

UNITED STATES NUCLEAR REGULATORY COMMISSION REGION IV 611 RYAN PLAZA DRIVE, SUITE 400 ARLINGTON, TEXAS 76011-4005

March 15, 2007

To: Dr. Jack Vonk

SUBJECT: Preceptor Attestation for Training & Experience

I've reviewed the documentation for your Training & Experience which was attested to by Dr. Jordan Hankins with The Nebraska Medical Center. There is some additional information required in order to meet the current NRC regulations in 10 CFR Part 35. Please provide the following information so that we may complete our review.

Authorization for 35.190 and 35.290 Uses

- 1. Please provide the equivalent clock hours for the 3 months and 11 months corresponding to diagnostic therapy under Section 5 "Experience with Radiation" of Form NRH-5A.
- 2. Please provide the "Supervised Work Experience" as documented in <u>Section 3.b</u> of NRC Form 313A (AUD). This also includes the name of the supervising individual, the respective License/Permit Number authorizing the supervising individual and the authorizations of use for the supervising individual.
- 3. Please have the preceptor complete *Part II Preceptor Attestation* as documented on NRC Form 313A (AUD). Part II includes the required attestation, which states in part that you have "achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200." This particular sentence was not included on Form NRH-5A that was submitted to our office.

Authorization for 35.392, 35.394 and 35.396 Uses

1. Please have the preceptor complete *Part II - Preceptor Attestation* as documented on NRC Form 313A (AUT). Part II includes the required attestation that you have completed the required case work for each section of the regulation and includes the statement that you have "achieved a level of competency sufficient to function independently as an authorized user" for the applicable medical uses requested. This particular sentence was not included on Form NRH-5A that was submitted to our office.

If you have any questions, please do not hesitate to contact me at (817) 276-6552. You may fax the completed forms to my attention at (817) 860-8188 or (817) 860-8263.

Very Respectfully,

Rachel & Browder

Rachel Browder, Health Physicist Nuclear Materials Licensing Branch

cc: Ms. Lee Ann Tople Director of Radiology / Radiation Therapy

NRC FORM 313A (AUD) (10-2006) AUTHORIZED USER TR AND PRECEPT (for uses defined under	AINING AND	TION		OMB: NO. 3150-0120 1/2008
[10 CFR 35.190,				
Name of Proposed Authorized User		State or Territory Where Licen	sed	
DR. Jack Vonk				
Requested Authorization(s) (check all that	apply)			
35,100 Uptake, dilution, and excretion	studies			
✓ 35.200 Imaging and localization studie	S			
35.500 Sealed sources for diagnosis (specify device)	
		G AND EXPERIENCE hree methods below)		
* Training and Experience, including boat the date of application or the individual the required training and experience was education and experience related to the	rd certification, mu must have obtaine as completed. Pro	ist have been obtained withi ed related continuing educat wide dates, duration, and de	ion and experie	nce since
1. Board Certification				
a. Provide a copy of the board certifi	cation.			
 b. If using only 35.500 materials, sto Preceptor Attestation. 	p here. If using 3	5.100 and 35.200 materials,	skip to and com	plete Part II
2. Current 35.390 Authorized User	Seeking Addition	nal 35.290 Authorization		
 a. Authorized user on Materials Licen State requirements seeking author b. Supervised Work Experience. (If more than one supervising indivi- copies of this section.) 	rization for 35.290			-
Description of Experience		f Experience/License or t Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs				
	Total Hours	of Experience:		
Supervising Individual		License/Permit Number listir authorized user	ng supervising inc	ividual as an
Supervisor meets the requirements b		nt Agreement State requirem e in 32.290(c)(1)(ii)(G)	ents (check all	that apply).

FORM 313A (AUD) ⁶⁾ AUTHORIZED USER TRAINING A	ND EXPERIENCE AND PRECEPTOR ATTE	ICLEAR REGULA STATION (CO	
. Training and Experience for Propo	sed Authorized User		
a. Classroom and Laboratory Training			<u></u>
Description of Training	Location of Training	Clock Hours	Dates of Training
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for</i> <i>35.590)</i>			
Radiation biology			
	Total Hours of Training:		
If more than one supervising individual provide multiple copies of this section	bletion of this table is not required for 35.590), dual is necessary to document supervised wo on.) Location of Experience/License or	rk experience, Clock	Dates o
Description of Experience	Permit Number of Facility	Hours	Experienc
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 checks for proper operation of survey meters			
Calculating, measuring, and safely preparing patient or human research subject dosages			

