

May 12, 2011

U.S. Nuclear Regulatory Commission Region III 2443 Warranville Road, Ste 210 Lisle, IL 60532-4352

Re: NRC License 13-188879-01

Dear Sir/Madam:

We would like to amend our NRC License No. 13-18879-01 to include the following physicians as authorized users:

Michael W. Dye Jr., M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here the preceptor form for Dr. Dye.

Sridevi Sompalli, M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here Dr. Sompalli's ABR Certification in Diagnoctic Radiology and record of his training and experience.

Thomas Kang Rhee, M.D. as authorized user for 10 CFR 35.100, 35.200 and 35.300 (for oral administration of sodium iodide-131 in quantities less than or equal to 33 millicuries). To support this request we have included here Dr. Rhee's ABR Certification in Diagnoctic Radiology and record of his training and experience.

Luisito Gonzales, M.D. and Wai Hung Lee, M.D. as authorized users for 10 CFR 35.200. Both physicians are currently authorized for the same under NRC License No. 13-32515-01 (copy attached).

We would also request to remove Janaki Moni, M.D. from our users' list.

If you have any question please contact me at (574) 523-7857.

Sincerely,

S. Steven Leung, Ph.D. Radiation Safety Officer

Elkhart General Healthcare System 600 East Boulevard Elkhart, IN 46514 Phone: 574/294-2621 www.egh.org

RECEIVED MAY 2 4 200

Fax	sent	Ъу	:	5742581101

2/13

	Alabama Department o	Fublic Health - Radiation Control		
AUTHORIZED USER AND PRECE (for uses defined und	PTOR ATTESTA	TION		
Name of Proposed Authorized User		Name of Licensee Where Phys	ician Wishes to	be Approved
Michael W. Dye Jr., M.D.				
Requested Authorization(s) (check all I	that apply)			
🗹 420-3-26.07(45) Uptake, dilution, a	nd excretion studies	κ.		
✓ 420-3-2607(42) Imaging and loca	lization studies	•		
420-3-2607(70) Sealed sources fo	or diagnosis (specify	device	11	
		G AND EXPERIENCE		
<ul> <li>Training and Experience, including t</li> </ul>	-	<b>three methods below)</b> ust have been obtained within	i the 7 veste n	neromine
the date of application or the individu the required training and experience education and experience related to	uai must have obtain was completed. Pro	ed related continuing education ovide dates, duration, and des	on and experie	nce since
1. Board Certification				
a. Frovide a copy of the board ce	rtification.			
<ol> <li>If using only .07(70) materials, Preceptor Attestation.</li> </ol>	stop here. If using .(	07(45) and/or .07(48) materia	is, skip to and (	complete Pa
2. Current .07(56) Authorized Us		<u>mat.v7(31) Autocrization</u> meeting .07(56) or ∈	a rivelant 1/20	
<ul> <li>Authorized user on Materials Li State requirements seeking aut</li> </ul>			quivalent NAC	, or soleen
<ul> <li>b. Supervised Work Experience. (If more than one supervising in copies of this section.)</li> </ul>			rk experience,	provide mul
	Location o			1
Description of Experience	Permi	of Experience/License or It Number of Facility	Clock Hours	Dates o Experience
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and	Permi	f Experience/License or It Number of Facility		
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and	Permi	f Experience/License or It Number of Facility		
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring any testing the eluate for radionuclidic punity, and processing the eluate	Permi	f Experience/License or It Number of Facility		
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic	Permi	f Experience/License or It Number of Facility		
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	Permi 1	f Experience/License or It Number of Facility		
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	Permi 1	f Experience/License or It Number of Facility License/Permit Number listing authorized user	Hours	Experien
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 Experienc	e:	License/Permit Number listing	Hours supervising incl	Experien

\*AGE 1

÷ : ! 

RM RM-HU(AUD) AUTHORIZED USER TRAININ	G AND EXPERIENCE AND PRECEPTOR ATTEST	TATION (C	continued)
3. Training and Experience for Pro			
a. Classroom and Laboratory Train	ing.		
Description of Training	Location of Training	Clock Hours	Dates of Training
Radiation physics and Instrumentation	University of South Alabama Medical Center & University of South Alabama College of Medicine	66	July 2006 to June 2010
Radiation protection	University of South Alabama Medical Center & University of South Alabama College of Medicine	42	July 2006 to June 2010
Mathematics pertaining to the use and measurement of radioactivity	University of South Alabama Medical Center & University of South Alabama College of Medicine	24	July 2006 to June 2010
Chemistry of byproduct material for medical use (not required for .07(70))	University of South Alabama Medical Center & University of South Alabama College of Medicine	77	July 2006 to June 2010
Radiation biology	University of South Alabama Medical Center & University of South Alabama College of Medicine	62	July 2006 to June 2010
	Total Hours of Training:	271	

b. Supervised Work Experience (completion of this table is not required for .07(70)). (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010
Calculating, measuring, and safely preparing patient or human research subject dosages	University of South Alabama Medical Center / Alabama Radioactive Materials License No. 584	1	July 2006 to June 2010

