

Bayonne Medical Center

Office of the President and Chief Executive Officer

29th Street at Avenue E
Bayonne, New Jersey 07002
Tel: 201.858.7111
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May 28, 2009

United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Attention: Medical Licensing Division

Re: Materials License: 29-12253-01
Control No. 143700

03002547

J-9
MS-16

Dear Ms. Weidner:

This letter is in response to your deficiency letter dated May 18, 2009 in regards to adding John T. McLean, M.S. as our Radiation Safety Officer. We will address the items from your letter individually as follows:

- Item 1.a. The control to be possessed by the consultant RSO would be substantially the same as if Mr. McLean was a direct employee of our facility. His input into any scenario in which the expertise of a Radiation Safety Officer is required will be treated with the utmost respect and confidence. His authority as the RSO will be enforced to the fullest extent possible at our facility with total support of management.
- Item 1.b. As the Radiation Safety Officer, Mr. McLean will have a variety of responsibilities that are of critical importance to our facility. In the event it has been determined that the expenditure of funds is necessary to facilitate the objectives of our radiation safety program, it will be dealt with in an appropriate manner. We realize our obligations towards regulatory requirements and are committed to maintaining compliance with them.
- Item 1.c. Mr. McLean is a consulting physicist for three other NRC licensed hospitals as well as two NRC licensed out-patient facilities aside from Bayonne Hospital Center. This amount of commitment provides a full time schedule for him. If approved as the Radiation Safety Officer for our facility, Bayonne Hospital Center will become his primary commitment in regards to radiation safety and availability. Having been our physicist for the past five years he has shown us that he is committed to our facility and our regulatory compliance. It has been determined that Mr. McLean will be at our facility at a minimum of 4-8 hours per week along with the opportunity to increase that time as it is deemed necessary as well as immediate availability 24 hours a day.

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www.bayonnemedicalcenter.org

143700
NRC/RGNI MATEF.ALS-002

- Item 1.d. We will be appointing John Esposito as Mr. McLean's in-house representative which will serve as a point of contact during his absence. Mr. Esposito, along with the department will have immediate phone access to Mr. McLean 24 hours a day during his absence. Mr. Esposito will also be allowed to assist Mr. McLean with his supervision and a limited amount of authority.
- Item 1.e. The availability of Mr. McLean to answer any questions or deal with any problems will be immediate via phone or no greater than one hour via travel in the event of an emergency. The contact information for Mr. McLean will be posted in all areas where it is required.
- Item 2. We have attached a new copy of NRC form 313A RSO for your review. This includes training and experience for 35.400 and 35.600. Also included is a copy of the HDR training certificate that was provided by Nucletron.

We believe that we have addressed each of your items with accuracy and honesty. Should you require any additional information regarding this matter please contact me at 201-858-5036.

Sincerely,



Daniel A. Kane
President and Chief Executive Officer

Attachments 2

**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

John T. McLean, M.S.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	Columbia University, New York City See enclosed transcript	270	9/03 - 10/04
Radiation protection	Columbia University, New York City See enclosed transcript	135	9/03 - 10/04
Mathematics pertaining to the use and measurement of radioactivity	Columbia University, New York City See enclosed transcript	270	9/03 - 10/04
Radiation biology	Columbia University, New York City See enclosed transcript	135	9/03 - 10/04
Radiation dosimetry	Columbia University, New York City See enclosed transcript	90	9/03 - 10/04
Total Hours of Training:		900.0	

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	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Securing and controlling byproduct material	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Using administrative controls to avoid mistakes in administration of byproduct material	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Using emergency procedures to control byproduct material	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Disposing of byproduct material	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present
Licensed Material Used (e.g., 35.100, 35.200, etc.)+ 35.300 _____ _____ _____	Englewood Hospital and Medical Center 29-08519-01	1/07 - Present

* Choose all applicable sections of 10 CFR Part 35 to describe radionuclides and quantities used: 35.100, 35.200, 35.300, 35.400, 35.500, 35.600 remote afterloader units, 35.600 teletherapy units, 35.800 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 Michael Mink, M.S., DABR	License/Permit Number listing supervising individual as a Radiation Safety Officer 29-03308-01
This license authorizes the following medical uses:	
<input checked="" type="checkbox"/> 35.100 <input checked="" type="checkbox"/> 35.200 <input checked="" type="checkbox"/> 35.300 <input checked="" 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	Michael Mink, M.S., DABR	1/07 to Present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Michael Mink, M.S., DABR	1/07 to present
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)

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.)

Michael Mink, M.S., DABR

License/Permit Number listing supervising individual

29-03308-01

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 **John T. McLean, M.S.** 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)**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 Tian Chen, M.S.	License/Permit Number listing supervising Individual as a Radiation Safety Officer 29-12253-01		
This license authorizes the following medical uses:			
<input checked="" type="checkbox"/> 35.100	<input checked="" type="checkbox"/> 35.200	<input checked="" type="checkbox"/> 35.300	<input checked="" type="checkbox"/> 35.400
<input type="checkbox"/> 35.500	<input checked="" 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	Tian Chen, M.S.	May 2009 to June 2009
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	Tian Chen, M.S.	June 2009
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>Tian Chen, M.S.</p>	<p>License/Permit Number listing supervising individual</p> <p style="text-align: center;">29-12253-01</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:

<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 checked="" 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 (_____)		

- 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 **John T. McLean, M.S.** 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 _____ 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 **John T. McLean, M.S.** 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

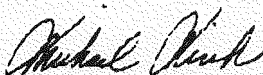
Third Section
Complete for ALL

☒ I attest that John T. McLean, M.S. 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 Overlook Hospital
Name of Facility

License/Permit Number: 29-03308-01

Name of Preceptor	Signature	Telephone Number	Date
Michael Mink, M.S., DABR		(908) 788-9440	06/15/2009



Nucletron

Nucletron Corporation8671 Robert Fulton Drive
Columbia, MD 21046

Telephone: 410-312-4100


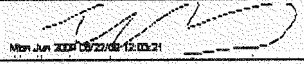
Toll Free: 800-336-2249

Canada Toll Free: 800-445-2249

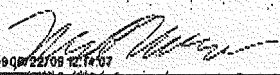
FAX: 410-312-4196

Nucletron Training Seminar Attendance Registration

Hospital: Bayonne Radiation Oncology Ass Date: Monday, June 22, 2009Course: Annual inservice emergency proceduresInstructor: Michael Marino

	Name	Department	Title	Signature
1				
2				
3	John T. McLean, M.S., DABR			 Mon Jun 2009 06/22/09 17:00:32
4	lian chen			 Mon Jun 2009 06/22/09 12:00:21
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I certify that the above individuals have been instructed in Equipment Operation, Safety Precautions and Emergency Procedures in accordance with Nucletron Corporation Training Standards.

Instructor Signature: 
Mon Jun 2009 06/22/09 12:14:07Instructor Title: FSE