*

3.	Training and Experience for Proposed Authorized User (continued)							
/	b. Supervised Work Experience. (continued)							
	Description of Experience		f Experience/License or Number of Facility	Clock Hours	Dates of Experienc			
	Using administrative controls to prevent a medical event involving th use of unsealed byproduct material							
	Using procedures to contain spilled byproduct material safely and using proper decontamination procedures							
	Administering dosages of radioactiv drugs to patients or human research subjects							
	Eluting generator systems appropria for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	ate						
		Total Hours of	Experience:					
*	Supervising Individual		License/Permit Number lis authorized user	ting supervising inc	lividual as an			
*	Supervisor meets the requirements below, or equivalent Agreement State requirements <i>(check one)</i> .							
	c. For 35.590 only, provide documentation of training on use of the device.							
	Device	Type of Traini	ng	Location and D	ates			

Note: T ir o re First Sec Check or <u>For 35</u> <u>B</u>	This part must be ondividual as long a one preceptor is no equired to meet tr stion <u>5.190</u> <u>Board Certification</u> I attest that 10 CFR 35.190	Completed by t as the precepto ecessary to do aining requirer ong for each us Name of Propos Name of Propos Name of Propos (a)(1) and has for the medic	PART II – PRECE the individual's pro- for provides, direct ocument experience ments in 35.590) se requested: ed Authorized User s achieved a level	EPTOR ATTESTATION eceptor. The precepto ts, or verifies training a ce, obtain a separate p has satisfactorily con	or does not have to be the and experience required. preceptor statement from mpleted the requirement ent to function independe	e supervising If more than each. (Not
ir o re First Sec Check or <u>For 35</u> B	ndividual as long a one preceptor is ne equired to meet tr stion ne of the followir 5.190 Board Certification I attest that 10 CFR 35.190 authorized use	completed by t as the precepto ecessary to do aining requirer ng for each us Name of Propos D(a)(1) and has t for the medic	the individual's pro- or provides, direct ocument experience ments in 35.590) se requested: ed Authorized User s achieved a level	eceptor. The precepto ts, or verifies training a ce, obtain a separate p has satisfactorily con of competency sufficie d under 10 CFR 35.10	or does not have to be the and experience required. preceptor statement from mpleted the requirement ent to function independe	If more than each. (Not
ir o re First Sec Check or <u>For 35</u> B	ndividual as long a one preceptor is ne equired to meet tr stion ne of the followir 5.190 Board Certification I attest that 10 CFR 35.190 authorized use	as the precepto ecessary to do aining requirer ng for each us Name of Propos D(a)(1) and has t for the medic	or provides, direct ocument experience ments in 35.590) se requested: ed Authorized User s achieved a level	ts, or verifies training a ce, obtain a separate p has satisfactorily con of competency sufficie d under 10 CFR 35.10	and experience required. preceptor statement from mpleted the requirement ent to function independe	If more than each. (Not
Check or For 35 B	ne of the followir 5.190 Board Certification I attest that 10 CFR 35.190 authorized use	Name of Propos D(a)(1) and has f for the medic	ed Authorized User	of competency sufficiend d under 10 CFR 35.10	ent to function independe	
B	Board Certification I attest that 10 CFR 35.190 authorized use	Name of Propos (a)(1) and has for the medic	achieved a level	of competency sufficiend d under 10 CFR 35.10	ent to function independe	
	I attest that 10 CFR 35.190 authorized use	Name of Propos (a)(1) and has for the medic	achieved a level	of competency sufficiend d under 10 CFR 35.10	ent to function independe	
I	10 CFR 35.190 authorized use)(a)(1) and has r for the medic	achieved a level	of competency sufficiend d under 10 CFR 35.10	ent to function independe	
I	authorized use)(a)(1) and has r for the medic	achieved a level	d under 10 CFR 35.10	ent to function independe 0.	ntly as an
I		rience		OR		
		rience Γ τ				
		JI. J	ack Vonk	has satisfactorily co	mpleted the 60 hours of	training and
	35.190(c)(1), a	luding a minin nd has achieve	ed a level of comp		tory training, required by nction independently as a 0.	
For 35	5.290					
	Board Certification					
	I attest that		ed Authorized User	has satisfactorily cor	mpleted the requirement	s in
)(a)(1) and has	achieved a level	of competency sufficie d under 10 CFR 35.10	ent to function independe 0 and \$5.200.	ently as an
Т	raining and Expe	rience		OR		
	I attest that		Cack Vonk	has satisfactorily cor	mpleted the 700 hours of	f training
	CFR 35.290(c)	(1), and has ad	chieved a level of		aboratory training, require to function independentl 0 and 35.200.	
Second S Complete	Section e the following fo	or preceptor a	attestation and s	ignature:	4 # # # # # # # # # # # # # # # # # # #) 물 면 전 월 위 및 별 별 별 별 별 별 별 별 별 별 별 별 별 별 별 별 별 별
	I meet the requ	irements below	w, or equivalent A	greement State require	ements, as an authorized	d user for:
	35.190	35.290	35.390	35.390 + genera	tor experience	
Name of P	Preceptor		Signature		Telephone Number	Date
License/Pe	ermit Number/Facili	ty Name				<u> </u>

