

ST. ELIZABETH MEDICAL CENTER | HOME HOSPITAL

September 15, 2009

U.S. Nuclear Regulatory Commission Region III Materials Licensing Branch 2443 Warrenville Rd. Suite 210 Lisle IL, 60532

RE: Amendment to Materials License number 13-09788-01

Dear Madam or Sir:

We wish to amend our Materials License number 13-09788-01 as follows:

## **DELETE AUTHORIZED USERS**

Please delete Paul DesRosiers, M.D. and Timothy J. Lach, M.D. they are no longer affiliated with this facility.

## AUTHORIZED USER – ADDITIONAL APPROVED USE

We wish to add the additional approved use of 10 CFR 35.300 to Michael F. Busch, M.D.. In support of this request we have enclosed an NRC 313A (AUT) Preceptor Form.

## **CHANGE RADIATION SAFTEY OFFICER**

Please remove Paul E. Gandy M.D. as the Radiation Safety Officer and replace him with Michael F. Busch M.D. Dr. Busch is presently listed as an authorized user on our license. In support of this request we have enclosed an NRC 313A (RSO) Preceptor Form. Additionally a letter of understanding between this facilities executive management and the proposed RSO is enclosed.

If you have any questions, please contact Thomas M Kumpuris, M.S., FACR of Medical Physics Consultants, Inc. at (800) 321-2207 or <a href="mailto:tkumpuris@mpcphysics.com">tkumpuris@mpcphysics.com</a>.

Sincerely,

Terrance E Wilson
President and CEO



ST. ELIZABETH MEDICAL CENTER | HOME HOSPITAL

September 15, 2009

United States Nuclear Regulatory Commission Region III, Materials Licensing 2443 Warrenville Road Suite 210 Lisle, IL 60532-4352

RE: Amendment to Materials License 13-097788-01

Dear Madam or Sir:

I attest that Michael Busch M.D. has the required training and experience and has satisfactorily completed the requirements to become a Radiation Safety Officer to include one year full-time radiation safety experience.

Michael Busch, M.D. is an authorized user identified on NRC license # 13-097788-01 and:

- Has experience with the radiation safety aspects of byproduct material for which they will have Radiation Safety Officer responsibilities.
- Has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer.
- Has training in radiation safety, regulatory issues and emergency procedures for the following types of use: 35.100, 35.200, 35.300 and 35.400.
- Has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for this materials license.

I am the Radiation Safety Officer for St. Elizabeth Regional Health d/b/a Greater Lafayette Health Services, Inc. License # 13-09788-01.

Sincerely,

Paul E. Gandy, M.D. Radiation Safety Officer



ISO1 Hartford St; | P.O. Box 7501 Lafayette, Indiana 47903 765-423-6011 | www.stewayoflife.org

ST, ELIZABETH MEDICAL CENTER | HOME HOSPITAL

September 15, 2009

Michael Busch M.D St. Elizabeth Regional Health d/b/a Greater Lafayette Health Services, Inc. Nuclear Medicine Department 1501 Hartford Street Lafayette, IN 47903

RE: Radiation Safety Officer/Executive management Letter of Understanding

Dear Dr. Busch:

You have been appointed the Radiation Safety Officer (RSO) of this facility for our United States Nuclear Regulatory Commission Materials License. This "Letter of Understanding" is prepared to comply with Title 10 Code of Federal Regulations (CFR) Part 35.24(b). This section of the regulations requires that you agree in writing to the following:

- Assume responsibility for implementing the Radiation Protection Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.
- Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:
- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
  - 1. Identify radiation safety problems;
  - 2. Initiate, recommend, or provide corrective actions:
  - 3. Stop unsafe operations; and,
  - 4. Verify implementation of corrective actions.

Our signatures noted below will attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

Terrance E Wilson

Terrance E. Wilson, President/CEO

Radiation Safety Officer

NRC FORM 313A (AUT) (3-2009) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: 3/31/2012

