



**March 7, 2012**

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

RE: Amendment to NRC License No. 21-21265-01  
St. Mary's of Michigan Standish Hospital

Dear Sir/Madam:

The purpose of this letter is to amend our current NRC License to reflect the following changes:

**Item #1** Please remove the following individual as the Radiation Safety Officer (RSO):

Mark Robert Ludka, M.D.

**Item #2** Please list the following individual as the RSO on our NRC Materials License:

Steve Min, D.O.

Additionally, we have enclosed a copy of the RSO/Executive Management Letter of Understanding and the NRC Form 313A (RSO) for your review.

Thank you for your cooperation. If you have any questions or require additional information, please contact our physicist, Kevin B. Miller at 734-662-3197.

Sincerely,

A handwritten signature in black ink that reads "Shawn Z Case".

Chief Administrator  
St. Mary's of Michigan Standish Hospital

RECEIVED MAR 28 2012

805 W. Cedar Street Standish, Michigan 48658

(989) 846-4521



**March 7, 2012**

Dr. Steve Min, D.O.  
Radiation Safety Officer  
St. Mary's of Michigan Standish Hospital  
805 W. Cedar Street  
Standish, MI 48658

Re: Radiation Safety Officer / Executive Management  
Letter of Understanding

Dear Dr. Steve Min, D.O.:

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.

Sincerely,

  
\_\_\_\_\_  
Chief Administrator

  
\_\_\_\_\_  
Radiation Safety Officer

**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

Steve Min, D.O.

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****a. 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  Mark Robert Ludka, M.D.	License/Permit Number listing supervising individual as a Radiation Safety Officer  21-21265-01		
This license authorizes the following medical uses:			
<input checked="" type="checkbox"/> 35.100	<input checked="" 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	Mark Robert Ludka, M.D.	May 2010 to present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Mark Robert Ludka, M.D.	May 2010 to present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses		
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><b>Supervising Individual</b> <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><b>Mark Robert Ludka</b></p>	<p><b>License/Permit Number listing supervising individual</b></p> <p style="text-align: center;"><b>21-21265-01</b></p>												
<p>License/Permit lists supervising individual as:</p> <p> <input checked="" type="checkbox"/> Radiation Safety Officer                 <input type="checkbox"/> Authorized User                 <input type="checkbox"/> Authorized Nuclear Pharmacist  <input type="checkbox"/> Authorized Medical Physicist         </p> <p>Authorized as RSO, AU, ANP, or AMP for the following medical uses:</p> <table style="width: 100%;"> <tr> <td><input checked="" type="checkbox"/> 35.100</td> <td><input checked="" type="checkbox"/> 35.200</td> <td><input type="checkbox"/> 35.300</td> <td><input type="checkbox"/> 35.400</td> </tr> <tr> <td><input type="checkbox"/> 35.500</td> <td><input type="checkbox"/> 35.600 (remote afterloader)</td> <td colspan="2"><input type="checkbox"/> 35.600 (teletherapy)</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</td> <td colspan="2"><input type="checkbox"/> 35.1000 ( _____ )</td> </tr> </table>		<input checked="" type="checkbox"/> 35.100	<input checked="" 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 ( _____ )	
<input checked="" type="checkbox"/> 35.100	<input checked="" 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 ( _____ )											

- 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 Steve Min, D.O. 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 Steve Min, D.O. 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 Steve Min, D.O. 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

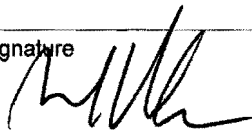
I am the Radiation Safety Officer for St Marys of Michigan Standish Hospital  
Name of Facility

License/Permit Number: 21-21265-01

Name of Preceptor

MARK WISKA MD

Signature



Telephone Number

989-797-5699

Date

3/22/12



## U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 15

**MATERIALS LICENSE**

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. <b>Saint Mary's of Michigan Standish Hospital</b></p> <p>2. 805 West Cedar Street Standish, MI 48658</p>	<p>In accordance with letter dated July 31, 2009,</p> <p>3. License number 21-21265-01 is amended in its entirety as follows:</p> <p>4. Expiration date January 31, 2014</p> <p>5. Docket No. 030-20121 Reference No.</p>
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- |  |   |   |
|--|---|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> | <p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> |
|--|---|---|

9. Authorized Use:
- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 805 West Cedar Street, Standish, MI 48658.
11. Radiation Safety Officer: Mark R. Ludka, M.D.
12. Licensed material is only authorized for use by, or under the supervision of:
- A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
- B. The following individuals are authorized users for the materials and uses indicated:

Authorized UsersMaterial and Use

Ram K. Gadam, M.D.

10 CFR 35.100 and 35.200.

Harvey Yee, M.D.

10 CFR 35.100 and 35.200.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
21-21265-01Docket or Reference Number  
030-20121

Amendment No. 15

Authorized UsersMaterial and Use

Joseph E. Talbot, M.D.

10 CFR 35.100 and 35.200.

Scott E. Cheney, M.D.

10 CFR 35.100 and 35.200.

Sanjay J. Talati, M.D.

