



A department of
McLaren Northern Michigan

May 10, 2016

Petoskey

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Petoskey, Michigan
49770

(231) 487-2490 p
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(231) 487-6055 f

Gaylord

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Gaylord, Michigan
49735

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Charlevoix

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Charlevoix, Michigan
49720

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michiganhvs.org

Cardiology

Louis A. Cannon, MD
Harry T. Colfer, MD
David C. M. Corteville, MD
Thomas J. Earl, MD
Gerald A. Gadowski, DO
Linda K. Gosssett, MD
Kerri Katona, PA-C
Peter E. Levanovich, MD
Dalton J. Miranda, MD
Rochelle N. Mitas, NP-C
AJ Nolan, FNP-BC
Naomi A. Overton, MD
Rebecca L. Price, PA-C
Jason M. Ricci, MD
Duane W. Schull, MD, PhD
Andrew H. Teklinski, MD

**Cardiothoracic
Surgery**

Chris W. Akins, MD
Jeffery B. Fox, PA-C
Marti Linn, PA-C
John D. Talbott, DO

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

Re: Amendment to License No. 21-32345-01

1. Please remove James J. Carson, CNMT as the Radiation Safety Officer from our license.
2. Please add David Christian-Moore Corteville, MD as the Radiation Safety Officer Please find a copy of Dr. Corteville's NRC 313A(RSO) form and Letter of Understanding for your review.

Thank you for you cooperation with this matter. If you have any question please contact our physicist, Michelle Kritzman, at (734) 662-3197.

Sincerely,

A handwritten signature in dark ink that reads "Marla Clark".

Marla Clark, DNP, RN
Senior Director
McLaren Northern Michigan d/b/a
Michigan Heart & Vascular Specialists

RECEIVED MAY 11 2016

NRC FORM 313A (RSO)
(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION



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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 03/31/2016

Name of Proposed Radiation Safety Officer

David Christian-Moore Corteville, MD

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"/>	

NRC FORM 313A (RSO)
(03-2016)

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		
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, 35.600, 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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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 (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	James I Carson CNMT	May 9, 2016
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):		

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(03-2016)

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)

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.)*

James J. Carson, CNMT

License/Permit Number listing supervising individual

21-32345-01

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.
 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

NRC FORM 313A (RSO)
(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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 Christian-Moore Corteville, 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 David Christian-Moore Corteville, 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:

NRC FORM 313A (RSO)
(03-2016)

U.S. NUCLEAR REGULATORY COMMISSION

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

AND

Third Section
Complete for ALL

☒ I attest that David Christian-Moore Cortevillo, 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

I am the Radiation Safety Officer for McLaren Northern Michigan d/b/a Michigan Heart & Vascular Specialists
Name of Facility

License/Permit Number: 21-32345-01

Name of Preceptor	Signature	Telephone Number	Date
James J. Carson, CNMT	<i>James J. Carson CNMT</i>	(231) 487-5878	05/09/2016



RSO / EXECUTIVE MANAGEMENT LETTER OF UNDERSTANDING

A department of
McLaren Northern Michigan

Petoskey

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Andrew I. Teklinski, MD

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Jeffery B. Fox, PA-C
Marti Linn, PA-C
John D. Talbott, DO

May 9, 2016

David Christian-Moore Corteville, MD
Radiation Safety Officer
McLaren Northern Michigan d/b/a
Michigan Heart & Vascular Specialists
560 West Mitchell, Suite 400
Petoskey, MI 49770

Re: Radiation Safety Officer / Executive Management
Letter of Understanding

Dear Dr. Corteville,

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.

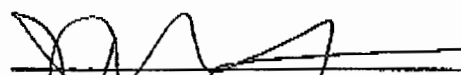
Furthermore, in compliance with 10 CFR 35.24(e),(g), the executive management of this facility agrees to provide you as RSO:

- 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,


Marla Clark DNP, RN
Sr. Director, Heart & Vascular Services


David Christian-Moore Corteville, MD
Radiation Safety Officer

**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 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 of 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.
 - b. A copy of the regulations governing the possession, use and disposal of licensed material, such as Title 10 Code of Federal Regulations.

RSO Authority, Duties & Responsibilities

2

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 a 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 10 CFR 35.24(f).

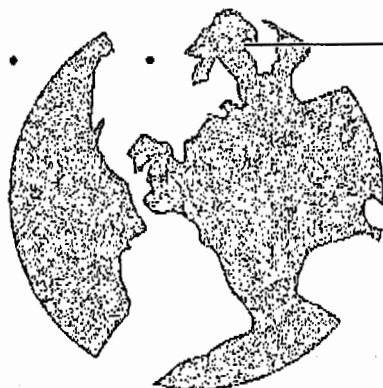


Michigan Heart & Vascular Specialists
560 W. Mitchell St, Suite 400
Petoskey, MI 49770
231-487-5870, 231-487-5854-Echo
231-487-6173

fax

To: US NRC Fax: 630-515-1078
From: JAMES CARSON RSO Date: 5-11-16
Re: RSO CHANGE Pages: 11
cc: ATTN: MATERIAL LICENSING

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle



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