PASE :

 $\mathbf{1} \in$ 

				JL
AUTHORIZED USER TRAIN			ATTESTATION	continuea;
<ul> <li><u>Training and Experience for Pre</u></li> <li>Supervised Work Experience.</li> </ul>		<u>I User</u> (continuea)		
A. cohortiere recurring	·		······	
Description of Experience	Pe	m of Experience/License or mit Number of Facility	Hours	Dates of Experience
Using administrative controls to prevent a medical event involving use of unsealed byproduct materi	the Center / Al	of South Alabama Me labama Radioactive License No. 584	edical 500	July 2006 June 2010
Using procedures to contain spille byproduct material safely and usin proper decontamination procedur	ng Center / Al	of South Alabama Mo labama Radioactive License No. 584	edical 1	July 2006 June 2010
Administering dosages of radioac drugs to patients or human resear subjects	rch Center / Al	of South Alabama Mo labama Radioactive License No. 584	edical 1	July 2006 June 2010
Eluting generator systems approp for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagen kits to prepare labeled radioactive drugs	University Center / Al Materials I	of South Alabama Me labama Radioactive License No. 584	edical 1	July 2006 June 2010
	Total Hours	of Experience:	506	
Supervising Individual Shikha Khullar, MD, M Supervisor meets the requirement	48 16 14 5 16 1 m m m + 60 0 m m 7 10 1 M 1 M 1 M 1 M 1 m 1 in m 1 m	License/Permit Number authorized user AL Radioactive Ma University of South ent NRC or Agreement Sta	terials license # Alabama Colleg	584 ge of Medicine
.07(47)	07(56)	2 .07(56) + generator exp	perience in .07(51)	c)1.(8)(Vil)
c. For .07(71) only, provide docu	mentation of trainin	g on use of the device.		- <u> </u>
Device	Type of Tra	uning	Location and D	)ates

F438 3

-----

orm f	AUTHORIZED	USER TRAINI	NG AND EXPERIE	NCE AND PRE	CEPTOR ATTESTATION (	continued}
	<u>a Circus Circing</u> tan (		PART II - PRECH	PTOR ATTEST	ATION	
łote:	individual, or ma	ay have provide a necessary to c	d, directed, or varia	ed all training an ce, obtain a sepa	sceptor may have been the id experience required. If n arate proceptor statement fr	none than
	iection one of the folio	wing for each	use requested:			
For	.07(47)					
	Board Cenificat	ion		· ·		
	i attest that	the second s	Dye Jr., M.D.	has satisfacto	rily completed the requirem	ents in
			has achieved a lev Ical uses authorize		y sufficient to function indep 607(45).	endent:y as an
	Training and Ex	Obtionce		OR		
			Dye Jr., M.D.	has esticiarin	rily completed the 60 hours	of itaining and
			CHEC ANTONIZES USER		ny competen 218 of nodes	or sanway and
	and has ach	ieved a level of			aboratory training, required idependently as an authoriz	
For	07(51)					
	Board Certificati	on				
	🗹 i attest that	Michael W.	Dye Jr., M.D.	has salisfacto	rily completed the requirem	ents in
	<b>420-3-2607</b> authorized u	(51)(a)1. and h ser for the med	as achieved a leve ical uses authorize	f of competency d under .07(45) :	sufficient to function indepe and (48).	ndently as an
	Training and Ex			OR		,
				hae caliefactor	ily completed the 700 hours	oftaioioa
	Y I allest that	The second s	Dye Jr., M.D.	1142 201/212(0)	ing completed are you notif	
	.07(51)(c)1.,	and has achiev		etency sufficient	and laboratory training, req to function independently a and (48).	
econ	d Section		والكالية البيران بالمرجع ومستخلفا فالمتعاد			
ompl	ete the following	for preceptor	attestation and si	gnature:		
<b>Г</b>	7 ( mast the	immente hale-		• or 1	Chata manufactura and a	
L.		·			State requirements, as an a	uununzed USBI T
	.07(47)	.07(51)	07(56)	<b>⊘</b> .07(56) – g	enerator experience	
9778 G	Preceptor		Signature		Telephone Number	Cate
hikh	a Khullar, MI	), MPH	S.Khul	w	(251) 471-7128	1.05-201

