

Thoracic (Cardiovascular Institute

A. Rap Bandi, MD T. Michael Brown, DO, FACC Mark D. Castellani, MD, FACC Nam 5. Cho, DO Joel M. Cohn, MD, FACC Christopher M. D'Haem, DO, FACC Ellen L. Kehoe, DO Gauray Dhar, MD, FACC

Edward T. Helble, DO, FACC Juan O. Hernandez, MD. FACC Todd G. Hickox, DO, FACC John H. Ip, MD, FACC Michael J. James, DO, FACC George E. Kleiber, DO, FACC

Kirk B. Laman, DO, FACC Date G. Leffler, DO, FACC Chad A. Link, DO, FACC Daryl R. Melvin, MD, FACC Richard M. Pinke, DO James A. Schafer, MD, FACC David J. Strobl, DO Ioni R. Summitt, DO, FACC R.K. Thakur, MD, FACC Ronald A. Voice, MD, FACC Matthew D. Wilcox, DO Peter J. Yoo, M.D. FACC

February 7, 2012

UNITED STATES NUCLEAR REGULATORY COMMISSION

Region III, Materials Licensing Section 2443 Warrenville Road Suite 210 Lisle, IL 60532-4352

Amendment of NRC License No. 21-20313-01

Control #576361

Dear Sir/Madam:

We wish to provide the following information, in an effort to amend our NRC license.

Item #1 We have enclosed signed preceptor statements for the following physicians:

Chad Allen Link, DO Group 35,200 Richard Michael Pinke, DO Group 35.200 Group 35.200 Joni R. Summit, DO

Item #2 Please delete our request to add these physicians at this time.

Mathew D. Wilcox, DO. Group 35.200 Peter J. Yoo, DO Group 35.200

Item #3: Please find the enclosed "Sealed Source Leak Test" for your review.

Item #4: Please be advised that no radioactive material was transferred or disposed of via licenses vendor at any time.

If you have any questions, please contact our physicist James M. Botti, MS by phone at (734) 662-3197 or by email at jbotti@mpcphysics.com.

Respectfully Your

Radiation Safety Officer

Enclosures

405 W. Greenlawn Suite 400 Lansing, Michigan 48910 T 517.483.7550 T 800.722.7549 F 517.483.8403 sparrow.org | tciheart.com

FROM

AND PRECEPTO (for uses defined under 3	INING AND EXPERIENCE ATTESTATION 5.100, 35.200, and 35.500) 5.290, and 35.590]	APPROVED BY EXPIRES: 3/31	OMB: NO. 3150-012 /2012
Name of Proposed Authorized User	State or Territory Where Lice	ensed	
Joni R. Summit, DO	Michigan		
Requested Authorization(s) (check all that a	pply)		
35.100 Uptake, dilution, and excretion st	udies		
35.200 Imaging and localization studies			
35.500 Sealed sources for diagnosis (sp	ecify device)	
	RT I TRAINING AND EXPERIENCE ect one of the three methods below)		
the date of application or the Individual m	certification, must have been obtained with ust have obtained related continuing educa completed. Provide dates, duration, and d uses checked above.	ition and experie	nce since
1. Board Certification			
a. Provide a copy of the board certification	ation.		•
 b. If using only 35.500 materials, stop Preceptor Attestation. 	here. If using 35.100 and 35.200 materials	, skip to and con	nplete Part II
2. Current 35,390 Authorized User S	eeking Additional 35.290 Authorization		
	The second secon	· •	
copies of this section.) Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs			
	Total Hours of Experience:		
Supervising Individual	License/Permit Number list authorized user	ing supervising inc	lividual as an
	ow, or equivalent Agreement State required erator experience in 32.290(c)(1)(ii)(G)	ments (check all	that apply).

