation physics and instrumentation Radiation protection Mathematics pertaining to the use and measurement of radioadtivity Chemistry of byproduct material street Training Training Training Training b. Supervised Work Experience 35.390 35.392 35.394 35.396 If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page. Supervised Work Experience Total Hours of Experience: Description of Experience Location of Experience-License or Permit Number of Facility Pres Dividence Total Hours of Experience Not Instruments Pres Description of Experience Location of Experience-License or Permit Number of Facility Pres Description of Experience Not Instruments Pres Dividence Total Hours of Experience Presidence Dividence Total Hours of Experience Presidence Description of Experience Dividence Presidence Description of Experience Presidence Presidence Description of Experience Presidence Presidence Description of Experience Description of Experience Presidence Description of Experience Description of Expe	IC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION			
a. Classroom and Laboratory Training	AUTHORIZED USER TRAI	NING AND EXPERIENCE AND PRECEPTOR ATT	ESTATION (co	ontinued)
Description of Training	3. Training and Experience for	r Proposed Authorized User		
Description of Training Location of Training Hours Training	Classroom and Laboratory Tr	aining 35.390 35.392 35.	394	35.396
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:	Description of Training	Location of Training		
Mathematics pertaining to the use and measurement of radioactivity Chemistry of byproduct material for medical use Radiation blology Total Hours of Training:				
use and measurement of radioactivity Chemistry of byproduct material for medical use Radiation blology Total Hours of Training:	Radiation protection			
Radiation biology Total Hours of Training:	use and measurement of			
b. Supervised Work Experience				
b. Supervised Work Experience	Radiation blology			
If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page. Supervised Work Experience Description of Experience Must include: Description of Experience Must include: Deforming, receiving, and unpacking radioactive materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material Using procedures to contain spilled byproduct material safely and using proper		Total Hours of Training:		
Description of Experience Must Include: Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing decks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material safely procedures to contain spilled byproduct material safely and using proper	If more than one supervising of this page.	Individual is necessary to document supervised trai	ining, provide n	
Ordering, receiving, and unpacking radioactive materials safety and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material Using procedures to contain spiled byproduct material safely and using proper	Supervised Wo	ork Experience Total Hours of Expe	erience:	
unpacking radioactive materials safely and performing the related radiation surveys Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material Using procedures to contain spilled byproduct material safely and using proper			Confirm	
procedures on Instruments used to determine the activity of dosages and performing checks for proper operation of survey meters Calculating, measuring, and safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event Involving the use of unsealed byproduct material Using procedures to contain spilled byproduct material safely and using proper	unpacking radioactive materials safely and performing the			
safely preparing patient or human research subject dosages Using administrative controls to prevent a medical event involving the use of unsealed byproduct material Using procedures to contain spilled byproduct material safely and using proper	procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		=	
prevent a medical event Involving the use of unsealed byproduct material Involving procedures to contain spilled byproduct material Involving proper Involving proper Involving proper Involving proper Involving proper Invo	safely preparing patient or human research subject			
spilled byproduct material Safely and using proper No	prevent a medical event involving the use of unsealed			
	spilled byproduct material safely and using proper		=	

See Supply and the court



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

_					
5.	Training and Experience for Proposed Authorized User (continued)				
	b. Supervised Work Experience (continued)				
	Supervising Individual		License/Permit Number listing supervising Indi- authorized user	vidual as an	
	Supervising Individual meets the apply)**:	requirements below,	or equivalent Agreement State requirements	(check all that	
	35.390 With experience	administering dosage:	s of:		
		requiring a written din 4s (33 millicuries)	ective in quantities less than or equal to 1.22		
	Oral Nai-131	_	han 1.22 gigabecquerels (33 millicuries)		
	Parenteral ad		mitter, or photon-emitting radionuclide with a p a written directive is required	photon	
		•	her radionuclide requiring a written directive		
			tering dosages in the same dosage category or categories	s as the individual	
	c. Supervised Clinical Case Ex If more than one supervising multiple copies of this page.		ry to document supervised work experience, p	vrovide	
	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				