`<u></u>

<u>.</u>

1

FORM RM-HU(AUT) Alabama Department of	Public Health - Radiation Control			
AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 420-3-2607(52)) [420-3-2607(56), (57), (58) and (59)]				
Name of Processed Authorized User Michael W. Dye Jr., M.D.	Name of Licensee Where Physician Wishes to be Approved			
Requested Authorization(s) (check all that apply):				
.07(52) Use of unsealed byproduct material for whi	ch a written directive is required			
OR				
<ul> <li>.07(52) Oral administration of sodium odide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerets (33 millicuries)</li> </ul>				
.07(52) Oral administration of sodium iodide (-131) gigabecquerels (33 millicuries)	equiring a written directive in quantities greater man 1.22			
.07(52) Parenteral administration of any beta-emitty than 150 keV for which a written directive is	er, or photon-emitting radionuclide with a photon energy less required			
.07(52) Parenteral administration of any other radio	nuclide for which a written directive is required			
	G AND EXPERIENCE hree methods below)			
	have been obtained within the 7 years preceding the date of ucation and experience since the required training and			
1. Board Certification				
a. Provide a copy of the board certification.				
<ol> <li>b. For .07(56), provide documentation of supervised clibe used to document this experience.</li> </ol>	nical case experience. The table in section 3.c. may			
c. For .07(59), provide documentation of classroom an and supervised clinical case experience. The tables document this experience.	d 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. <u>Current .07(52)07(60). or .07(72)</u> Authorized Use	rs Seeking Additional Authorization			
a. Authorized User on Materials License	under the requirements below or			
ecuivalent NRC or Agreement State requirements (c	heck all that apply).			
C7(56) 07(57) 07(58)	07(68) 07(89)			
b. If currently authorized for a subset of clinical uses un required supervised case experience. The table in s experience. Also provide completed Part II Precepto	ection 3.c. may be used to document this			
<ul> <li>If currently authorized uncer .07(68) or .07(89) and re documentation on classroom and laboratory training, case experience. The tables in sections 3.a., 3.b., ar Also provide completed Part II Preceptor Attestation. New or first-time Authorized Users must complete section.</li> </ul>	supervised work experience, and supervised clinical ad 3.c. may be used to document this experience.			

۰**.** 

RADIOLOGY INC.

:

3. <u>Training and Experience fo</u> 3. Classroom and Laboratory T		7(58)	.07(59)
Description of Training	Location of Training	Ciock Hours	Dates of Training
Radiation physics and instrumentation	University of South Alabama Medical Center University of South Alabama College of Medicine	66 e	July 2006 June 2010
Radiation protection	University of South Alabama Medical Center University of South Alabama College of Medicine	42	July 2006 June 2010
Mathematics pertaining to the use and measurement of radioactivity	University of South Alabama Medical Center University of South Alabama College of Medicine	24	July 2006 June 2010
Chemistry of byproduct material for medical use	University of South Alabama Medical Center University of South Alabama College of Medicine	77	July 2006 June 2010
Radiation biology	University of South Alabama Medical Center University of South Alabama College of Medicine	62	July 2006 June 2010
Total Hours	s of Classroom and Laboratory Training:	271	
b. Supervised Work Experience			.07(59)
	Location of Experience/License or	ning, provide n Clock	Dates of
if more than one supervising of this page.	individual is necessary to document supervised train Location of Experience/License or Permit Number of Facility	ning, provide n	Dates of Experience
if more than one supervising of this page. Description of Experience Ordering, receiving, and unpacking radioactive materials safely and performing the	Individual is necessary to document supervised train Location of Experience/License or Permit Number of Facility University of South Alabama Medical Center	ning, provide n Clock Hours	Dates of Experience July 2006 to June 2010
if more than one supervising of this page. Description of Experience 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	Location of Experience/License or Permit Number of Facility University of South Alabama Medical Center Alabama Radioactive Materials License # 584 University of South Alabama Medical Center	ning, provide p Clock Hours 1	Dates of Experience July 2006 to June 2010 July 2006 to June 2010
if more than one supervising of this page. Description of Experience 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	Location of Experience/License or Permit Number of Facility University of South Alabama Medical Center Alabama Radioactive Materials License # 584 University of South Alabama Medical Center Alabama Radioactive Materials License # 584	ning, provide a Clock Hours 1	Dates of Experience July 2006 to June 2010 July 2006 to June 2010 June 2010
if more than one supervising of this page. Description of Experience 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 Using administrative controls to prevent a medical event involving the use of unsealed	Location of Experience/License or Permit Number of Facility University of South Alabama Medical Center Alabama Radioactive Materials License # 584 University of South Alabama Medical Center Alabama Radioactive Materials License # 584 University of South Alabama Medical Center Alabama Radioactive Materials License # 584 University of South Alabama Medical Center Alabama Radioactive Materials License # 584	ning, provide a Clock Hours 1 1	Dates of Experience July 2006 to June 2010 July 2006 to June 2010 July 2006 to June 2010 July 2006 to

PASES

۰.

