



A Duke LifePoint Hospital

July 8, 2015

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Materials License No: 21-05432-04

This letter and enclosed documents are to request approval of Kevin S. Gostenik, M.D. as Radiation Safety Officer for the license named above. He is replacing Julie (Shan) Marlette who has retired. Dr. Gostenik is an authorized user on this license. His form 313A (RSO) is enclosed along with his letter of acceptance of responsibility. We have also contracted for Medical Physics services with MPC (Medical Physics Consultants). A representative of MPC will be on-site at least quarterly for audits and attendance at RSC meetings.

We also wish to inform you that AU Paul Thieme, D.O. has terminated duties here as of May 31, 2015.

Please expedite this RSO approval. If you have further questions, please contact Dr. Kevin Gostenik at (906) 225-3540 or via fax at (906) 225-7753.

Sincerely,

A handwritten signature in black ink, appearing to read 'JPerry', with a stylized flourish at the end.

Jeffery R. Perry
Chief Operating Officer

RECEIVED JUL 10 2015



A Duke LifePoint Hospital

June 12, 2015

Kevin Gostenik, M.D.
UP Health System-Marquette
420 W. Magnetic Street
Marquette, MI 49855

Dear Dr. Gostenik:

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:

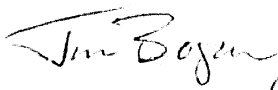
- Assume responsibility for implementing the Radiation Safety Program
- Ensure that radiation safety activities are being performed in accordance with our own approved procedures and all regulatory requirements.


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 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,


Jim Bogan, Interim C.E.O.


Kevin Gostenik, M.D., R.S.O.

RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION **[10 CFR 35.50]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Radiation Safety Officer

Kevin S. Gostenik, M.D.

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 (Y-90 Spheres)

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:			<input type="text"/>

(05-2012)

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.)+ <div style="border: 1px solid black; height: 40px; width: 100%; margin-top: 5px;"></div>		

+ 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	Julia (Shan) Marlette, RSO	Mar, Apr. June 2015
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Shan Marlette, RSO	Mar, Apr. June 2015
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Shan Marlette, RSO	Mar, Apr. June 2015
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): P-90 SiSpheres	Shan Marlette, RSO	Mar, Apr. June 2015

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.)*

Julia (Shan) Marlette

License/Permit Number listing supervising individual

21-05432-04

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 (Y-90 SiR Spheres)

- 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. 21-05432-04
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 Kevin Gostenik, MD 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 Kevin Gostenik, 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:

Y-90 Sinspheres

(05-2012)

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

AND

Third Section

Complete for ALL

☒ I attest that Kevin Gostenik, 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

^{was}
I ~~am~~ the Radiation Safety Officer for DLP Marquette General Hospital
Name of Facility O/B/c UPHS-Marquette

License/Permit Number: 21-05432-04

Name of Preceptor

Signature

Telephone Number

Date

Julia (Shaw) Marquette Julia (Shaw) Marquette 906-273-0249 6/23/15