. Training and Experience for Propos	ed Authorized User	*	
a. Classroom and Laboratory Training.			
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity		:	
Chemistry of byproduct material for medical use (not required for 35.590)			
Radiation blology			
1	Total Hours of Training:		L
	Total Hours of		
Description of Experience Must Include:	Experience: Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience
Ordering, receiving, and unpacking radioactive materials safety 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	:

8	
9	
а.	
3	

Training and Experience for Propose b. Supervised Work Experience. (co.		ed User (contin	ued)		
Oescription of Experience Must Include:	Locat	ion of Experienc		Confirm	Dates of Experienc
Calculating, measuring, and safely preparing patient or human research subject dosages				Yes	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material				Yes No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		/		Yes No	
Administering dosages of radioactive drugs to patients or human research subjects	· ·	·		Yes No	İ
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				∐ Yes	
Supervising Individual		License/Pe authorized	s m it Number listin Luser	g supervising Ind	ividual as an
Supervisor meets the requirements be				-	-
c. For 35.590 only, provide documen	35.390		enerator experie	1100 III 33.230(C	ДТДПДО
Device	Type of I	raining	L	ocation and Da	ites
	-		<u> </u>		

NRC FORM 313A (AUD)

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE #

me of Proposed Authorized User	State or Territory Where Lice	ensed	······································
chard M. Pinke, DO	Michigan		
quested Authorization(s) (check all that a	pply)		-
35.100 Uptake, dilution, and excretion st	udles		
35.200 imaging and localization studies			
35.500 Sealed sources for diagnosis (sp	ecify device)	
	RT I - TRAINING AND EXPERIENCE		
	ust have obtained related continuing eductions completed. Provide dates, duration, and diseaschecked above.		
Provide a copy of the board certification		•	
• •		*	
 b. If using only 35.500 materials, stop Preceptor Attestation. 	here. If using 35,100 and 35,200 material	s, skip to and com	iplete Part II
 b. If using only 35.500 materials, stop Preceptor Attestation. current 35.390 Authorized User Section 1 	here. If using 35.100 and 35.200 material		
 b. If using only 35.500 materials, stop Preceptor Attestation. 	here. If using 35.100 and 35.200 material seking Additional 35.290 Authorization meeting 10 CFR	s, skip to and corr 35.390 or equival	
 b. If using only 35.500 materials, stop Preceptor Attestation. j 2. <u>Current 35.390 Authorized User Season</u> a. Authorized user on Materials Licens State requirements seeking authorized b. Supervised Work Experience. 	here. If using 35.100 and 35.200 material seking Additional 35.290 Authorization meeting 10 CFR	35.390 or equival	ent Agreemer
 b. If using only 35.500 materials, stop Preceptor Attestation. j 2. Current 35.390 Authorized User Sea. Authorized user on Materials Licens State requirements seeking authorized. b. Supervised Work Experience. (If more than one supervising individual contents of the /li>	here. If using 35.100 and 35.200 material seking Additional 35.290 Authorization meeting 10 CFR ration for 35.290.	35.390 or equival	ent Agreemer provide multi
 b. If using only 35.500 materials, stop Preceptor Attestation. j 2. <u>Current 35.390 Authorized User S.</u> a. Authorized user on Materials Licens State requirements seeking authorized. b. Supervised Work Experience. (If more than one supervising individuality copies of this section.) 	here. If using 35.100 and 35.200 material seking Additional 35.290 Authorization meeting 10 CFR ration for 35.290. dual is necessary to document supervised Location of Experience/License or	35.390 or equivaluors work experience,	ent Agreemer
 b. If using only 35.500 materials, stop Preceptor Attestation. 2. Current 35.390 Authorized User Sea. Authorized user on Materials Licens State requirements seeking authorized. Supervised Work Experience. (If more than one supervising individuality of the section.) Description of Experience Eluting generator systems appropriate for the preparation of radioactive drugs for Imaging and localization studies, measuring and testing the cluate for radionuclidic purity, and processing the cluate with reagent kits to prepare labeled 	here. If using 35.100 and 35.200 material seking Additional 35.290 Authorization meeting 10 CFR ration for 35.290. dual is necessary to document supervised Location of Experience/License or	35.390 or equivaluors work experience,	ent Agreemer provide multi

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 313A (AUD)

NRC FORM 313A (AUD)

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training.