CONTRACTOR OF THE PROPERTY OF



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) For \$5.395: Current 35.490 or 35.690 authorized user:	NRC FORM 313A (AUT)			U.S. NUCLEAR REGULATION	ORY COMMISSION		
For 35.396: Current 35.490 or 35.690 authorized user: lattest that	AUTHORIZED USER TRAIN	NING AND EXPERIENCE	E AND PRECEPTO	OR ATTESTATION (con	ntinued)		
Current 35.490 or 35.690 authorized user:	Fourth Section						
lattest that	and a second and a second as						
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 auti	norized user:					
or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CPR 35.396 (d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for. Parentleral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required Parentleral administration of any other radionuclide for which a written directive is required OR Roard Cartifloation: I attest that Name of Proposed Authorized User requirements of 35.396(g); has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CPR 35.395 (d)(1); and the 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: Parentleral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required Parentleral administration of any other radionuclide for which a written directive is required Parentleral 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 35.392 35.394 35.394 15.395 I have experience administration of any other radionuclide isses than or equal to 1.22 gigabecquereis (33 milliouries) Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquereis (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 is required		Innovant & Shortest User	is an authorized us	ser under 10 CFR 35.49	0 or 35.690		
than 150 keV for which a written directive is required Parenteral administration of any other radionuclide for which a written directive is required Roard Certification:	or equivalent Agreement St laboratory training, as requi experience required by 35.3	ate requirements, has s red by 10 CFR 35.396 (396(d)(2), and has achie	d)(1), and the super	rvised work and clinical o	case		
Date Date				dionuclide with a photon	energy less		
lattest that	Parenteral administratio	n of any other radionuc	lide for which a writt	en directive is required			
I attest that Name 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 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 \$3.56(c), has satisfatorized their requirements of \$3.56(c), has satisfatorized work and clinical case experience 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:						
requirements of 35.396(g), 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 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			has satisfactorily o	completed the board cert	tfication		
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 is requirements, as an authorized user for: 35.390	required by 10 CFR 35.396 35.396(d)(2), and has achie authorized user for:	(d)(1) and the supervis eved a level of compete	ed work and clinical ncy sufficient to fund	case experience require tion independently as a	ed by		
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				diological will a prictor	chegy reso		
I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for: 35.390	Parenteral administratio	n of any other radionuc	lide 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 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 Name of Preceptor Signature Telephone Number Date	Fifth Section Complete the following for precept	or 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 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 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				
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		g dosages in the follow	ing categories for wi	hich the proposed Autho	rized User is		
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 Signature Telephone Number Date							
150 keV requiring a written directive is required Parenteral administration of any other radionuclide requiring a written directive Vame of Preceptor Signature Telephone Number Date	Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)						
Name of Preceptor Signature Telephone Number Date							
	Parenteral administration of any other radionuclide requiring a written directive						
Icense/Permit 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)				
3. Training and Experience fo				
a. Classroom and Laboratory Tr		394 :	35.396 Dates of	
Description of Training	Location of Training	Hours	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. Individual is necessary to document supervised train		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 ☐ No		
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		
C SOSSI 1418 (BLIT), HIS 1045			24000	



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)				
3.	3. Training and Experience for Proposed Authorized User (continued)				
	b. Supervised Work Experience	e (continuea)			
	Supervising Individual		License/Permit Number listing supervising Indi authorized user	vidual as an	
	Supervising individual meets the apply) ":	e requirements below,	or equivalent Agreement State requirements	(check all that	
		administering dosage			
	35.394 glgabecquere	ds (33 millicuries)	ective in quantities less than or equal to 1.22		
	35.396 Parenteral ad	Iministration of beta-e	han 1.22 gigabecquerels (33 millicuries) mitter, or photon-emitting radionuciide with a p a written directive is required	photon	
	" Supervising Authorized User must h	•	ner radionuciide requiring a written directive ering doseges in the same dosege category or categorie		
c. Supervised Clinical Case Experience If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.			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				

AND DESCRIPTION OF THE PARTY OF THE PARTY.



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 THE PROPERTY OF THE PARTY OF THE	USER TRAINING AND EXPERIEN	CE AND PRECEPTOR ATTESTATION (continued)				
Preceptor Attestation (continued)					
First Section (contin	nued)					
For 35.392 (Identica	al Attestation Statement Regardles	ss of Training and Experience Pathway):				
I attest that	BIT BUT THE THE BEST	has satisfactorily completed the 80 hours of classroom				
	training, as required by 10 CFR 35. guired in 35.392(c)(2).	392(c)(1), and the supervised work and clinical case				
For 35.394 (Identical	al Attestation Statement Regardles	ss of Training and Experience Pathway):				
I attest that		has satisfactorily completed the 80 hours of classroom				
	Name of Proposed Authorized User					
	training, as required by 10 CFR 35. guired 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				
	Name of Proposed Authorized User					
experience rec	quired in 35.390(b)(1)(II)G listed belo	MC.				
	31 requiring a written directive in qua erels (33 millicuries)	antities less than or equal to 1.22				
Oral Nai-13	31 in quantities greater than 1.22 gig	jabecquerels (33 millicuries)				
	administration of beta-emitter, or ph s than 150 keV requiring a written di	oton-emitting radionuclide with a photon rective is required				
Parenteral	administration of any other radionuc	elide requiring a written directive				
Third Section						
I attest that		has satisfactorily achieved a level of competency to				
-	Name of Proposed Authorized User	-				
function indep	endently as an authorized user for:					
	31 requiring a written directive in qua ereis (33 millicuries)	antities less than or equal to 1.22				
Oral Nai-13	31 In quantities greater than 1.22 gig	jabecquerels (33 millicurles)				
	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 radionuc	slide requiring a written directive				

NRC FORM (19A (AUT) (16-0015)



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.

IRC FORM 313A (AUT)				U.S. NUCLEAR REGULA	TORY COMMISSION
AUTHORIZED	USER TRAINI	NG AND EXPERIEN	CE AND PRECEPT	OR ATTESTATION (co	ontinued)
Fourth Section					
For 35.396:					
Current 35.490 c	r 35.690 autho	orized user:			
I attest that	Name of Do	posed Authorized User	is an authorized u	iser under 10 CFR 35.4	90 or 35.690
laboratory trai experience re	Agreement Star	te requirements, has ed by 10 CFR 35.396 (d)(2), and has ach	(d)(1), and the supe	eted the 80 hours of clar ervised work and clinical petency sufficient to fun	case
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 radionu	clide for which a writ	ten directive is required	i i
OR					
Board Certificat	on:				
I attest that			has satisfactorily completed the board certification		
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:					
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 gr	eater than 1.22 glgab	ecquerels (33 millio	uries)	
Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required					
Parenteral ad	ministration of a	any other radionuclid	e requiring a written	The state of the s	
Name of Preceptor		Signature		Telephone Number	Date
Joense/Permit Number/Fa	clity Name	-t.			
Decide the second decided by the second control of the second cont					THE R. P. LEWIS CO., LANSING, MICH.



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 at least 3 cases 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?