1

!

:

÷

÷

<ul> <li>Training and Experience for Proposed Authors</li> <li>Supervised Work Experience (continued)</li> </ul>	orized User (continued)
Sucervising Individual Shikha Khullar, MD, MPH	License/Permit Name and Number listing supervising ind vidua as an authorized user University of South Alabama / Alabama
Supervisor meets the requirements below (or e	Radioactive Materials License No. 584 quivalent from NRC or Agreement State). [check al: that apoly] <sup>=+</sup> :
.07(56) With experience administering d	୦୨୫୦ୁବ୍ୟ ହାଁ.
gigabecquerels (33 millicune	
Oral Nal-131 in quantities go	eater than 1.22 gigabecquerels (33 millicunes)
energy less than 150 keV rec	beta-emitter, or photon-emitting radionuclide with a photon quiring a written directive
	any other radionuclide requiring a written directive

c. Supervised Clinical Case Experience If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)	10	University of South Alabama Medic: Center Alabama Radioactive Materials License No. 584	l July 2006 to June 2010
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	7	University of South Alabama Medic: Center Alabama Radioactive Materials License No. 584	l July 2006 to June 2010
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	NONE		
Parenteral adminstration of any other radionucide for which a written directive is required	NONE		
jLiet rasionuclides)			· · ·

F4983

,

. . .

<u>,</u>-

FORM RM-HU(AUT)	
	RIENCE AND PRECEPTOR ATTESTATION (continued)
3. Troining and Experience for Proposed Authoriz	zed User (continued)
c. Supervised Clinical Case Experience (continue	d)
Supervising Individual Shikha Khullar, MD, MPH Supervisor meets the requirements below (or equin	License/Permit Number listing supervising individuol as an authorized user University of South Alabama Radioactive Materials License No. 584 valent from NRC or Agreement State). [check all that apply]**:
gigabecquerels (33 millicuries) Q.07(58) Gral Nal-131 in quantities greate Parenteral administration of beta energy less than 150 keV requir	directive in quantities less than or equal to 1.22 er than 1.22 gigabecquerels (33 millicurfes) a-emitter, or photon-emitting radionuclide with a photon ing a written directive is required
Parenteral administration of any	other radionuclide requiring a written directive
<sup>24</sup> Supervising Authorized User must have experience in admined user status.	inistering dosages in the same dosage category or categories as the individual
d. Provide completed Part II Preceptor Attestation.	
Note: This part must be completed by the individual's individual as long as the preceptor provides, din one preceptor is necessary to document experies	CEPTOR ATTESTATION preceptor. The preceptor does not have to be the supervising ects, or verifies training and experience required. If more than ence, obtain a separate preceptor statement from each.
Check one of the following for each requested authors	brization:
<u>For .07(56);</u>	
Board Certification	
I attest that	has satisfactorily completed the training and experience
requirements in 420-3-2607(56)(a)1.	
	OR
Training and Experience	
I attest that	has satisfactority completed the 760 hours of training
Name of Proposed Activated Une and experience, including a minimum of 200 429-3-2607(56)(b)1	r hours of classroom and laboratory training, as required by
	PASIA

.

2

i

: ! .

FORM RM-HU(AUT)	
AUTHORIZE	D USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attestation	(continued)
First Section (con	dinued)
For .97(57) (identi	ical Attestation Statement Regardless of Training and Experience Pathway):
I attest that	Michael W. Dye Jr., M.D. has satisfactorily completed the 80 hours of classroom
	ecuired in 420-3-2607(57)(c)1., and the supervised work and clinical case ecuired in 420-3-2607(57)(c)2.
For .07(58) (identi	cal Attestation Statement Regardless of Training and Experience Pathway):
I attest that	Michael W. Dye Jr., M.D. has satisfactorily completed the 80 hours of classroom
	ry training, as required by 420-3-2607(58)(c)1 and the supervised work and clinical case equired in 420-3-2607(58)(c)2.
Second Section	
I attest that	Michael W. Dye Jr., M.D. has satisfactority completed the required clinical case
experience r	equired in 420-3-2607(57)(b)1.(ii)(VII) listed below:
	131 requiring a written directive in quantities less than or equal to 1.22 uerels (33 millicuries)
🖌 Oral Nal-	131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
Parentera energy le	al administration of beta-emitter, of photon-emitting radionuclide with a photon ss than 150 keV requiring a written directive is required
Parenter:	al administration of any other radionuclide requiring a written directive
*********	
Third Section	
I attest that	Michael W. Dyc Jr., M.D. has satisfactorily achieved a level of competency to
function inde	pendently as an authorized user for:
	131 requiring a written directive in quantities less than or equal to 1.22 uerels (33 millicuries)
🔽 Oral Nal-	131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
	I administration of beta-emitter, or photon-emitting radionuclide with a photon ss than 150 keV requiring a written directive is required
Parentera	administration of any other radionuclide requiring a written directive
	PASES

.