Description of Training

Radiation physics and

Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material or medical use (not required for 35.590)		ì	
Radiation biology			
		1	1
	Total Hours of Training:		I
	npletion of this table is not required for 3 vidual is necessary to document supervi		
(If more than one supervising indi- provide multiple copies of this sec	npletion of this table is not required for 3 vidual is necessary to document supervi	sed work experience,	
(If more than one supervising indi- provide multiple copies of this sec	npletion of this table is not required for 3 vidual is necessary to document supervition.) Total Hours	sed work experience,	Dates of Experience
(If more than one supervising indic provide multiple copies of this sec Supervised Work Experience Description of Experience	npletion of this table is not required for 3- vidual is necessary to document supervi- tion.) Total Hours Experience: Location of Experience/License	sed work experience,	Dates of Experience

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Location of Training

U.S. NUCLEAR REGULATORY COMMISSION

Dates of

Training*

Clock

Hours

FORM 313A (AUD) '	AINING AN	D EXPERIENCE AND PRECI			TORY COMMISS Intinued)
Training and Experience fo	r Proposed	Authorized User (continued	1)		-
 b. Supervised Work Experie 	nce. (contin	ued)			
Description of Experier Must Include:	nce	Location of Experience/Li Permit Number of Fa		Confirm	Dates of Experience
Calculating, measuring, and preparing patient or human resulting to subject dosages	safely esearch			Yes	
Using administrative controls prevent a medical event invouse of unsealed byproduct m	lving the		•	Yes	
Using procedures to contain byproduct material safely and proper decontamination proc	dusing			Yes	
Administering dosages of rac drugs to patients or human re subjects		The second distribution of the second se		Yes	
Eluting generator systems ap for the preparation of radioac drugs for imaging and localiz studies, measuring and testir eluate for radionuclidic purity processing the eluate with re kits to prepare labeled radioa drugs	tive ation og the , and agent			Yes	
Supervising Individual		License/Permit authorized use	Number listing s	upervising indi	vidual as an
Supervisor meets the require 35.190 35.29	-	w, or equivalent Agreement Sta 5.390 35.390 + gene			
c. For 35.590 only, provide	documentation	on of training on use of the de	vice.		
Device		Type of Training	Loca	ation and Da	ites
		· .		·	
d. For 35.500 uses only, sto	p here. For	35.100 and 35.200 uses, skip	to and complet	e Part II Prec	eptor
Attestation.		•			

Note:	This part must be complete	PART II - PRE	OEDTOD ATTECTAL		
vote:	This part must be complet		ECEPTOR ALIESTA	FION .	
	individual as long as the p	preceptor provides, di ry to document experi	rects, or verifies trainis ience, obtain a separa	eptor does not have to be to ng and experience required ate preceptor statement from	. If more than
	By checking the boxes be position sought and not a			ridual has knowledge to fulf competency."	ill the duties of th
	ection one of the following for a	each use requested:	:		
For	35.190				
	Board Certification				
	attest that		has satisfactorile	y completed the requiremen	nts in
		of Proposed Authorized User	·		
	10 CFR 35.190(a)(1) authorized user for the			fficient to function independ 5.100.	dently as an
			OR		
•	Training and Experience				
	attest that		has satisfactorily	y completed the 60 hours o	f training and
	Name	of Proposed Authorized User	-		
		achieved a level of co	ompetency sufficient t	ocratory training, required b o function independently as 5.100.	
For	35.290				
	Board Certification				
	attest that Richard	M. Pinke, DO	has satisfactorily	y completed the requirement	nts in
	Name	of Proposed Authorized User			
	10 CFR 35.290(a)(1) authorized user for the			fficient to function independ 5,100 and 35,200.	dently as an
			OR		
	Training and Experience				
	I attest that			y completed the 700 hours	of training
		of Proposed Authorized User			
		d has achieved a leve	of competency suffic	nd laboratory training, requi cient to function independer 5.100 and 35.200.	
Secon	d Section		اد سیب کا انظی که تو بیشت است کا بی یه 10 در شد ب		
	ate the following for prec	eptor attestation an	id signature:	•	
	I meet the requirement	nts below, or equivale	nt Agreement State re	equirements, as an authoriz	ed user for:
	35.190 🗸 35	5.290 35.390	35.390 + ge	nerator experience	
	f Preceptor	Signature	1/11/1	Telephone Number	Date
vame o	•				
	Ielvin, MD	March		(517) 492-8443	02/07/2012

