

From: "Patrick Byrne" <pbyrne@mpcphysics.com>
To: "Brandy Brugh" <brughb@sjrmc.com>
CC: "Sharon Updike" <supdike@mpcphysics.com>
Date: 9/19/2011 3:23 PM
Subject: License Amendment
Attachments: Amendment0911.docx; nrc313a(rso)SharonSigned.pdf; RSO-MNGTSharon.doc

Brandy,

In support of the change of Radiation Safety Officer from myself to Sharon, I have attached all the necessary documentation. Could you print the attached "Amendment0911.docx" onto SJRMC letterhead for Chris' signature? In addition, please print the RSO-MNGTSharon.doc document onto SJRMC letterhead for Chris and Sharon to sign tomorrow. Once signed, two copies will need to be made, along with two copies of the attached "nrc313a(rso)SharonSigned.pdf" document. The originals plus one set of the copies will be mailed to the NRC (to the NRC address listed on the amendment request letter). The second set of copies are for SJRMC's records.

Thanks and see you tomorrow.

patrick

RECEIVED SEP 27 2011

RSO / EXECUTIVE MANAGEMENT
LETTER OF UNDERSTANDING

September 20, 2011

Sharon Updike, M.S.
Saint Joseph Regional Medical Center
5215 Holy Cross Parkway
Mishawaka, Indiana 46545

Re: Radiation Safety Officer / Executive Management Letter of Understanding

Mrs. 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.

Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:

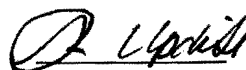
- Specific written notation of your authority, duties and responsibilities, see attached.
- Sufficient authority, organizational freedom, time, resources and management prerogative to:
 1. Identify radiation safety problems;
 2. Initiate, recommend, or provide corrective actions;
 3. Stop unsafe operations; 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,



Chris Karam
Chief Operating Officer



Sharon Updike
Radiation Safety Officer

SAINT JOSEPH
Regional Medical Center
125 Years of Faith Based Healthcare in Michiana
A MEMBER OF TRINITY HEALTH

Saint Joseph Regional Medical Center
5215 Holy Cross Parkway
Mishawaka, IN 46545
(574) 335-5000

Plymouth Campus
1915 Lake Avenue
Plymouth, IN 46563
(574) 936-3181

Elm Road Medical Campus
60101 Bodnar Boulevard
Mishawaka, IN 46544

Saint Joseph Pediatric Specialty Clinics
611 East Douglas Road, Suite 405
Mishawaka, IN 46545
(574) 335-6240

Saint Joseph Physician Network
810 East Park Place
Mishawaka, IN 46545
(574) 472-6700

Saint Joseph Regional Medical Center
Rehabilitation Institute
60205 Bodnar Boulevard
Mishawaka, IN 46544
(574) 335-8800

Saint Joseph Urgent Care
53830 Generations Drive, Suite 110
South Bend, IN 46635
(574) 472-6333

The Foundation of
Saint Joseph Regional Medical Center
837 East Cedar Street, Suite 350
South Bend, IN 46617
(574) 237-7377

Saint Joseph Administrative Offices
837 East Cedar Street, Suite 350
South Bend, IN 46617
(574) 335-5000

Withhold from public disclosure under 10 CFR 2.390
Personal Privacy Information

September 19, 2011

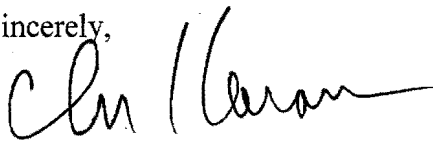
U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

Saint Joseph Regional Medical Center would like to amend its NRC Byproduct Materials License, Number 13-02650-02, to list Sharon Updike, M.S. as the Radiation Safety Officer. Mrs. Updike is currently listed as the Radiation Safety Officer for The South Bend Clinic, U.S.N.R.C. Materials License 13-32393-01. The South Bend Clinic is authorized for materials licensed under 10 C.F.R. 35.100, 35.200, and 35.300. Mrs. Updike has received training for materials licensed under 10 C.F.R. 35.400 as documented by the enclosed N.R.C. Form 313A(RSO).

If there are any questions concerning this license amendment request, please contact the Saint Joseph Regional Medical Center Radiation Safety Officer, Mr. Patrick J. Byrne, DABR, CHP, DABSNM, at 1-877-321-2207x343.

Sincerely,



Chris Karam
Chief Operating Officer
Saint Joseph Regional Medical Center

enclosures

Saint Joseph Regional Medical Center
5215 Holy Cross Parkway
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(574) 335-5000

Plymouth Campus
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**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
[10 CFR 35.50]APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Radiation Safety Officer

Sharon A. Updike

Requested Authorization(s) *The license authorizes the following medical uses (check all that apply):*

- ☒ 35.100 ☒ 35.200 ☒ 35.300 ☒ 35.400 ☐ 35.500 ☐ 35.600 (remote afterloader)
☐ 35.600 (teletherapy) ☐ 35.600 (gamma stereotactic radiosurgery) ☐ 35.1000 (_____)

PART I -- TRAINING AND EXPERIENCE
(Select one of the four methods below)

*Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ 1. **Board Certification**

- Provide a copy of the board certification.
- Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- Skip to and complete Part II Preceptor Attestation.