ر <sup>۱</sup>

۰. ۲ ----

:

1 1 1

FORM RM-HU(AUT)						
AUTHORIZE	D USER TRAINI	NG AND EXPERI	ENCE AND PRECE	PTOR ATTESTATION (C	mtinued)	
Fourth Section			· · · · · · · · · · · · · · · · · · ·			
For .07(59):						
Current .07(68)	or .07(89) autho	rized user:				
I attest that	Name of From	DOSED ANTICIZEC USA	is an authorize	d user under 420-3-2607	(68) or (89) or	
equivalent NRC or Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 420-3-2607(59)(d)1., and the supervised work and clinical case experience required by 420-3-2607(59)(d)2., and has achieved a level of competency sufficient to function independently as an authorized user for:						
Parenten than 150	al administration ( keV for which a )	of any bala-emitte written directive is	r, or photon-emitting required	g radionuclide with a photo	n energy less	
Parenter:	al adminstration o	of any other radio	nuclide for which a w	witten directive is required		
			OR			
<b>Board Certifica</b>	<u>tion:</u>					
🔲 i attest that			has satisfactor	ity completed the board ce	rtification	
Network of Proposed Authorized User requirements of 420-3-2607(59(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 420-3-2607(59)(d)1., and the supervised work and clinical case experience required by 420-3-2607(59)(d)2., and has achieved a level of competency sufficient to function independently as an authorized user for:						
		of any beta-emitte written directive is		radionuclide with a photo	n energy less	
Parenter.	al adminstration o	of any other radio	ucüde for which a w	mitten directive is required		
Fifth Section Complete the following for preceptor attestation and signature:						
I meet the requi	rements below, o	r equivalent Agre	ement State require	ments, as an authorized us	ier for:	
.07(56)	.07(57)	.07(58)	.07(59)			
I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.						
Oral Nal-131 reculring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)						
✓ Oral Not-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 radionucide requiring a written directive						
Name of Preceptor Shikha Khullar, M	The second se	Signature J.Ch	Mar.	Telephone Number (251) 471-7128	Date 1.05.201V	
License/Permit Number/F University of Sout		Alabama Radi	pactive Material	s License No. 584		

RADIOLOGY INC.

Form A

### American Board of Radiology - Program Director Attestation

### **COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS**

More information can be found at the following link: http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0290.html

W. Dye Jr. AD U. of South Alabama 420-01-11-008 Program Program # Michael Resident Name

	YES	NO
By the time of the ABR oral examination, this applicant will have successfully completed the hours of training and experience as outlined in 10 CFR 35.290 and 35.392	$\checkmark$	
This applicant has taken part in $\geq$ 3 cases of oral administration of I-131 therapy ( $\leq$ 33mC <i>i</i> )	$\checkmark$	
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached		
The work and experience cited above for § 35.290 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements		
The work and experience cited above for § 35.392 was obtained under the supervision of an		

Authorized User (AU) who meets the requirements under § 35.390, 35.392 or 35.394 or equivalent Agreement State requirements.....

RANE

Residency Program Director (Print Name)

Director Signature)

1/5/10

<u>Date</u>

<u>\_</u>

Form B

### I-131 Therapy Experience

Michael W Dre Jr MD Resident Name

**Dose Administered** 

U. of South Alabama <u>420-01-11-008</u> Program & Number

1. 3/12/09 33.5 mCc I-13/ 2. 8/11/09 15-1 m Ci I-131 3. 9/8/09 98.6mCiI-131 4. 9/10/09 34.1 mCc I-131

Shikha Khullar MD Print Name Stanlas

Preceptor (AU) Print & Sign Name

Shikha khallar, MD Print Name Sign Name

Shikha Khullar MD Print Name Khullas Sign Name

Shi kha Khullar MD Print Name Challar Sign Name

Form A

### American Board of Radiology - Program Director Attestation

## COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

# More information can be found at the following link: http://www.nrc.gov/reading-rm /doc-collections/cfr/part035/part035-0290.html