2 million	NRC F	ORM 313A (AUT)	U.S. NUCLE	AR REGULATORY COMMISSION	n na mana mana mana mana mana mana mana
	(10-2000)	AUTHORIZED USER TR AND PRECEPT (for uses defin [10 CFR 35.390, 35.3	OR ATTESTA led under 35.3	TION 300)	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
	Name	of Proposed Authorized User		State or Territory Where License	
		DR. Jack Vor	ik		······································
	Requ	ested Authorization(s) (check all that	apply):		
		35.300 Use of unsealed byproduc	t material for whic	ch a written directive is require	d
N	OF				
\langle)	392 35. 300 Oral administration of sodi 1.22 gigabecquerels (33 m		equiring a written directive in o	quantities less than or equal to
		aiaabecauerels (33 millicu		equiring a written directive in a	quantities greater than 1.22
/		than 150 keV for which a v	vritten directive is	required	lide with a photon energy less
		396 Parenteral administration of	of any other radio	nuclide for which a written dire	ective is required
				G AND EXPERIENCE hree methods below)	
	applic exper the us	ng and Experience, including board c ation or the individual must have rela ience was completed. Provide dates ses checked above. . <u>Board Certification</u>	ted continuing ed	ucation and experience since	the required training and
14		a. Provide a copy of the board certific	oction		
		 For 35.390, provide documentation be used to document this experien 	Non supervised c	linical case experience. The t	able in section 3.c. may
and an and a state of the state of the	c	 For 35.396, provide documentation and supervised clinical case exper document this experience. 	n on classroom ar ience. The tables	nd laboratory training, supervis s in sections 3.a., 3.b., and 3.c	ed work experience, . may be used to
	с	. Skip to and complete Part II Prece	ptor Attestation.		
	2	. <u>Current 35.300, 35.400, or 35.600</u>	Authorized Use	r Seeking Additional Author	ization
	а	a. Authorized User on Materials Licer			er the requirements below or
		equivalent Agreement State requir	ements (<i>check all</i>	that apply):	
		35.390 35.392	35.394	35.490 35.69	0
50 - 10 - 10	t	 If currently authorized for a subset required supervised case experien experience. Also provide complete 	ce. The table in s	section 3.c. may be used to do	
an a saadha sido gara galaan sadar sa saasaa sa	C	If currently authorized under 35.49 documentation on classroom and l case experience. The tables in se Also provide completed Part II Pre-	aboratory training ctions 3.a., 3.b., a	, supervised work experience and 3.c. may be used to docum	, and supervised clinical

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RC FORM 313A (AUT) 0-2006) AUTHORIZED USER TRAIN	U.S. NU		TORY COMMISSION ntinued)
3. <u>Training and Experience for</u> a. Classroom and Laboratory Tr		Provid	e d 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 biology			
	Total Hours of Training:	§	
b. Supervised Work Experience If more than one supervising of this page.	individual is necessary to document supervised train	ning, provide m	35.396 ultiple copies
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, reseiving, 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 decontamination procedures			
Total Hours	of Supervised Work Experience:	· · · · · · · · · · · · · · · · · · ·	

FORM 313A (AUT) OG) AUTHORIZED USER TF	RAINING AND EXPERIE	U.S. NUCLEAR REGULAT	
Training and Experience fo			
b. Supervised Work Experie			
Supervising Individual		License/Permit Number listing supervising indi authorized user	vidual as an
Supervising individual meets apply)**:	the requirements below,	or equivalent Agreement State requirements	(check all that
35.390 With experien	ce administering dosages	s of:	
35.392 Oral Nal-1	31 requiring a written dire lerels (33 millicuries)	ective in quantities less than or equal to 1.22	
35 394	ι ,	han 1.22 gigabecquerels (33 millicuries)	
Parentera	l administration of beta-ei ss than 150 keV requiring	mitter, or photon-emitting radionuclide with a p	hoton
		her radionuclide requiring a written directive	
** Supervising Authorized User mu requesting authorized user statu	ust have experience in administ	tering dosages in the same dosage category or categorie	s as the individu
multiple copies of this page	Number of Cases	Location of Experience/License or Permit Number of Facility	Dates of Experience
Oral administration of sodium iodide I-131 requiring a writted directive in quantities less that or equal to 1.22 gigabecquer (33 millicuries) Oral administration of sodium	en an rels n		
iodide I-131 requiring a writte directive in quantities greater than 1.22 gigabecquerels (33 millicuries) Parenteral administration of	r 🔨		
any beta-emitter, or photon-emitting radionuclide with a photon energy less tha 150 keV for which a written directive is required Parenteral adminstration of a	an		
other radionuclide for which written directive is required			

