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Allergy, Asthma

& Immunology

March 12, 2010

Ambulatory Surgery

Audiology

Cardiology

United States Nuclear Regulatory Commission

Clinical Research

Region III, Materials Licensing 2443 Warrendale Road Suite 210

Dermatology

Lisle, IL 60532-4352

The South Bend Clinic

Endocrinology Family Medicine

Gastroenterology

RE: Amendment to NRC License No. 13-32393-01

Vascular Surgery

General &

Genatrics

Internal Medicine

Laboratory

Neurology

Nuclear Medicine

Nutrition

Obstetrics

& Gynecology

Oncology-Hematology

Ophthalmology Optometry

Orthopaedic Surgery

Otolaryngology-

Head & Neck Surgery

**Pediatrics** 

Pediatric Pulmonology Pharmacy

Physical Medicine

& Rehabilitation

**Podiatry** Radiology

Rheumatology

Speech Pathology

Sports Medicine

Surgery Center Urology

Vascular Laboratory

Dear Sir/Madam:

We would like to amend our current NRC license to reflect the following changes:

Item #1:

Please remove Thomas Bowers, M.D. as the Radiation Safety

Officer (RSO):

Item #2:

Please list Sharon A. Updike, BA, CNMT as the RSO on our NRC license. She is listed as the RSO on NRC license #13-32478-01 for 35.100 and 35.200. We have enclosed a copy of her previously submitted NRC313A form which documents the required 35.300 Also included are the RSO/Executive Management training.

agreement letter and a letter stating the RSO availability.

If you have any questions or require additional information, please contact our physics consultant, Sharon A. Updike, Medical Physics Consultants at 734-662-3197

Paul Mever **Executive Director** South Bend Clinic

RECEIVED MAR 1 7 2018



### www.southbendclinic.com

Allergy, Asthma & Immunology

**RSO / EXECUTIVE MANAGEMENT** LETTER OF UNDERSTANDING

Ambulatory Surgery

Audiology

Cardiology

Clinical Research

Dermatology

Endocrinology

Family Medicine

Gastroenterology

General &

Vascular Surgery

Genatrics

Internal Medicine

Laboratory

Neurology

Nuclear Medicine

Nütrition

Obstetrics & Gynecology

Oncology-Hematology

Ophthalmology

Optometry

Orthopaedic Surgery

Otolar yngology-

Head & Neck Surgery

**Pediatrics** 

Pediatric Pulmonology

Pharmacy

Physical Medicine

& Rehabilitation

Podiatry

Radiology

**Pheumatology** 

Speech Pathology

Sports Medicine

Surgery Center

Urology

Vascular Laboratory

March 8, 2010

Sharon A. Updike, BA, CNMT

The South Bend Clinic 211 North Eddy Street South Bend, IN 46334

Radiation Safety Officer / Executive Management Re: Letter of Understanding

Dear Sharon A. Updike,

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.

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.