Michael W. Dye Jr, MD U. o Resident Name Program	<u>f South Alabama</u> n P	<u> 420-01-11</u> rogram #	-00	8
			YES	NO
By the time of the ABR oral examination, this applicant will training and experience as outlined in 10 CFR 35.290 and 32	l have successfully compl 5.392	eted the hours of		
This applicant has taken part in $\geq 3$ cases of oral administration	ion of $l-131$ therapy ( $\leq 3$	3mCi)	$\checkmark$	
The resident's logbook of these therapy experiences (date, d	lose, and preceptor) is atta	ched		
The work and experience cited above for § 35.290 was obtain Authorized User (AU) who meets the requirements under re- Agreement State requirements	levant sections of § 35.29	0 or equivalent	$\checkmark$	
The work and experience cited above for § 35.392 was obtain Authorized User (AU) who meets the requirements under § equivalent Agreement State requirements	35.390, 35.392 or 35.394		$\square$	

TRANE

Residency Program Director (Print Name)

Director (Signature)

1/5/10 Date

Date

RADIOLOGY INC.

3/3

Form B

### **I-131 Therapy Experience**

Michael W Dye Jr. MD Resident Name

**Dose Administered** 

U. of South Alabama <u>420-01-11-008</u> Program & Number

1. 3/12/09 33.5mCi I-13/ 2. 8/11/09 15.1 m C. I-131 3. 9/8/09 98 6 m C. I-131 4. 9/10/09 34.1 mCc I-131

Shikha Khullar MD Print Name

Preceptor (AU) Print & Sign Name

Shikha Khallar, MD Print Name, Khullar

Sign Name

Shikha Khullar MD Print Name/ Chullas Sign Name

Shikha Khullar MD Print Name P. Khallar

Sign Name

The American Board of Radiology Organized through the coopenation of the American College of Radiology, the American Roentgen Ray Society, the American Radium Society, the Radiological Society of North America, the Section on Radiology of the American Medical Association, the American Society for Radiation Oncology, the Association of University Radiologists, and the American Association of Physicists in Medicine Hereby certifies that Sridevi Sompalli, MD Has pursued an accepted course of graduate study and clinical work, has met certain standards and qualifications, including passing the examinations conducted under the authority of The American Board of Radiology, demonstrating to the satisfaction of the Board that she is qualified to practice, AU Bligible and is therefore awarded the Board's contification in the specially of Diagnostic Radiology Effective June 30, 2010 fre HANDER

Walid through 2020

Certificate No. 59048

Fax sent by	: 5	742581101	RADIO	LOGY INC.		04-14-	-11 02:10	dp Pg:	2/4
Jan 20-2010 02	:03 pm	From-RADIOLOGY, A	DMINISTRATION	. +		1-153	P.002/003	F-219	
For	m A								
		American	Board of Radiolo	ogy <u>– Program Dir</u>	ector Attesta	<u>tion</u>			
	COI	MPLIANCE WIT	TH NRC TRAIN	ING AND EXPER	LENCE REQ	UIREN	MENTS		
	Mor <u>http</u>	e information can ://www.nrc.gov/r	be found at the for eading-rn1/doc-	llowing link: collections/cfr/par	t035/part035	<u>-0290.</u> '	<u>htm</u> l		
	RIDEV ident No		Streger Ho: Program	spiral of los & Country Pro	14-01-0 ogram #	3-2			
					• •	VES	NO		
By the time of training and t	of the Alexperior	BR oral examination, ace as outlined in 10 C	this applicant will ha 2FR 35.290 and 35.39	ve successfully comple 2	ted the hours of				
This applican	it has ta	ken part in $\geq 3$ cases of	of aral administration	o[1-131 therapy (≤ 33)	mC/)	$\checkmark$			
				and preceptor) is attac					
Authorized U	ser (AL	I) who meets the requ	irements under releva	under the supervision int sections of § 35.290	or equivalent				
Authorized U	Iser (AL	) who meets the requ	irements under § 35.3	under the supervision 190, 35.392 or 35.394 o	ſ	V			
Rusidency Pro (Print Na		Director	Program E (Signatu	Director		1/ Date	7/10		

(

Form B

"Jan=20-2010 02:03pm

# I-131 Therapy Experience

SRIDEVI SOMPALLI Resident Name

From-RADIOLOGY, ADMINISTRATION

Stroger Hospital of Cook County 14-01-03-2\_ Program & Number

Dosc Administered Date 29.9 mCi 2/4/09 1. 19,8 mLi 2/11/09 2. 27. 3mli 6/17/09 з. 15.0 mGi 6/24/09 4.

