

**WOODLAWN HOSPITAL**

ROCHESTER — INDIANA  
1400 E. Ninth Street  
Rochester, Indiana 46975-8937

December 21, 2006

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

Re: Amendment to Material's License 13-20338-01

Dear Madam or Sir:

Pursuant to our telephonic discussion on 12/20/2006, we are nominating Mr. Remo George, M.S., CNMT as our hospital's Radiation Safety Officer. We also hereby withdraw our nomination of Dr. Suk Lee, MD for the position of Radiation Safety Officer. Please consider this application as an addendum to our previous application dated September 12, 2006 to nominate Dr. Suk Lee, M.D. as our Authorized User.

Thus, we wish to amend our Material's License 13-20338-01 as follows:

**CHANGE AUTHORIZED USER (AU)**

Add Dr. Suk Lee, M.D. as our Authorized User.

**CHANGE RADIATION SAFETY OFFICER (RSO)**

Add Mr. Remo George, M.S., CNMT as our Radiation Safety Officer.

**DELETE AUTHORIZED USER AND RSO**

Richard Fox, M.D.

If you require any additional information, please contact our Medical Nuclear Physicist, Thomas M. Kumpuris, M.S. DABR of Medical Physics Consultants, Inc. 800.321.2207.

Sincerely,



John Alley  
CEO

315732

REC'D DEC 22 2006

**WOODLAWN HOSPITAL**

ROCHESTER — INDIANA  
1400 E. Ninth Street  
Rochester, Indiana 46975-8937

December 21, 2006

Mr. Remo George, M.S., CNMT  
Radiation Safety Officer  
Woodlawn Hospital  
1400 East 9<sup>th</sup> Street  
Rochester, Indiana 46975

Re: Radiation Safety Officer / Executive Management Letter of Understanding

Dear Mr. Remo George,

You have been appointed the Radiation Safety Officer (RSO) for 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 notification 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 below attest to the issues noted above. Please make a copy of this document for your files and return the original to my attention.

Sincerely,

  
Executive Management

  
Radiation Safety Officer

Woodlawn Hospital Nuclear Medicine  
Policies & Procedures February 24, 2003

## RADIATION SAFETY OFFICER AUTHORITY, DUTIES AND RESPONSIBILITIES

The Radiation Safety officer (RSO) shall:

1. Have the authority to implement the Radiation Protection Program as referenced in 10 CFR 20.1101.
2. Have the authority, organizational freedom, time, resources, and management prerogative to:
  - a. Identify radiation safety problems;
  - b. Initiate, recommend or provide corrective actions,
  - c. Stop unsafe operations; and,
  - d. Verify implementation of corrective actions.
3. Investigate deviations from the radiation safety practices approved by the facility management and/or the radiation Safety Committee, if applicable.
4. Collect in a centralized location, executive management approved procedures that can include policy and technical issues which, would makeup the Radiation Protection Program as follows:
  - a. Authorization for the purchase of radioactive material.
  - b. Receipt and opening of packages containing radioactive material.
  - c. Storage and opening of packages containing radioactive material.
  - d. Inventory control of radioactive material.
  - e. Safe use of radioactive material.
  - f. Emergency procedures in the event of loss, theft, etc.
  - g. Periodic radiation surveys and wipe tests.
  - h. Checks of radiation survey and other radiation safety instruments.
  - i. Disposal of radioactive material.
  - j. Personnel training of those who work in or frequent areas of radioactive material use or storage.
5. Oversee a record system of the Radiation protection Program per 10 CFR 20.2102 to include at least the following:

The provisions of the Radiation Protection Program until the license is terminated by the NRC such as:

- a. All records, reports, written policies and procedures required by regulatory agencies concerning radioactive material.