(List radionuclides)

PAGE 3

	AUTHORIZED USER TRAINING	AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
3.	Training and Experience for Propo	sed Authorized User (continued)
	c. Supervised Clinical Case Experier	nce (continued)
	Supervising Individual	License/Permit Number listing supervising individual as an authorized user
	Supervising individual meets the requ apply)**:	uirements below, or equivalent Agreement State requirements (check all
	35.390 With experience admin	nistering dosages of:
	35.392 Oral Nal-131 requi gigabecquerels (33	iring a written directive in quantities less than or equal to 1.22 3 millicuries)
1999 Managara		antities greater than 1.22 gigabecquerels (33 millicuries)
	Parenteral adminis	stration of beta-emitter, or photon-emitting radionuclide with a photon 50 keV requiring a written directive is required
	Parenteral adminis	stration of any other radionuclide requiring a written directive
	** Supervising Authorized User must have ex requesting authorized user status.	perience in administering dosages in the same dosage category or categories as the indivi-
	one preceptor is necessary to doc	r provides, directs, or verifies training and experience required. If more t sument experience, obtain a separate preceptor statement from each.
	t Section	uested authorization.
Che	ck one of the following for each req	uested authorization:
Che		uested authorization:
Che	ck one of the following for each req	quested authorization:
Che	ck one of the following for each red <u>For 35.390:</u> <u>Board Certification</u> I attest that	
Che	ck one of the following for each red <u>For 35.390:</u> <u>Board Certification</u> I attest that	has satisfactorily completed the training and exper
Che	ck one of the following for each red <u>For 35.390:</u> <u>Board Certification</u> I attest that Name of Prope	has satisfactorily completed the training and exper
Che	ck one of the following for each red <u>For 35.390:</u> <u>Board Certification</u> I attest that Name of Prope	has satisfactorily completed the training and exper
Che	ck one of the following for each red <u>For 35.390:</u> <u>Board Certification</u> I attest that Name of Proper requirements in 35.390(a)(1). <u>Training and Experience</u> <u>I attest that</u> <u>D R . J</u>	has satisfactorily completed the training and exper

	NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMISSION
	AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
	Preceptor Attestation (continued)
(First Section (continued)
	For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):
	I attest that has satisfactorily completed the 80 hours of classroom
X	and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required 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 Name of Proposed Authorized User has satisfactorily completed the 80 hours of classroom
	and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).
/	Second Section
	I attest that has satisfactorily completed the required clinical case
	Name of Proposed Authorized User
	experience required in 35.390(b)(1)(ii)G listed below:
	Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
X	Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	Parenteral administration of any other radionuclide requiring a written directive
C	
(Third Section
	I attest that has satisfactorily achieved a level of competency to
	Name of Proposed Authorized User function independently as an authorized user for:
)	\Box Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 (35.392)
×	gigabecquerels (33 millicuries)
	\Box Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries) (35.394)
	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon (35, 396) energy less than 150 keV requiring a written directive is required
	Parenteral administration of any other radionuclide requiring a written directive (35.396)
	-

	NRC FORM 313A (AUT) U.S. NUCLEAR REGULATORY COMMIS				
	AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)				
	Fourth Section				
	For 35.398:				
	Current 35.490 or 35.690 authorized user:				
	I attest that				
	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 adminstration of any other radionuclide for which a written directive is required				
	OR				
	Board Certification:				
	I attest that has satisfactority completed the board certification				
	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 adminstration of any other radionuclide for which a written directive is required				
	Fifth Section Complete the following for preceptor attestation and signature:				
	35.390 35.392 35.394 35.396				
	I have experience administering dosages in the following categories for which the proposed Authorized User i requesting authorization.				
	Oral Nal-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)				
Oral Nal-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)					
	Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than				
	150 keV requiring a written directive is required				