Preceptor (AU) Print & Sign Name

The American Board of Radiology Organized through the cooperation of the American College of Radiology, the American Roentgen Ray Society, the American Radium Society, the Radiological Society of North America, the Section on Radiology of the American Medical Association, the American Society for Radiation Oncology, the Association of University Radiologists, and the American Association of Physicists in Medicine Hereby certifies that Chamas Kang Rhee. MD Has pursued an accepted course of graduate study and clinical work, has met certain standards and qualifications, including passing the examinations conducted under the authority of The American Board of Radiology, demonstrating to the satisfaction of the Board that he is qualified to practice, AM CROSS and is therefore awarded the Board's certification in the specialty of Bugnostic Radiology Copieline June St. 2011 forme Altopper Richard I Monin

Certificate (And Lands 8

Ualid through 2020

e.

NRC FORM 313A (AUD) (3-2009)	U.S. NUCLI	EAR REGULATORY COMMISSIO	N	·
AUTHORIZED USER TR AND PRECEPT (for uses defined under [10 CFR 35.190,	APPROVED BY EXPIRES: 3/31/	OMB: NO. 3150-0120 2012		
Name of Proposed Authorized User		State or Territory Where Licer	rsed	
THOMAS KING RHEE		INDIANA		
Requested Authorization(s) (check all that	apply)			
X 35.100 Uptake, dilution, and excretion :	studies			
35.200 Imaging and localization studies		·		
35.500 Sealed sources for diagnosis (s			7	
	······	A		
		G AND EXPERIENCE		
<ul> <li>Training and Experience, including boar the date of application or the individual r the required training and experience was education and experience related to the</li> </ul>	must have obtaine s completed. Pro	ed related continuing educat by ide dates, duration, and de	ion and experier	nce since
1. Board Certification				
a. Provide a copy of the board certific	cation.			
<ul> <li>b. If using only 35,500 materials, stop Preceptor Attestation,</li> </ul>		5.100 and 35.200 materials,	skip to and com	plete Part II
2. Current 35,390 Authorized User S	Seeking Addition	al 35 290 Authorization		
a. Authorized user on Materials Licen		meeting 10 CFR 3	5 200 or equival	ent Aamemont
State requirements seeking author		/* #* # ** ·** ·** ·** ·**	or of a darran	ant Walestineir
<ul> <li>b. Supervised Work Experience. (If more than one supervising indiv copies of this section.)</li> </ul>			ork experience,	provide multiple
Description of Experience	Location o Permi	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	•			
				<u> </u>
	Total Hours	of Experience:		
Supervising Individual	· · · ·	License/Permit Number listin authorized user		vidual as an
Supervisor meets the requirements be 35.290 35.390 ◆ gen	-	• • • • • • • • • • • • • • • • • • • •		hat apply).
			*\	
NRC FORM 313A (AUD) (3-2009)				

х 1 Ф

,

	RM 313A (AUD) U.S. NUCLEAR REGULATORY COMMISSION					
3-2009)	AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)					
	PART II - PRECEPTOR ATTESTATION					
Note:	This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35,590)					
	By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of th position sought and not attesting to the individual's "general clinical competency."					
	ection one of the following for each use requested:					
	35.190					
	Board Certification					
	A satisfactorily completed the requirements in					
	10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.					
	OR					
	Training and Experience					
	I attest that has satisfactorily completed the 60 hours of training and					
	experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.					
For	35.290					
	Board Certification					
	I attest that Thomas Rhee has satisfactorily completed the requirements in					
	10 CFR 35.290(a)(1) and has 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.					
	OR OR					
	Training and Experience					
	I attest that     has satisfactorily completed the 700 hours of training     Name of Proposed Authorized User					
	and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has 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.					
	d Section ete the following for preceptor attestation and signature:					
	I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:					
	35.190       35.290       35.390       35.390 + generator experience					
Name o	f Preceptor Signature / Telephone Number Date					
Wil	lim Spies MD. Mun Ding 312-926-0422 4 28/11					
. \	/Permit Number/Facility Name					
No	MUNICIPEN Nemorial Hospital, Chicago, IL.					

: 5742581101

RADIOLOGY INC.