10 CFR 35.100 and 35.200.

C. E. Mueller, M.D.

10 CFR 35.100 and 35.200.

Mark R. Ludka, M.D.

10 CFR 35.100 and 35.200.

Kristin M. Nelsen, M.D.

10 CFR 35.100 and 35.200.

Robert B. Saltzman, M.D.

10 CFR 35.100 and 35.200.

Sigrid Messana, D.O.

10 CFR 35.100 and 35.200.

Sultan Bhimani, M.D.

10 CFR 35.100 and 35.200.

Sambasiva Kottamasu, M.D.

10 CFR 35.100 and 35.200.

Rita Ratani, M.D.

10 CFR 35.100 and 35.200.

Steve Min, D.O.

10 CFR 35.100 and 35.200.

Chirdeep Bhutani, M.D.

10 CFR 35.100 and 35.200.

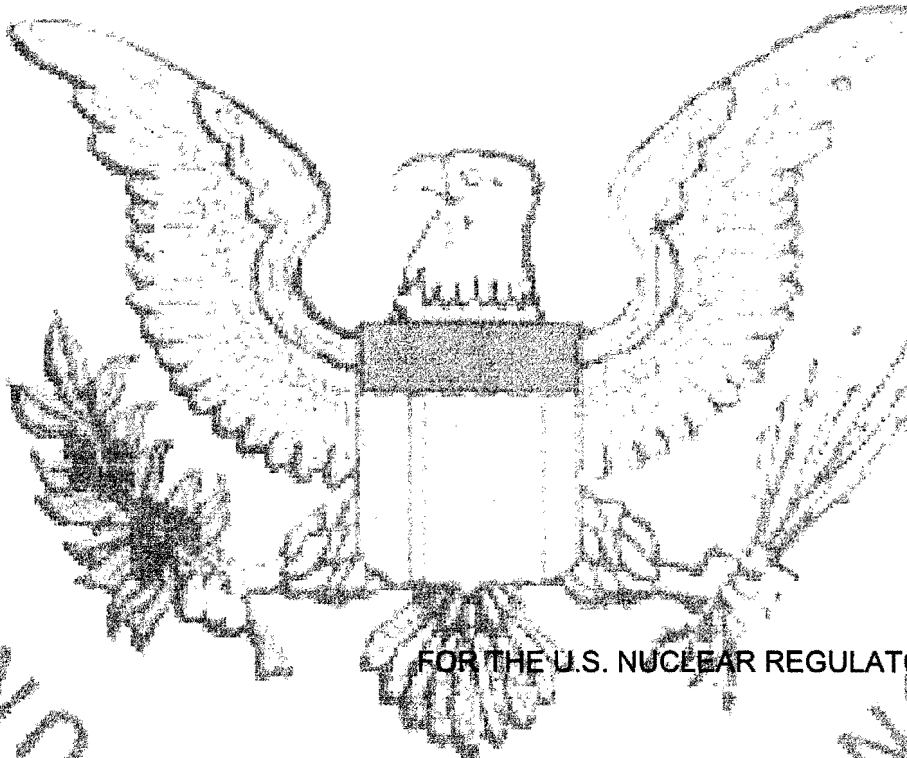
13. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
14. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
21-21265-01Docket or Reference Number  
030-20121

Amendment No. 15

The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated Augst 21, 2003 (with attached facsimile dated January 21, 2004);
- B. Letters dated March 19, 2004, November 29, 2004 (with enclosures), and **July 31, 2009**; and
- C. Facsimile letters dated May 7, 2004 and February 14, 2005.



Date

OCT 06 2009

By

Loren J. Hueter  
Materials Licensing Branch  
Region III

**UPS CampusShip: View/Print Label**

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.
2. **Fold the printed sheet containing the label at the line so that the entire shipping label is visible.** Place the label on a single side of the package and cover it completely with clear plastic shipping tape. Do not cover any seams or closures on the package with the label. Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.
3. **GETTING YOUR SHIPMENT TO UPS**  
**UPS locations include the UPS Store®, UPS drop boxes, UPS customer centers, authorized retail outlets and UPS drivers.**  
Find your closest UPS location at: [www.ups.com/dropoff](http://www.ups.com/dropoff)  
Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services(SM) (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the Resources area of CampusShip and select UPS Locations.

**Customers with a Daily Pickup**

Your driver will pickup your shipment(s) as usual.

FOLD HERE

MIKE GWISDALA 989-846-3580 ST MARY'S OF MICHIGAN - STACOM 805 W. CEDAR STREET STANDISH MI 48658		0.0 LBS LTR	1 OF 1
<b>SHIP TO:</b> REGION 111 UNITED STATES NUCLEAR REGULATORY CO MATERIALS LICENSING BRANCH SUITE 210 2443 WARRENVILLE RD <b>LISLE IL 60532-4352</b>			
	<b>IL 603 9-03</b> 		
<b>UPS NEXT DAY AIR SAVER 1P</b> TRACKING #: 1Z R93 75E 13 9277 1570			
			
BILLING: P/P			
LHM: STACOM Cost Center: 7140		 CS 14.1.10. WXPTE70 24.0A 01/2012	