

Oakwood Southshore
Medical Center

5450 Fort St.
Trenton, Michigan
48183-4625

734.671.3800



Oakwood

February 22, 2017

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

Re: Amendment to 21-16656-01

Dear Madam or Sir:

We wish to amend our Materials License 21-16656-01 as follows:

REMOVE AUTHORIZED RADIOACTIVE MATERIAL

We wish to remove authorization to use radioactive material under 10 CFR 35.400 – brachytherapy. We have not received radioactive material authorized under CFR 35.400 in almost a year. We confirm that all residual brachytherapy sources have been returned to the supplier. All areas of receipt, use and storage have been surveyed and wipe tested, with all results equal to background levels of 0.03 mR/hr and 0 dpm/100 sq cm.

CHANGE IN RADIATION SAFETY OFFICER

Michael D. Arsenault, D.O. was our Radiation Safety Officer (RSO) and is now deceased. In compliance with 10 CFR 35.24(c) and 10 CFR 35.13(c), please note the following:

35.13(c) We have named Donald J. Conn, M.D., an active authorized user, as our RSO. A letter of appointment / acknowledgement / responsibilities has been jointly signed by executive management and Dr. Conn.

Enclosed is a signed delegation of authority form as well as a form 313A

If you have any questions regarding this issue, please contact us.

Sincerely,

Christine Stesney-Ridenour

Division President

Oakwood Hospital – Trenton (part of Beaumont Health)

Donald J. Conn, M.D.

Radiation Safety Officer

Oakwood Hospital – Trenton (part of Beaumont Health)



February 22, 2017

Donald J. Conn, M.D.
Radiation Safety Officer
Oakwood Hospital – Trenton (part of Beaumont Health)

RE: Radiation Safety Officer/Executive Management Letter of Understanding

Dear Dr. Conn:

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:

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
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,

Christine Stesney-Ridenour
Division President
Oakwood Hospital – Trenton (part of Beaumont Health)

Donald J. Conn, M.D.
Radiation Safety Officer
Oakwood Hospital – Trenton (part of Beaumont Health)



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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

Name of Proposed Radiation Safety Officer

Donald J. Conn, M.D. (requesting to be RSO for Oakwood Hospital Trenton - License #21-16656-01

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.)+ <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"/> 35.500	<input type="checkbox"/> 35.600 (remote afterloader)
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input type="checkbox"/> 35.400
	<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	Already authorized on License # 21-16656-01	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Already authorized on License # 21-16656-01	N/A
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - teletherapy uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - remote afterloader uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.600 - gamma stereotactic radiosurgery uses	N/A	
Radiation safety, regulatory issues, and emergency procedures for 35.1000, specify use(s):	N/A	

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 <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>	License/Permit Number listing supervising individual
Evelyn Sebastian, M.S.	21-04515-01
License/Permit lists supervising individual as:	
<input type="checkbox"/> Radiation Safety Officer	<input type="checkbox"/> Authorized User
<input checked="" type="checkbox"/> Authorized Medical Physicist	<input type="checkbox"/> Authorized Nuclear Pharmacist
Authorized as RSO, AU, ANP, or AMP for the following medical uses:	
<input type="checkbox"/> 35.100	<input type="checkbox"/> 35.200
<input type="checkbox"/> 35.500	<input checked="" type="checkbox"/> 35.600 (remote afterloader)
<input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)	<input checked="" type="checkbox"/> 35.1000 (1125 Breast Local)
<input type="checkbox"/> 35.300	<input checked="" type="checkbox"/> 35.400
	<input type="checkbox"/> 35.600 (teletherapy)

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 Donald J. Conn, 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 Donald J. Conn, 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:

1125 Breast Localization

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

AND

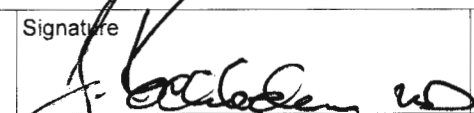
Third Section
Complete for ALL

I attest that Donald J. Conn, 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 Oakwood Hospital - Taylor
Name of Facility

License/Permit Number: 21-17789-01

Name of Preceptor	Signature	Telephone Number	Date
James K. Kochkodan, M.D., RSO		(313) 295-5145	02/22/2017



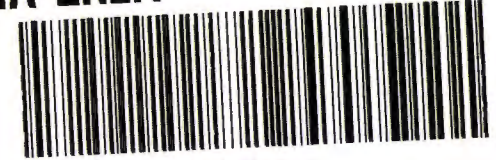
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FedEx Express Package US Airbill FedEx Tracking Number **8111 8811 7720**

1 From
Date 2-28-17
Sender's Name ARLENE COOK Phone 734 671-3670
Company BEAUMONT HOSPITAL TRENTON
Address 3450 FORT ST State MI ZIP 48183-4601
City TRENTON

2 Your Internal Billing Reference 831275 372157

3 To
Recipient's Name US Nuclear Regulatory Commission
Company 1000 III
Address 1155 N. Lincoln Ave
Address 2153 McCrearyville St
City Little State IL ZIP 62532

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Hold Saturday: FedEx location address required. Available only for FedEx Priority Overnight and FedEx 2Day to select locations.



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- Next Business Day**
- FedEx First Overnight
 - FedEx Priority Overnight
 - FedEx Standard Overnight

- 2 or 3 Business Day**
- FedEx 2Day A.M.
 - FedEx 2Day
 - FedEx Express Saver

5 Packaging

- FedEx Envelope*
- FedEx Pak*
- FedEx Box
- FedEx Tube
- Other

6 Special Handling and Delivery Signature Options

- Saturday Delivery
 - No Signature Required
 - Direct Signature
 - Indirect Signature
- Does this shipment contain dangerous goods?
 No Yes (per attached Shipper's Declaration) Dry Ice Cargo Aircraft Only

7 Payment B/L#

Sender Acct. No. in Section 7 will be billed Recipient Third Party Credit Card Cash/Check Obtain recip. Acct. No.

Total Packages Total Weight Credit Card Auth.

RECEIVED MAR 01 2017

Insert shipping document here.