Date

Form A

### American Board of Radiology - Program Director Attestation

### COMPLIANCE WITH NRC TRAINING AND EXPERIENCE REQUIREMENTS

Northwestern 0401062 Program Program #

More information can be found at the following link: http://www.nrc.gov/reading-rm./doc-collections/cfr/part035/part035-0290.html

Resident Name

Residency Program Director

(Print Name)

	YES	NO
By the time of the ABR oral examination, this applicant will have successfully completed the hours of training and experience as outlined in 10 CFR 35.290 and 35.392		
This applicant has taken part in $\geq$ 3 cases of oral administration of I-131 therapy ( $\leq$ 33mCi)	F	
The resident's logbook of these therapy experiences (date, dose, and preceptor) is attached	Æ	
The work and experience cited above for § 35.290 was obtained under the supervision of an Authorized User (AU) who meets the requirements under relevant sections of § 35.290 or equivalent Agreement State requirements	, E	
The work and experience cited above for § 35.392 was obtained under the supervision of an Authorized User (AU) who meets the requirements under § 35.390, 35.392 or 35.394 or equivalent Agreement State requirements.	2	
Robert Ryu, mis	2 22	110

Program Director

(Signature)

: 5742581101

RADIOLOGY INC.

Form B

#### 1-131 Therapy Experience

THOMAS KHEE Resident Name

Northwestern 0401062 \_\_\_\_

Program & Number

## Preceptor (AU) Print & Sign Name

1. 11/20/06

4.

Date

10.1 NCE

Dose Administered

GAOY DILCHAY Pring Name GUGULOLON Sign Name

STEWART NO Soves, Print Nan

Sign Nat

3. 2/3/10 25 MCz

2. 12/7/06 8 mc

Frint Name A w.O Sign Name

Print Name

Sign Name

# M Northwestern Memorial<sup>®</sup> Hospital

May 9, 2011

To whom it may concern,

This letter confirms that under Northwestern Memorial Hospital's Radioactive Material License granted by the State of Illinois (IL-01037-02) that Dr. William G. Spies, MD is an authorized user of radioactive material as approved by the Radiation Safety Committee.

Dr. William G. Spies is authorized for any radiopharmaceutical indentified in 32 Illinois Administrative Codes: 335.3010, 335.4010, 335.5010, and 335. 6010 for diagnostic, therapeutic and research purposes.

Dr. Spies has been an authorized user at Northwestern Memorial Hospital for the past 20 years. Dr. Spies recently received renewal as an authorized user by the RSC for a two-year period extension on April 29<sup>th</sup>, 2011.

This institution is granted a radioactive material license under the state of Illinois through the agreement compact with the Nuclear Regulatory Commission (NRC). The hospital is not governed directly through the NRC, but through the Illinois Emergency Management Agency (IEMA).

Any questions please feel free to contact me directly.

Respectfully,

Mark D. Pflug, M.S., RRPT, CMLSO, AARST Radiation Safety Officer / Laser Safety Officer Radiation Safety Program Manager Radiation Safety Department 710 North Fairbanks Court, 7th floor, Suite 428 Chicago, IL 60611-3013 (312) 926-8553 • Pager (312) 716-3551 • Fax (312) 926-2294 mpflug@nmh.org

251 East Huron Street, Chicago, Illinois 60611-2908 312.926.2000 www.nmh.org

NRC FORM 374	PAGE         1         OF         2         PAGES           LATORY COMMISSION         Amendment No. 03         03				
MATERIALS	LICENSE				
<b>MATERIALS LICENSE</b> Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.					
Licensee	In accordance with application dated January 20, 2010,				
1. Elkhart Clinic	3. License number 13-32515-01 is amended in its entirety to read as follows:				
2. 303 South Nappanee Street	4. Expiration date June 30, 2014				
Elkhart, IN 46514	5. Docket No. 030-36581 Reference No.				
<ol> <li>Byproduct, source, and/or special nuclear 7. Chemical ar material</li> <li>A. Any byproduct material A. Any permitted by 10 CFR 35.200</li> </ol>	nd/or physical form 8. Maximum amount that licensee may possess at any one time under this license A. As needed				
9. Authorized use:					
A. Any imaging and localization study permitted by 10 CFR 35.200.					
CONDIT	<u>rions</u>				
<ol> <li>Licensed material may be used or stored only at the licensee's facilities located at 303 South Nappanee Street, Elkhart, Indiana.</li> </ol>					
11. The Radiation Safety Officer for this license is Luisito Gonzales, M.D.					
12. Licensed material is only authorized for use by, or under the supervision of:					
A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.					
B. The following individuals are authorized users for medical use as indicated:					
Authorized Users	Material and Use				
Luisito Gonzales, M.D.	10 CFR 35.200.				
Wai Hung Lee, M.D.	10 CFR 35.200.				
13. In addition to the possession limits in Item 8, the lice material to quantities below the minimum limit spec decommissioning financial assurance.	ensee shall further restrict the possession of licensed ified in 10 CFR 30.35(d) for establishing				

S. LEUNG /ROC Elkhart General Hospital Elkhart, IN 46574

1100

FIRST-CLASS

U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road, Suite 210 2443 I bos 32-4352 Lisle, IL 60532-4352