



*George J. Kelen, M.D., F.A.C.C.*

August 20, 2007

UNITED STATES NUCLEAR REGULATORY COMMISSION  
Region III, Materials Licensing Section  
2443 Warrenville Road, Suite 210  
Lisle, IL 60532-4352

**Re: Amendment to License No. 21-32560-01, George J. Kelen, M.D., PLLC**

Please amend our license as follows:

1. Remove William LaPenna, M.D. as authorized user and Radiation Safety Officer. He will be leaving our facility August 31, 2007.
2. Add David B. Johnson, M.D. as authorized user of 10 CFR 35.100 and 35.200. He is currently listed as an authorized user on license number 21-36543-01.
3. Add David B Johnson, M.D. as Radiation Safety Officer. Form 313A (RSO) is enclosed for your review.

Thank you for your cooperation in this matter. If you have any questions, please contact our consulting physicist, Dawn Edwards at 734-662-3197.

Sincerely,

A handwritten signature in black ink, appearing to read "George Kelen".

George J. Kelen, M.D.

RECEIVED AUG 29 2007



*George J. Kelen, M.D., F.A.C.C.*

August 20, 2007

Re: Radiation Safety Officer / Executive Management  
Letter of Understanding

Dear David B. Johnson, M.D.:

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,

A handwritten signature in black ink, appearing to read "George J. Kelen".

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George J. Kelen, M.D.

A handwritten signature in black ink, appearing to read "David B. Johnson".

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David B. Johnson, M.D.

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

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

Name of Proposed Radiation Safety Officer  
David B. Johnson, 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 ( \_\_\_\_\_ )

**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			
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	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 (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		
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses		
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>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  <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  <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 \_\_\_\_\_ 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 David B. Johnson, M.D. 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 David B. Johnson, 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:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

AND

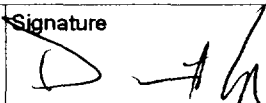
Third Section  
Complete for ALL

I attest that David B. Johnson, M.D. 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 West Michigan Heart, P.C.  
Name of Facility

License/Permit Number: 21-26543-01

Name of Preceptor	Signature	Telephone Number	Date
David Laywitz		416 885-5000	8/22/07



034948 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100  
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0402-8482  
P: YELLOW S: 488  
I: 405  
LISLE IL 60532-3673  
STE 210  
2443 WARRENVILLE RD  
UNITED STATES NUCLEAR REGULATORY

LAKESHORE CARDIOLOGY  
231-845-7677  
LAKESHORE CARDIOLOGY  
913 E LUDINGTON AVE  
LUDINGTON MI 49431

1 LBS

1 OF 1

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2443 WARRENVILLE RD, SUITE 210  
REGION III, OFFICE OF MATERIAL LICE  
LISLE IL 60532-4352



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