



**ST. MARY MERCY
LIVONIA**
SAINT JOSEPH MERCY HEALTH SYSTEM

36475 Five Mile Road
Livonia, MI 48154
Phone: 734-655-4800

stmarymercy.org

June 20, 2011

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

Re: Amendment to 21-14849-01

Dear Madam or Sir:

We wish to amend our Materials License as follows:

CHANGE RADIATION SAFETY OFFICER

Remove: Nader Mohtadi, M.D.

Add: Oneil Lee, M.D., Ph.D.

In support of this request we have enclosed the following documents for your review and approval:

- NRC form 313(RSO) - Preceptor Statement and Attestation
- Management / RSO Agreement Letter

If you have any questions regarding this matter, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S., FACR 800.321.2207 or tkumpuris@mpcphysics.com.

Sincerely,

Bud Lauderbach
Chief Operating Officer

RECEIVED JUN 28 2011

REMARKABLE MEDICINE. REMARKABLE CARE.

June 20, 2011

Oneil Lee, M.D., Ph.D.
St. Mary Mercy Hospital
36475 Five Mile Road
Livonia, Michigan 48154

Re: Radiation Safety Officer / Executive Management
Letter of Understanding

Dear Dr. Lee:

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.



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LIVONIA**

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Livonia, MI 48154
Phone: 734-655-4800

stmarymercy.org

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,

Bud Lauderbach
Chief Operating Officer

Oneil Lee, M.D., Ph.D.
Radiation Safety Officer

NRC FORM 313A (R&O) (3-2009)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012																													
RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION [10 CFR 35.50]																															
Name of Proposed Radiation Safety Officer Onell Lee, M.D.																															
Requested Authorization(s) The license authorizes the following medical uses (check all that apply): <table style="width: 100%;"><tr><td><input checked="" type="checkbox"/> 35.100</td><td><input checked="" type="checkbox"/> 35.200</td><td><input checked="" type="checkbox"/> 35.300</td><td><input checked="" type="checkbox"/> 35.400</td><td><input type="checkbox"/> 35.500</td><td><input type="checkbox"/> 35.600 (remote afterloader)</td></tr><tr><td><input type="checkbox"/> 35.600 (teletherapy)</td><td><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</td><td colspan="4"><input type="checkbox"/> 35.1000 ()</td></tr></table>			<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 ()																				
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<input type="checkbox"/> 35.600 (teletherapy)	<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.1000 ()																													
PART I -- TRAINING AND EXPERIENCE (Select one of the four methods below)																															
<p>*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.</p>																															
<input type="checkbox"/> 1. Board Certification <ul style="list-style-type: none">a. Provide a copy of the board certification.b. Use Table 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.																															
OR																															
<input type="checkbox"/> 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Uses Checked Above <ul style="list-style-type: none">a. 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 an ISO is sought.b. Skip to and complete Part II Preceptor Attestation.																															
OR																															
<input type="checkbox"/> 3. Structured Educational Program for Proposed Radiation Safety Officer <ul style="list-style-type: none">a. Classroom and Laboratory Training																															
<table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="width: 35%;">Description of Training</th><th style="width: 35%;">Location of Training</th><th style="width: 15%;">Clock Hours</th><th style="width: 15%;">Dates of Training*</th></tr></thead><tbody><tr><td>Radiation physics and instrumentation</td><td></td><td></td><td></td></tr><tr><td>Radiation protection</td><td></td><td></td><td></td></tr><tr><td>Mathematics pertaining to the use and measurement of radioactivity</td><td></td><td></td><td></td></tr><tr><td>Radiation biology</td><td></td><td></td><td></td></tr><tr><td>Radiation dosimetry</td><td></td><td></td><td></td></tr><tr><td colspan="4" style="text-align: center;">Total Hours of Training:</td></tr></tbody></table>				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:			
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NRC FORM 313A (R80)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRESENTATION OR 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: 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).