				ned under 35. 392, 35.394, a			20.000.20.2	
Name	of Propos	ed Authori:	zed User		State or Territory	Where License	ed	_
Michae	el F. Busch	ı, M.D.			Indiana			
Reque	ested Aut	horization	n(s) (check all tha	t apply):				
	35.300	Use of u	unsealed byprodu	ict material for whi	ch a written direct	tive is require	ed .	
OF	₹							
✓	35.300		ministration of soc gabecquerels (33)		requiring a written	directive in o	quantities less than or equal to	
✓.	35.300		ministration of soc equerels (33 millic		requiring a written	directive in o	quantities greater than 1.22	
	35.300			of any beta-emitte written directive is		ting radionuc	clide with a photon energy less	
	35.300	Parente	ral administration	of any other radio	nuclide for which	a written dire	ective is required	
				ART I TRAININ				
of ex	f applicati kperience	ion or the	individual must h npleted. Provide	ave related contin	uing education ar	nd experience	n the 7 years preceding the dat e since the required training and lucation and experience related	t
1.	Board (	Certificat	<u>tion</u>					
а	. Provide	е а сору с	of the board certifi	ication.				
b.			vide documentation ment this experient		linical case exper	rience. The ta	able in section 3.c. may	
c.	and su	pervised of	vide documentatio clinical case expe xperience.	on on classroom a erience. The table	nd laboratory trair s in sections 3.a.,	ning, supervis 3.b., and 3.c	sed work experience, c. may be used to	
d.	. Skip to	and com	plete Part II Prece	eptor Attestation.				
2.	Current	t 35.300,	35.400, or 35.600	0 Authorized Use	r Seeking Additi	onal Author	ization	
a.	Authoriz	zed User	on Materials Lice	nse		unde	er the requirements below or	
	equival	ent Agree	ement State requi	irements (check al	'l that apply):		·	
	35.	390	35.392	35.394	35.490	35.690	0	
b.	require	d supervi:	sed case experier	et of clinical uses u nce. The table in ted Part II Precept	section 3.c. may b	ride documen be used to do	ntation on additional ocument this	
c.	docume clinical	entation o case exp	on classroom and perience. The tabl	90 or 35.690 and r laboratory training les in sections 3.a ted Part II Precept	g, supervised work ., 3.b., and 3.c. ma	k experience,	, and supervised	

St. Elizabeth Regional Health

13-09788-01

Using procedures to contain

decontamination procedures

spilled byproduct material safely and using proper

May, 2008 to

Present

Yes

No

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work Experience (continued)

Supervising Individual	: License/Permit Number listing supervising individual as an
	authorized user
Paul E. Gandy, M.D.	13-09788-01

Supervising individual meets the requirements below, or equivalent Agreement State requirements (check all that apply)\*\*:

✓	35.390	į	With experience administering dosages of:

35.392 35.394

35.396

- ✓ 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
- ✓ Parenteral administration of 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)	Four (4)	St. Elizabeth Regional Health 13-09788-01	May. 2008 to Present
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	Four (4)	St. Elizabeth Regional Health 13-09788-01	May, 2008 to Present
Parenteral administration of any beta-emitter, or ohoton-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			
(List radionuclides)			

<sup>\*\*</sup> Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

NRC F 3-2009)		•	U.S. NUCLEAR REGULATORY COMMISSION  G AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)						
3. ]	raining and	d Experience for Propo	osed Authorized User (continued)						
(	c. Supervise	Supervised Clinical Case Experience (continued)							
\$	Supervising Ir	dividual	License/Permit Number listing supervising individual as an authorized user						
F	Paul E. Gandy	, M.D.	13-09788-01						
	Supervising individual meets the requirements below, or equivalent Agreement State requirements (che apply)**:								
	✓ 35.390 With experience administering dosages of:								
	35.392 35.394	Oral Nal-131 required gigabecquerels (3	iring a written directive in quantities less than or equal to 1.22 3 millicuries)						
1.	35.396	✓ Oral Nal-131 in qu	uantities greater than 1.22 gigabecquerels (33 millicuries)						
	00.000	✓ Parenteral admini energy less than	stration of beta-emitter, or photon-emitting radionuclide with a photon 150 keV requiring a written directive is required						
		✓ Parenteral admini	stration of any other radionuclide requiring a written directive						
*		Authorized User must have e authorized user status.	xperience in administering dosages in the same dosage category or categories as the individual						
C	d. Provide c	ompleted Part II Precep	or Attestation.						
		F	PART II – PRECEPTOR ATTESTATION						
Note:	individual	as long as the precepto	ne individual's preceptor. The preceptor does not have to be the supervising or provides, directs, or verifies training and experience required. If more than cument experience, obtain a separate preceptor statement from each.						
	By checki position se	ng the boxes below, the bught and not attesting	preceptor is attesting that the individual has knowledge to fulfill the duties of the to the individual's "general clinical competency."						
	Section k one of the	e following for each re	quested authorization:						
E	For 35.390:								
	Board Ce	ertification							
	☐ I attes	st that	has satisfactorily completed the training and experience						
		Name of Prop	osed Authorized User						
	requir	ements in 35.390(a)(1).							
			OR						
	Training	and Experience							
	I attes	t that	has satisfactorily completed the 700 hours of training						
		Name of Prop	osed Authorized User						
		kperience, including a m R 35.390 (b)(1).	inimum of 200 hours of classroom and laboratory training, as required by						

Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon

Parenteral administration of any other radionuclide requiring a written directive

energy less than 150 keV requiring a written directive is required

For 35.396:			
<b>Current 35.4</b>	90 or 35.690 autho	rized user:	
l attest tha			is an authorized user under 10 CFR 35.490 or 35.690
laboratory experienc	ent Agreement State training, as require	ed by 10 CFR 35.3 96(d)(2), and has a	has satisfactorily completed the 80 hours of classroom and 396 (d)(1), and the supervised work and clinical case achieved a level of competency sufficient to function
	teral administration 50 keV for which a		ter, or photon-emitting radionuclide with a photon energy less is required
Parent	eral administration	of any other radio	onuclide for which a written directive is required
			OR
<b>Board Certifi</b>	cation:		
I attest that		pposed Authorized User	has satisfactorily completed the board certification
required b	by 10 CFR 35.396 (d (2), and has achiev	d)(1) and the supe	ompleted the 80 hours of classroom and laboratory training ervised work and clinical case experience required by spetency sufficient to function independently as an
	teral administration 50 keV for which a		ter, or photon-emitting radionuclide with a photon energy less s required
Parent	eral adminstration	of any other radio	onuclide for which a written directive is required
Fifth Section Complete the follow	wing for preceptor	r attestation and	signature:
✓ I meet the red	quirements below, o	or equivalent Agre	eement State requirements, as an authorized user for:
✓ 35.390	35.392	35.394	35.396
	ence administering uthorization.	dosages in the fo	ollowing categories for which the proposed Authorized User is
requesting at			
		ten directive in qu	antities less than or equal to 1.22 gigabecquerels (33
✓ Oral Nal-1 millicuries	3)	·	gabecquerels (33 millicuries)
✓ Oral Nal-1  ✓ Oral Nal-1  ✓ Parentera	s) 131 in quantities gre	eater than 1.22 giç peta-emitter, or ph	gabecquerels (33 millicuries) hoton-emitting radionuclide with a photon energy less than
✓ Oral Nal-1 millicuries ✓ Oral Nal-1 ✓ Parentera 150 keV re	s) 131 in quantities gre Il administration of b equiring a written di	eater than 1.22 gig beta-emitter, or ph irective is required	gabecquerels (33 millicuries) hoton-emitting radionuclide with a photon energy less than
✓ Oral Nal-1 millicuries ✓ Oral Nal-1 ✓ Parentera 150 keV re	s) 131 in quantities gre Il administration of b equiring a written di	eater than 1.22 gig beta-emitter, or ph irective is required	igabecquerels (33 millicuries) hoton-emitting radionuclide with a photon energy less than d

NRC FORM 313A (RSO) (3-2009)		U.S. NUCLEAR REGULATO	RY COMMISSION		
RADIATION SA AI	APPROVED B EXPIRES: 3/3	Y OMB: NO. 3150-012 1/2012			
Name of Proposed Radiatio	n Safety Officer				
Michael F. Busch, M.D.					
Requested Authorization	(s) The license author	izes the following medical u	ses (check all t	hat apply):	
<b>√</b> 35.100 <b>√</b> 35	5.200 🗸 35.300	<b>✓</b> 35.400 <b>✓</b> 35.	500 35	5.600 (remote	afterloader)
35.600 (teletherap	y) 35.600 (e	gamma stereotactic radiosu	rgery) 35	5.1000 (	)
		I TRAINING AND EXPEI t one of the four methods			
application or the individu	ual must have obtained pleted. Provide dates	fication, must have been old related continuing educate, duration, and description	on and experie	nce since the	required training
1. <u>Board Certificati</u>	ion				
a. Provide a copy o	of the board certification	n.			
	o describe training in racal use on the license.	adiation safety, regulatory is	ssues, and eme	rgency proce	dures for
c. Skip to and comp	olete Part II Preceptor	Attestation.			
Officer for the Ac a. Use the table in procedures for	Iditional Medical Usen section 3.c. to descri	be training in radiation safe medical use for which reco	ty, regulatory is	sues, and em	
		OR Proposed Radiation Safet	y Officer		
a. Classroom and	Laboratory Training				
Description o	f Training	Location of Training		Clock Hours	Dates of Training*
Radiation physics instrumentation	and				
Radiation protection	no				
Mathematics perta use and measuren radioactivity					
Radiation biology					
Radiation dosimetr	ny .				