FROM

AND PRECEPTO (for uses defined under 3	AINING AND EXPERIENCE OR ATTESTATION 35.100, 35.200, and 35.500) 35.290, and 35.590]	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012
Name of Proposed Authorized User	State or Territory Where Lie	censed
Chad Allen Link, DO	Michigan	
Requested Authorization(s) (check all that a	apply)	
35,100 Uptake, dilution, and excretion s	studies	
✓; 35.200 Imaging and localization studies	•	
35.500 Sealed sources for diagnosis (s	pecify device)
	RT I TRAINING AND EXPERIENCE lect one of the three methods below)	
 Training and Experience, including board the date of application or the individual n 	d certification, must have been obtained w must have obtained related continuing edu s completed. Provide dates, duration, and	cation and experience since
✓ 1. Board Certification	,	
a. Provide a copy of the board certific	ation.	
• •	here. If using 35.100 and 35.200 materia	ls, skip to and complete Part II
Current 35.390 Authorized User S Authorized user on Materials Licen	Seeking Additional 35.290 Authorization	: 35,390 or equivalent Agreement
State requirements seeking author		oo.ooo o equitatom rigidement
b. Supervised Work Experience.	idual is necessary to document supervised	l work experience, provide multiple
Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Dates of Hours 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 li authorized user	sting supervising individual as an
	elow, or equivalent Agreement State requir	ements (check all that apply).

U.S. NUCLEAR REGULATORY COMMISSION

NRC FORM 313A (AUD)

. Training and Experience for Propos			
a. Classroom and Laboratory Training.		City - N	
Description of Training	Location of Training	Clock Hours	Dates o Training
Radiation physics and instrumentation			1
instrumentation		,	I
Radiation protection		1	į
		i	
			l
Mathematics pertaining to the use and measurement of radioactivity		1	
and measurement of regioactivity		1	
Chemistry of byproduct material for medical use (not required for		-	•
35.590)			i
Radiation biology			i
		!	1
	Total Hours of Training:		
 Supervised Work Experience (complete from the supervising individual provide multiple copies of this section) 	letion of this table is not required for 35.590). lual is necessary to document supervised words.)	rk experience,	
Supervised Work Experience	Total Hours of Experience:		
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience
Ordering, receiving, and unpacking	-	Yes	•
radioactive materials safely and performing the related radiation		No	1
surveys			<u> </u>
Performing quality control procedures on instruments used to		Yes	
determine the activity of dosages		No	Í
and performing checks for proper operation of survey meters			l .

<u> Fraining and Experience for Prop</u>	osed Authorized User (continued	d)	
Supervised Work Experience. (continued)		
Description of Experience Must Include:	Location of Experience/L Permit Number of Fa		Dates of Experience
Calculating, measuring, and safely preparing patient or human researc subject dosages	h	Yes No	
Using administrative controls to prevent a medical event involving thuse of unsealed byproduct material		Yes No	
Using procedures to contain spilled byproduct material safety and using proper decontamination procedures	ı 1	Yes	
Administering dosages of radioactive drugs to patients or human research subjects.		Yes	
Eluting generator systems appropriate the preparation of radioactive 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	ale	Yes No	
Supervising Individual	License/Permi authorized use	it Number listing supervising independent	vidual as an
35.190 35.290	below, or equivalent Agreement St 35.390 35.390 + gene entation of training on use of the de	erator experience in 35.290(c	-
Device	Type of Training	Location and Da	ites
•	•		