Woodlawn Hospital Nuclear Medicine  
Policies & Procedures February 24, 2003

- b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.  
Audits and other reviews of the Radiation Protection Program content and implementation for a period of three (3) years after the record is made.
6. Periodically evaluate "action levels" for continued appropriateness to ensure compliance with 10 CFR 20.1501 and 1502 for the following:
  - a. Personnel exposure investigation levels
  - b. Area surveys dose rate and contamination levels
  - c. Bioassays, if necessary
  - d. Radioactive effluent concentrations, if necessary
7. Review the following Radiation Protection Program records, if applicable:
  - a. Sealed source inventories
  - b. Sealed source leak tests
  - c. Dose calibrator linearity tests
  - d. Dose calibrator accuracy tests
  - e. Dose calibrator geometrical variation tests
  - f. Occupational radiation exposure reports
  - g. Medical event documentation
  - h. Spill / incident reports for cause and corrective action
  - i. Dose rate and contamination survey results
  - j. Changes in the radiation safety program
8. Ensure the use of reasonable practices and controls to strive to maintain doses to workers and to the public are ALARA, in compliance with 10 CFR 20.1101(b).
9. Review with facility management at least annually of the content of the Radiation Protection Program and determine if the written program is being implemented in compliance with 10 CFR 20.1101(c).
10. Ensure as part of the ALARA effort that individual members of the public shall not receive a Total Effective Dose Equivalent (TEDE) of more than 10 mrem (0.1 mSv) per year from airborne radioactive material releases as per 10 CFR 20.1101(d) as necessary.
11. Be a member of the Radiation Safety Committee (RSC), if applicable, that will oversee all uses of byproduct material permitted by the license as per CFR 35.24(f).

NRC FORM 313A (RSO) (10-2006)	U.S. NUCLEAR REGULATORY COMMISSION	APPROVED BY OMB: NO. 3150-0120 EXPIRES: 10/31/2008
<b>RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE                  AND PRECEPTOR ATTESTATION</b> [10 CFR 35.50]		

Name of Proposed Radiation Safety Officer  
REMO GEORGE, M.S., CNMT.

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**

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

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

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 RSO is sought.

b. 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	MED-SHARE, INC., 26222 TELEGRAPH RD, SOUTHFIELD, MI - 48034. WOODLAWN HOSPITAL, 1400 E 9 <sup>th</sup> STREET, ROCHESTER, IN 46975.	100	Nov. 21, 2001 - to - Present
Radiation protection	"	60	"
Mathematics pertaining to the use and measurement of radioactivity	"	50	"
Chemistry of byproduct material for medical use	"	20	"
Radiation biology	"	10	"

**Total Hours of Training:**

NRC FORM 313A (RSO)  
(10-2006)

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)**

**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	MED-SHARE, INC, 2622 TELEGRAPH RD, SOUTHFIELD, MI - 48034 (LIC.# 21-26098-01) WOODLAWN HOSPITAL, 1400 E 9 <sup>TH</sup> STR, ROCHESTER, IN-46975 (LIC.# 13-20338-01)	Nov. 21, 2001 - 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	"	"
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.)+ <u>35.100, 35.200</u>	"	"

\* 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).

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(10-2006)

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**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  <p style="text-align: center;">RICHARD F. FOX, M.D.</p>	License/Permit Number listing supervising individual as a Radiation Safety Officer  <p style="text-align: center;">13-20338-01</p>
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	RICHARD F. FOX, M.D.	JULY 20, 2005 - 10 - SEPT. 12, 2006
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	N. A.	N. A.
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):	"	"

NRC FORM 313A (R80)  
(10-2008)

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)

<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 style="text-align: center;">RICHARD F. FOX, M.D.</p>	<p><b>License/Permit Number listing supervising individual</b></p> <p style="text-align: center;">13-20338-01</p>
<p>License/Permit lists supervising individual as:</p> <p> <input checked="" type="checkbox"/> Radiation Safety Officer                     <input checked="" 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> <p> <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 ( _____ )             </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 REMO GEORGE, M.S., CNMT. 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**



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(10-2006)

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**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 REMO GEORGE, M.S., CNMT 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

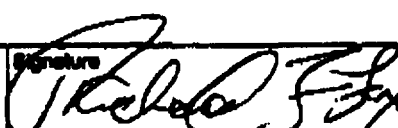
35.500

35.600 remote afterloader units

35.600 teletherapy units

35.600 gamma stereotactic radiosurgery units

35.1000 emerging technologies, including:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)			
<b>AND</b>			
<b>Third Section</b> Complete for ALL			
<input checked="" type="checkbox"/> I attest that <u>REMO GEORGE M.S. CNMT</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.			
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<b>Fourth Section</b> Complete the following for Preceptor Attestation and signature			
I am the Radiation Safety Officer for <u>WOODLAWN HOSPITAL</u> <small>Name of Facility</small>			
License/Permit Number: <u>13-20338-01</u>			
Name of Preceptor RICHARD F. FOX, MD.		Signature 	Telephone Number 350 673 8417
			Date 12/22/2002