NRC FORM 313A (R50)
(3-2008)

U.S. NUCLEAR REGULATORY COMMISSION

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRESENTATION OR 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 of 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 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.600 (teletherapy)
	<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	John E. Freitas, M.D.	04/01/11 to present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	John E. Freitas, M.D.	04/01/11 to present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	John E. Freitas, M.D.	04/01/11 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):		

NRC FORM 313A (R80)
(3-2006)

U.S. NUCLEAR REGULATORY COMMISSION

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)

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.)

John E. Freitas, M.D.

License/Permit Number listing supervising individual

21-03194-01

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:

- ☒ 35.100 ☒ 35.200 ☒ 35.300 ☒ 35.400
☐ 35.500 ☐ 35.600 (remote afterloader) ☐ 35.600 (teletherapy)
☐ 35.600 (gamma stereotactic radiosurgery) ☐ 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(b)(1).

OR

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

☐ 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

NRC FORM 313A (R80)
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

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 Onell Lee, M.D. 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

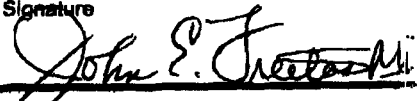
Second Section

Complete for all (check all that apply):

☒ I attest that Onell Lee, M.D. 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:

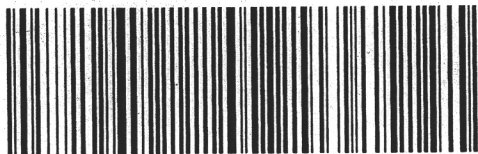
NRC FORM 313A (R80) (3-2008)		U.S. NUCLEAR REGULATORY COMMISSION	
RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
AND			
Third Section Complete for ALL			
<input checked="" type="checkbox"/> I attest that <u>Oneil Lee, M.D.</u> has achieved a level of radiation safety knowledge <small>Name of Proposed Radiation Safety Officer</small> 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 <u>E.L. Bixby Medical Center</u> <small>Name of Facility</small>			
License/Permit Number: <u>21-03194-01</u>			
Name of Preceptor	Signature	Telephone Number	Date
John E. Freitas, M.D.		(734) 712-3052	6/6/11

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Sender's Name Michelle Baer Phone 734 655-2525

Company ST. MARY Mercy Hospital

Address 36475 Five mile Rd

City Livonia State MI ZIP 48154

2 Your Internal Billing Reference

3 To Recipient's Name U.S. Nuclear Regulatory Commission

Company Materials Licensing Branch Region III

Address 2443 Warrenville Road

Address Suite 210

City Lisle State Illinois ZIP 60532

Barcode 8723 0055 6863

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01 ☐ FedEx Priority Overnight
02 ☐ FedEx 2Day
03 ☐ FedEx 1Day Freight
04 ☐ FedEx 2Day Freight
05 ☐ FedEx Standard Overnight
06 ☐ FedEx First Overnight
07 ☒ FedEx Express Saver

4b Express Freight Service

08 ☐ FedEx 1Day Freight
09 ☐ FedEx 2Day Freight
10 ☐ FedEx 3Day Freight

5 Packaging
01 ☒ FedEx Envelope
02 ☐ FedEx Pak
03 ☐ FedEx Box
04 ☐ FedEx Tube
05 ☐ Other

6 Special Handling and Delivery Signature Options
01 ☒ No Signature Required
02 ☐ Direct Signature
03 ☐ Indirect Signature

03 SATURDAY DELIVERY
01 ☒ No Signature Required
02 ☐ Direct Signature
03 ☐ Indirect Signature

Does this shipment contain dangerous goods?
01 ☒ No
02 ☐ Yes

7 Payment Bill to:
01 ☒ Sender
02 ☐ Recipient
03 ☐ Third Party
04 ☐ Credit Card
05 ☐ Cash/Check

Total Packages Total Weight

606

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