



Harbor Beach Community Hospital
210 South First Street
Harbor Beach, MI 48441
(989) 479-3201
Fax (989) 479-5000
www.hbch.org

Lakeview Extended Care and Rehab
210 South First Street
Harbor Beach, MI 48441
(989) 479-3201
Fax (989) 479-5010

Harbor Beach Medical Clinic
8970 Sand Beach Road
Harbor Beach, MI 48441
(989) 479-3291
Fax (989) 479-3365

Port Hope Medical Clinic
4255 N. Lakeshore Road
Port Hope, MI 48468
(989) 428-1000
Fax (989) 479-1001

State Street Medical Clinic
301 State Street
Harbor Beach, MI 48441
(989) 479-3111
Fax (989) 479-9880

Physical Therapy
Occupational Therapy
210 South First Street
Harbor Beach, MI 48441
(989) 479-3201 ext. 157
Fax (989) 479-5000

Senior Life Solutions
301 State Street, Suite #6
Harbor Beach, MI 48441
(989) 479-0200
Fax (989) 479-0203

Specialty Clinic
234 South First Street
Harbor Beach, MI 48441
(989) 479-3201 ext. 253
Fax (989) 479-5014

Walk In Clinic
210 South First Street
Harbor Beach, MI 48441
(989) 479-3201
Fax (989) 479-5000

January 26, 2015

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

Re: Amendment for License No. 21-32634-01

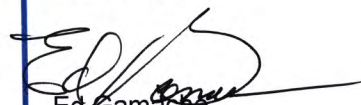
1. Please add the following physician, David Dubriwny, D.O., to our license as an authorized user for Groups 35.100 and 35.200.
2. Please change our Radiation Safety Officer from Dr. Mukkamala to Dr. Dubriwny.

We have enclosed the Letter of Understanding showing that Dr. Dubriwny has been delegated as Radiation Safety Officer by our management and that he has accepted these duties. Dr. Dubriwny is currently listed as an authorized user and Radiation Safety Officer for these uses on License No. 21-16642-01.

3. Please remove Group 35.300 from our license. We do not intend to provide this service and have not performed therapeutic procedures at this facility since 2008.

Thank you for your time and assistance with this matter.

Sincerely,


Ed Gamache
President/CEO



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Physical Therapy
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Fax (889) 479-0203

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(889) 479-3201 ext. 263
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January 26, 2015

To: David Dubriwny, D.O., Nuclear Medicine Radiation Safety Officer

From: Ed Gamache, CEO

Subject: Delegation of Authority

You, David Dubriwny, D.O., have been appointed Radiation Safety Officer for the Nuclear Medicine Department at Harbor Beach Community Hospital and are responsible for ensuring the safe use of radiation as authorized under 10 CFR 35.100 and 35.200.

You are responsible for managing the Radiation Protection Program, identifying radiation protection problems; initiating, recommending, or providing corrective actions, verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations.


You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time.

It is estimated that you will spend 1 hour per week conducting radiation protection activities.


Ed Gamache, President/CEO

1/26/15
Date

I accept the above responsibilities.


David Dubriwny, D.O.

1-26-15
Date

cc: Matt Rick, Director of Imaging

"Providing Community Access to Quality Healthcare"

**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

David Dubriwny, 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

- 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:		<input type="text"/>	

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: 50px; 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		
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>Howard Dworkin, M.D.</p>	<p>License/Permit Number listing supervising individual</p> <p>21-01333-01</p>
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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 (_____)

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. 21-16642-01
- 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 Dubriwney, 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 David Dubriwney, 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 David Dubriwney 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 Huron Medical Center
Name of Facility

License/Permit Number: 21-17093-01

Name of Preceptor	Signature	Telephone Number	Date
David L. Carter M.D.		989-269-9521	3/6/15

Harbor Beach Community Hospital
Ed Gamache, President/CEO
210 South First Street
Harbor Beach, MI 48441

SUE LLOYD
989-479-3201 239
HARBOR BEACH COMMUNITY HOSPITA
210 SOUTH FIRST STREET
HARBOR BEACH MI 48441

1 LBS

1 OF 1

SHIP TO:

MEDICAL LICENSING, REGION III
UNITED STATES NUCLEAR REGULATORY CO
SUITE 210
2443 WARRENVILLE ROAD
LISLE IL 60532-4352

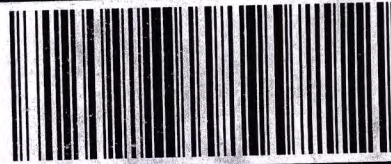


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