FROM

(3-2009)	AUTHORIZED U	ISER TRAINI	NG AND EXPER	ENCE AND PRECEPT	FOR ATTESTATION (co	ontinued)
			PART II - PREC	EPTOR ATTESTATIO)N	
Note:	individual as long one preceptor is	as the precep necessary to d	the individual's potor provides, dire	receptor. The precept cts, or verifies training nce, obtain a separate	tor does not have to be the and experience required preceptor statement from	. If more than
				testing that the individu 's "general clinical con	ual has knowledge to fulfi npetency."	ill the duties of the
	Section cone of the follow	ing for each	use requested:			
For	35.190					
	Board Certification	<u>n</u>				
	1 attest that	Name of Pror	osed Authorized User	has satisfactorily c	ompleted the requiremen	nts in
		90(a)(1) and h	as achieved a lev	el of competency suffic sed under 10 CFR 35.1	cient to function independ	fently as an
				OR		
İ	Training and Exp	erience	ř.			
l	l attest that			has satisfactorily c	ompleted the 60 hours of	f training and
l		Name of Prop	posed Authorized User	_ ·	•	-
	35.190(c)(1),	and has achie	eved a level of con		atory training, required by function independently as 100.	
Fo	35.290					
	Board Certification	<u>20</u>				
	✓ I attest that	Chad Allen Lin	sk, DO	has satisfactorily c	completed the requiremen	nts in
		Name of Prop	osed Authorized Use:			
				el of competency suffic ted under 10 CFR 35.1	cient to function independ 100 and 35,200.	dently as an
	•			OR		
	Training and Exp	erience				
	I attest that			has satisfactorily c	completed the 700 hours	of training
		Name of Prop	posed Authorized User			
	CFR 35.290(c)(1), and has	achieved a level of		laboratory training, requ nt to function independen 100 and 35.200.	
	nd Section lete the following	for preceptor	r attestation and	signature:		100 to 100 to 100 to 100 to 100 to 100 to 100 to 100 to
	✓ I meet the rec	quirements be	low, or equivalent	Agreement State requ	ilrements, as an authoriz	ed user for:
	35.190	√ 35.290	35.390	35.390 + gene	rator experience	
Name	of Preceptor		Signature	10	Telephone Number	Date
Daryi	Melvin, MD		1///	11/1	(517) 492-8443	02/07/2012



9

Sealed Source Leak Test

Licensee: Thoracic Cardiovascular Institute-Sparrow Date: 10/11/11

Performed by: James Botti

		Calibration	Calibratio	on			
Nuclide	Type	Activity	Date	Location	M/N	S/N	
Cs-137	Vial	192.9 uCi	02/01/10	Hot Lab	RV-137-200U	1393-38-21	
Current Activity: 185.51 uCi							
Co-57	Flood	10 mCi	06/01/09	Hot Lab	PF16R-057-10M	1374-069	
Current Activity: 1.102mCi							
Cs-137	Vial	200.5 uCi	11/01/06	Hot Lab	RV-137-200U	1044-25-10	
Current Activity: 178.86uCi							
Co-57	Flood	10 mCi	07/01/10	Hot Lab	MED3709	1453-42	
Current Ac	tivity: 3.	.028mCi					

Comment: The sources listed above were leak tested using a dry wipe technique and were found to have less than 0.005 uCi removable activity. The following Minimum Detectable Activities are based upon a background at the indicated value. Background was at or below these levels when the above tests were completed.

Well Counter: Captus 3000

 Nuclide
 MDA
 Background

 Cs-137
 2.0 x 10 ⁻⁴ uCi
 145 counts/1 min

 Ba-133
 8.8 x 10 ⁻⁵ uCi
 204 counts/1 min

 Co-57
 1.7 x 10 ⁵ uCi
 53 counts/1 min

RADIATION SAFETY OFFICER:

405 W. Greenlawn Avenue • Suite 400 • Lansing, MI 48910 Phone: (517) 483-7588 Fax: (517) 483-7575

Facsimile Transmittal Sheet

To: NRC Region III	From: Thoracic Cardiovascular Institute Grey Stiles
Fax: (630) 829-9892 K	Direct Phone: (\$17) 492-8440
Phone: (630) 515-(078 (Date: スー2 4ー1ス
Re: Control # 576850	Total Number of Pages Including Cover Sheet:

Comments:

License Amendment Additional Info

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