OR

☒ 2. **Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above**

- Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for the additional types of medical use for which recognition as RSO is sought.
- Skip to and complete Part II Preceptor Attestation.

OR

☐ 3. **Structured Educational Program for Proposed Radiation Safety Officer**

- 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			
Radiation biology			
Radiation dosimetry			

Total Hours of Training:

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.)+ _____ _____ _____ _____		

* 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).

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 (continued)

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

Supervising Individual	License/Permit Number listing supervising individual as a Radiation Safety Officer		
This license authorizes the following medical uses:			
<input type="checkbox"/> 35.100	<input type="checkbox"/> 35.200	<input type="checkbox"/> 35.300	<input type="checkbox"/> 35.400
<input type="checkbox"/> 35.500	<input type="checkbox"/> 35.600 (remote afterloader)	<input type="checkbox"/> 35.600 (teletherapy)	
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.1000 (_____)		

c. Describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.

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		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Patrick J. Byrne	6/09 to 07/11
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):		

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

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

- c. Training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license (continued)

<p><small>Supervising Individual If training was provided by supervising RSO, AU, AMP, or ANP. (If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</small></p> <p>Patrick J. Byrne</p>	<p><small>License/Permit Number listing supervising individual</small></p> <p style="text-align: center;">13-02650-02</p>
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License/Permit lists supervising individual as:

☒ Radiation Safety Officer
 ☐ Authorized User
 ☐ Authorized Nuclear Pharmacist
☐ Authorized Medical Physicist

Authorized as RSO, AU, ANP, or AMP for the following medical uses:

<input checked="" type="checkbox"/> 35.100	<input checked="" type="checkbox"/> 35.200	<input checked="" type="checkbox"/> 35.300	<input checked="" type="checkbox"/> 35.400
<input type="checkbox"/> 35.500	<input type="checkbox"/> 35.600 (remote afterloader)	<input type="checkbox"/> 35.600 (teletherapy)	
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.1000 (_____)		

- d. Skip to and complete Part II Preceptor Attestation.

OR

☐ **4. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist identified on the licensee's license**

- a. Provide license number.
- b. Use the table in section 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- c. Skip to and complete Part II Preceptor Attestation.

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.

First Section

Check one of the following:

☐ **1. Board Certification**

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Radiation Safety Officer
 10 CFR 35.50(a)(1)(i) and (a)(1)(ii); or 35.50 (a)(2)(i) and (a)(2)(ii); or 35.50(c)(1).

OR

☐ **2. Structured Educational Program for Proposed Radiation Safety Officers**

☐ I attest that _____ has satisfactorily completed a structural educational
Name of Proposed Radiation Safety Officer
 program consisting of both 200 hours of classroom and laboratory training and one year of full-time radiation safety experience as required by 10 CFR 35.50(b)(1).

OR

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

Preceptor Attestation (continued)

First Section (continued)

Check one of the following:

☒ **3. Additional Authorization as Radiation Safety Officer**

☒ I attest that Sharon Updike is an
Name of Proposed Radiation Safety Officer

☐ Authorized User

☐ Authorized Nuclear Pharmacist

☐ Authorized Medical Physicist

identified on the Licensees license and has experience with the radiation safety aspects of similar type of use of byproduct material for which the individual has Radiation Safety Officer responsibilities

AND

Second Section

Complete for all (check all that apply):

☒ I attest that Sharon A. Updike has training in the radiation safety, regulatory issues, and
Name of Proposed Radiation Safety Officer

emergency procedures for the following types of use:

☒ 35.100

☒ 35.200

☒ 35.300 oral administration of less than or equal to 33 millicuries of sodium iodide I-131, for which a written directive is required

☒ 35.300 oral administration of greater than 33 millicuries of sodium iodide I-131

☒ 35.300 parenteral administration of any beta-emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

☐ 35.300 parenteral administration of any other radionuclide for which a written directive is required

☒ 35.400

☐ 35.500

☐ 35.600 remote afterloader units

☐ 35.600 teletherapy units

☐ 35.600 gamma stereotactic radiosurgery units

☐ 35.1000 emerging technologies, including:

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

AND

Third Section
Complete for ALL

☒ I attest that Sharon A. Updike has achieved a level of radiation safety knowledge
Name of Proposed Radiation Safety Officer
sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Fourth Section
Complete the following for Preceptor Attestation and signature

I am the Radiation Safety Officer for Saint Joseph Regional Medical Center
Name of Facility

License/Permit Number: 13-02650-02

Name of Preceptor <u>Patrick J. Byrne</u>	Signature 	Telephone Number <u>734-717-8731</u>	Date <u>8-17-11</u>
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Saint Joseph Regional
Medical Center
5215 Holy Cross Parkway
Mishawaka, IN 46545

POSTAGE

SEP 21 2011

U. S. Nuclear Regulatory Commission
Materials Licensing Section
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352