Sharon A. Updike, BA, CNMT Radiation Safety Officer

Show Updill

# NRC FORM 313A (RSO) (2-2007)

# U.S. NUCLEAR REGULATORY COMMISSION

AND PRECEI	CER TRAINING AND EXPERIENCE PTOR ATTESTATION CFR 35.50]	EXPIRES: 10	
Name of Proposed Radiation Safety Officer			
Sharon A. Updike, BA, CNMT			
Requested Authorization(s) The license	authorizes the following medical uses (check a	II that apply):	
<u> </u>	35.300 35.400 35.500	35.600 (remot	e afterloader)
	35.600 (gamma stereotactic radiosurgery)	35.1000 (	٦
35.600 (teletherapy) 3	55.000 (gainina stereotactic radiosurgery)	55, 1000 (	
	PART I TRAINING AND EXPERIENCE (Select one of the four methods below)		
landication or the individual must have	ard certification, must have been obtained within obtained related continuing education and expede dates, duration, and description of continuing	rience since th	e required training
1. Board Certification			
a. Provide a copy of the board ce			
<ul> <li>b. Use Table 3.c. to describe train all types of medical use on the</li> </ul>	ning in radiation safety, regulatory issues, and er license.	mergency proc	edures for
c. Skip to and complete Part II Pr	eceptor Attestation.		
	OR		
2. Current Radiation Safety Offic Officer for the Additional Med	er Seeking Authorization to Be Recognized a ical Uses Checked Above	as a Radiation	Safety
a. Use the table in section 3.c. to procedures for the additional	to describe training in radiation safety, regulatory types of medical use for which recognition as R	/ issues, and e SO is sought.	mergency
b. Skip to and complete Part II	Preceptor Attestation.		
	OR		
√ 3. Structured Educational Progr	am for Proposed Radiation Safety Officer		
a. Classroom and Laboratory T			
Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and	Oregon State University, Corvallis, OR	30	1/08 to 3/09
instrumentation	WCC, Ann Arbor, MI	10	9/07 to 12/07
		10	4/08
Radiation protection	Oregon State University, Corvallis, OR Medical Physics Cons. AU Course, IN	50 10	1/08 to 3/09 4/08
Mathematics pertaining to the	Oregon State University, Corvallis, OR	30	1/08 to 3/09
use and measurement of	WCC, Ann Arbor, MI	10	4/06 to 12/07
radioactivity	Medical Physics Cons. AU Course, IN	5	4/08
Radiation biology	Oregon State University, Corvallis, OR	40	1/08 to 3/09 4/08
	Medical Physics Cons. AU Course, IN	10	4/00
Dediation designator	Oregon State University, Corvallis, OR	10	1/08 to 3/09
Radiation dosimetry	Medical Physics Cons. AU Course, IN	5	4/08
	Total Hours of Training:	220.0	

# 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	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants,Inc/21-20153-01	4/06 to present
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants,Inc/21-20153-01	4/06 to present
Securing and controlling byproduct material	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present
Using administrative controls to avoid mistakes in administration of byproduct material	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present
Using emergency procedures to control byproduct material	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present
Disposing of byproduct material	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 35.100, 35.200, 35.300	MidMichigan Medical Center/21-01549-02 Advanced PET Imaging Network/1358-1 Medical Physics Consultants, Inc./21-20153-01	4/06 to present

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).

3.	structured Educational Program for Proposed Radiation Safety Officer (continued)		
	b. Supervised Radiation Safety Experience (continued)		
	(If more than one supervising individual is necessary copies of this section.)	to document supervised work experience, provide multiple	
	Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer	
	James M. Botti, M.S.	21-01190-05	
	This license authorizes the following medical uses:		
	<b>✓</b> 35.100 <b>✓</b> 35.200 <b>✓</b> 35.300	<b>√</b> 35,400	
	√ 35.500  √ 35.600 (remote afterloader)	35.600 (teletherapy)	
	35.600 (gamma stereotactic radiosurgery)	35.1000 ()	

Description of Training	Training Provided By	Dates of Training*
Radiation safety, regulatory issues, and emergency procedures for 35.100, 35.200, and 35.500 uses	James M. Botti, M.S.	4/06 to present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	James M. Botti, M.S.	4/06 to present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	7	
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):		

NRC FORM 313A (R	SO)	U.S. NUCLEAR REGULATORY COMMISSION
RADIATION SA	AFETY OFFICER TRAINING	G AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)
Preceptor Attesta	tion (continued)	
First Section (cor Check one of the		
3. Addition	al Authorization as Radia	tion Safety Officer
l attest tha	at	is an
	Name of Proposed Radiation	n Safety Officer
Au	thorized User	Authorized Nuclear Pharmacist
Au	thorized Medical Physicist	
aspect		e and has experience with the radiation safety yproduct material for which the individual has polities
		AND
Second Section		AND
	(check all that apply):	
<b>7</b>	G1	has training in the radiation safety, regulatory issues, and
✓ I attest that	Sharon A. Updike Name of ProposedRadiation Safe	
emergency p	rocedures for the following	
<b>√</b> 35.100		
<b>35.200</b>		
<b> √</b> 35.300	oral administration of les which a written directive	es than or equal to 33 millicuries of sodium iodide I-131, for is required
<b>3</b> 5.300	oral administration of gre	eater than 33 millicuries of sodium iodide I-131
<b> √</b> 35.300	parenteral administration a photon energy less that	n of any beta-emitter, or a photon-emitting radionuclide with an 150 keV for which a written directive is required
<b>√</b> 35.300	parenteral administration required	n of any other radionuclide for which a written directive is
35.400		
35.500		
35.600	remote afterloader units	
35.600	teletherapy units	
35.600	gamma stereotactic rad	iosurgery units
35.1000	emerging technologies,	including:

	0)	U.S. NUCLEAR REGULATORY	COMMISSIO
RADIATION SA	AFETY OFFICER TRAINING	G AND EXPERIENCE AND PRECEPTOR ATTESTATION (co	ontinued)
		AND	
hird Section Complete for ALL	-		
I attest that	Sharon A. Updike  Name of Proposed Radiation Safe	has achieved a level of radiation safety knowledge	
sufficient to fi	unction independently as a R	Radiation Safety Officer for a medical use licensee.	
	(E)		
ourth Section complete the following the complete the following the control of th	owing for Preceptor Attest	station and signature	
	į.		
I am the Radiation	on Safety Officer for St. Jo	John Macomb Oakland Hospital Name of Facility	
	I NOCE ALAI	1100.05	
License/Permit Nu	mber: NRC License 21-01	1190-05	
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Name of Preceptor

James M. Botti, M.S.

Signature

& Box

Telephone Number

Date

(734) 662-3197

04/01/2009



March 8, 2010

**United States Nuclear Regulatory Commission** 

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

RE: RSO Availability and Ability to Perform Duties

To Whom It May Concern:

Please find the information listed below concerning my availability and ability to perform RSO duties at this facility.

**Item #1:** My position at Medical Physics Consultants allows me adequate time and flexibility to address both my contractual and regulatory obligations to any facility that I am listed as the Radiation Safety Officer.

The position of Radiation Safety Officer is what we are contracted for by these facilities. All facilities have a signed contract by both them and Medical Physics Consultants. These contracts clearly outline both my responsibilities and the facilities. All facilities have also signed a RSO / Management Agreement form which has been forwarded to the NRC in all applications and / or amendments.

All facilities are audited on a quarterly basis which is standard of practice. These audits are forwarded to both management and the supervising technologist. These audits are reviewed and signed by both of these individuals. Any items that require attention are documented by the supervising technologist.

Item #2: The amount of time for me to respond to an emergency involving radioactive material will vary depending upon my activities that day. Typically I would be able to respond immediately by phone. All facilities have both my cell phone and office phone numbers. The office staff at Medical Physics Consultants has a copy of my daily schedule at all times. The staff has phone numbers to any location that I might be working.

Medical Physics Consultants has an answering service that operates 24 hours a day, 7 days a week, 365 days a year. They have phone numbers for my home, cell and office. If for some reason they are not able to contact me, they have a list of other physicists that are employed by Medical Physics Consultants to contact. These individuals are board certified physicists with a great deal of expertise. This same mechanism has been in place for years whenever one of our facilities is in need of immediate expertise and advice. If we are contacted for a radiological emergency we direct the account to notify the appropriate management individual.

As stated earlier we audit the program quarterly, any unsafe practices or incidents are reported to management in writing. Items of significant concern are always reported to management verbally in addition to the written documentation.

**Item #3:** The amount of time that I will spend at this facility will vary. Time will depend upon the status of the Radiation Protection Program and other variables. As stated above quarterly reports are sent to management.

Item #4: All individuals who handle or have access to radioactive material are overseen by a supervisor. These supervisors reports directly to management and the Radiation Safety Officer. All individuals are in-serviced yearly. Management in their license application have committed to supplying the necessary resources for these individuals to achieve regulatory compliance. Additionally, they have committed to this in the RSO / Management Agreement letter.

If you have any questions or if I may be of assistance, please contact me by phone at (734) 662-3197 or by e-mail at supdike@mpcphysics.com.

Respectfully Yours,

Sharon Updike, BA, CNMT Medical Physics Consultant

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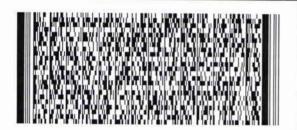


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