



February 2, 2010

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

Re: 21-11651-01 Amendment Request

Dear Madam or Sir:

We wish to amend our Materials License # 21-11651-01 as follows

RADIATION SAFETY OFFICER

Delete: Michael Lala, M.D.

Add: Khuraam Rashid, M.D.

In support of this request we have enclosed the following items:

- NRC Form 313A RSO - Preceptor Statement
- Delegation of RSO Authority letter from executive management

REMOVE ADDRESS OF USE

Please remove the following address of use from our Material License:

1375 South Lapeer Road
Suite 104
Lake Orion, Michigan 48360

This location was never used for Nuclear Medicine services. The only dosages delivered to the facility were Tc-99m (40 mCi) for the conduction of dose calibrator linearity tests. In support of this request we have enclosed:

- NRC Form 314
- Closeout surveys and wipe test results indicating no residual contamination
- Diagram of the facility noting survey / wipe test locations

RECEIVED FEB 19 2010

If you have any questions regarding this matter, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S., FACR of Medical Physics Consultants, Inc. 800-321-2207 and / or tkumpuris@mpcphysics.com.

Sincerely,



Shannon Striebich
Vice President of Operations

SS/lb



RSO / EXECUTIVE MANAGEMENT
LETTER OF UNDERSTANDING

February 2, 2010

Khurram Rashid, MD
Radiation Safety Officer
St. Joseph Mercy Oakland
44405 Woodward Avenue
Pontiac, MI 48341

Re: Radiation Safety Officer / Executive Management
Letter of Understanding

Dear Dr. Rashid:

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,

Shannon Striebich
Vice President of Operations

Khurram Rashid, M.D.
Radiation Safety Officer

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

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	Michael Lala, MD	11/1/08 - present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Michael Lala, MD	11/1/08 - present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Michael Lala, MD	11/1/08 - 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):		

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>Supervising Individual <i>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.)</i></p>	<p>License/Permit Number listing supervising individual</p>
<p>License/Permit lists supervising individual as:</p> <p><input type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Nuclear Pharmacist</p> <p><input type="checkbox"/> Authorized Medical Physicist</p> <p>Authorized as RSO, AU, ANP, or AMP for the following medical uses:</p> <p><input type="checkbox"/> 35.100 <input type="checkbox"/> 35.200 <input type="checkbox"/> 35.300 <input type="checkbox"/> 35.400</p> <p><input type="checkbox"/> 35.500 <input type="checkbox"/> 35.600 (remote afterloader) <input type="checkbox"/> 35.600 (teletherapy)</p> <p><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery) <input type="checkbox"/> 35.1000 (_____)</p>	

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 **Khurram Rashid, MD** 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 _____ is an
Name of Proposed Radiation Safety Officer

Authorized User

Authorized Nuclear Pharmacist

Authorized Medical Physicist

identified on the Licensee's 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 **Khurram Rashid, MD** _____ 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 Khurram Rashid, MD 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 St. Joseph Mercy Oakland, Pontiac, Michigan
Name of Facility

License/Permit Number: 21-11651-01

Name of Preceptor	Signature	Telephone Number	Date
Michael Lala, MD		(248) 858-3266	2/12/10

Close Out Survey Map

St. Joseph Mercy Oakland
Bald Mountain Facility
Lake Orion, Michigan