### (3-2009)

## RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. Structured Educational Program for Proposed Radiation Safety Officer (continued)

b. Supervised Radiation Safety Experience (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Training/ License or Permit Number of Facility	Dates of Training*
Shipping, receiving, and performing related radiation surveys		
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides		
Securing and controlling byproduct material		
Using administrative controls to avoid mistakes in administration of byproduct material		
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures		
Using emergency procedures to control byproduct material		
Disposing of byproduct material		
Licensed Material Used (e.g., 35,100, 35,200, etc.)+		

<sup>+</sup> Choose all applicable sections of 10 CFR Part 35 to describe radioisotopes and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.600 gamma stereotactic radiosurgery units, emerging technologies (provide list of devices).

Structured Educational Program for Propos	sed Radiation Safety Officer (continued)	
b. Supervised Radiation Safety Experience (	continued)	
(If more than one supervising individual is a copies of this section.)	necessary to document supervised work exper	ience, provide multiple
Supervising Individual	License/Permit Number listing supervis Radiation Safety Officer	sing individual as a
This license authorizes the following medical u	uses:	
35.100 35.200 35.300	35.400	
35.500 35.600 (remote afterloade	er) 35.600 (teletherapy)	
35.600 (gamma stereotactic radiosurgery)	35.1000 (	)
use on the license.	atory issues, and emergency procedures for all	types of medical  Dates of
Description of Training	Training Provided By	Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	Paul E. Gandy, M.D., RSO	June, 2008 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Paul E. Gandy, M.D., RSO	June, 2008 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Paul E. Gandy, M.D., RSO	June, 2008 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses		
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses		
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):		

(3-2009)	ORM 313A (R DIATION SA	•	U.S. NUCLEAR REGULATORY COMMISSION AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
Precep	tor Attesta	ntion (continued)				
	ection (cor	•				
√ 3	. Addition	al Authorization as Radiati	on Safety Officer			
✓	l attest tha	at Michael F. Busch, M.D.	is an			
		Name of Proposed Radiation	Safety Officer			
	✓ Authorized User Authorized Nuclear Pharmacist					
	Au	thorized Medical Physicist				
	aspect		and has experience with the radiation safety product material for which the individual has lities			
			AND			
	Section ete for all	(check all that apply):				
la	ittest that	Michael F. Busch, M.D.	has training in the radiation safety, regulatory issues, and			
en	nergency n	Name of ProposedRadiation Safety rocedures for the following ty				
	35.100	ocedures for the following ty	Jes of use.			
7	35.200					
<b>V</b>						
<b>✓</b>	35.300	which a written directive is	than or equal to 33 millicuries of sodium iodide I-131, for required			
✓	35.300	oral administration of grea	ter than 33 millicuries of sodium iodide I-131			
✓	35.300		of any beta-emitter, or a photon-emitting radionuclide with 150 keV for which a written directive is required			
✓	35.300	parenteral administration or required	of any other radionuclide for which a written directive is			
$\checkmark$	35.400					
	35.500					
	35.600	remote afterloader units				
	35.600	teletherapy units				
	35.600	gamma stereotactic radios	surgery units			
	35.1000	emerging technologies, in	cluding:			

NRC FORM 313A (RSO) (3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFF	ICER TRAINING AND	EXPERIENCE AND PREC	SEPTOR ATTESTATION	(continued)		
		AND				
Third Section Complete for ALL						
l attest that Michael F. B	usch, M.D.	has achieved a level of	f radiation safety knowle	dge		
Name of Pr	roposed Radiation Safety Officer					
sufficient to function indep	pendently as a Radiatio	on Safety Officer for a medi	cal use licensee.			
Fourth Section Complete the following for P	receptor Attestation a	and signature				
I am the Radiation Safety Of	ficer for St. Elizabeth R		Greater Lafayette Health Services  Name of Facility			
License/Permit Number: 13-09	7799-01	Name of Fa	Cinty			
			×			
Name of Preceptor	Signature	10	Telephone Number	Date		
Paul E. Gandy, M.D.	Signature	Cly	(765) 449-5127	09/15/2009		



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