SMD Superior Medical Diagnostics II, L.L.C

235 Franklin Ave. Nutley, NJ 07110
973 235-9090 Fax 973 235-0795

Br.2

October 31, 2008

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

Attention: Medical Licensing Division

Re: Materials License: 29-30730-01 03035993

Dear Sir or Madam:

Superior Medical Diagnostics II, L.L.C. would like to amend our Radioactive Materials License to add John T. McLean, M.S. as our new Radiation Safety Officer. We also request that Mr. McLean be granted use for non-medical uses of Cs-137 and Tc-99m for instrument calibration. Attached are copies of NRC Form 313A (RSO), a copy of his resume, and a copy of the delegation of authority of the RSO position.

Please remove Charles Giomuso, M.S. from our license as Radiation Safety Officer and as an Authorized User for non-medical uses.

Your attention to our amendment request is appreciated. If you have any questions or require any additional information concerning this issue please contact me at 973-235-9090.

Sincerely,

John Galdi
Administrator

Attachments (3)

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REGION 1
2008 NOV 14 AM 11:27

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NMSS/RGN1 MATERIALS-002

NRC FORM 313A (RSO) (2-2007) 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: 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	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 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
Michael Mink, M.S., DABR	**29-03308-01**

This license authorizes 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 ( )	

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		
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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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.)*	License/Permit Number listing supervising individual
Michael Mink, M.S., DABR	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)

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

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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:

_____ _____ _____ _____
_____ _____ _____ _____
_____ _____ _____ _____

NRC FORM 313A (RSO) U.S. NUCLEAR REGULATORY COMMISSION
(9-2007)

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	Michael Mink	201.667.4255	11/11/08

NRC 6

John T. McLean

[redacted]

Academic Background

M.S.	**Medical Physics** Columbia University, School of Engineering And Applied Science	**October 2004**
B.S.	**Allied Health** Fairleigh Dickinson University	**December 2001**
Cert.	**Nuclear Medicine** University of Medicine and Dentistry of New Jersey	**December 2001**

Areas of Expertise

- Qualified Medical Physicist for the Supervision of Quality Assurance Programs for Diagnostic X-Ray
- Qualified Medical Physicist for the Supervision of Quality Assurance Programs for Computed Tomography Equipment
- Qualified Medical Physicist for the Supervision of Quality Assurance Programs for Mammography
- Qualified Medical Physicist for the Supervision of Quality Control Programs for Therapy Simulators
- General Nuclear Medicine

Clinical Experience

1/2005-Present — *Employment as Medical Physicist*
BioMed Associates, Inc., Flemington, NJ
Daily, weekly, monthly, and annual tasks required to ensure that clients maintain regulatory compliance. This includes both state and federal agencies for all diagnostic modalities including Diagnostic X-Ray, Diagnostic CT as well as CT simulators, and Nuclear Medicine.

5/2004-8/2004 — *Practical Application Course*
Columbia Presbyterian Hospital, New York, NY
Weekly sessions in a hospital setting performing all basic responsibilities of the Radiation Therapy physicists. Concentration in dosimetry, calibrations, treatment planning, and quality assurance techniques performed for radiation therapy units.

PERSONAL INFORMATION WAS REMOVED BY NRC. NO COPY OF THIS INFORMATION WAS RETAINED BY THE NRC.

5/2004-8/2004 *Practical Application Course*
Community Medical Center, Toms River, NJ
Weekly sessions in a hospital setting intended to introduce one with the many responsibilities of a staff Physicist in a diagnostic Radiology department. Hands on learning of image quality, half value layer, collimator calibration, and every other quality control test performed.

Other Experience

2/2004-8/2004 *Nuclear Medicine Technologist*
Lenox Hill Hospital, New York, NY
Concentrated nuclear medicine in a dedicated cardiac imaging department. High volume department with the use of ADAC imaging equipment.

10/2003-2/2004 *Nuclear Medicine Technologist*
St Luke's Hospital, New York, NY
General nuclear medicine department imaging all types of nuclear scans ranging from bone scans to gated cardiac studies. All types of SPECT imaging done as well. Imaging done on GE equipment.

12/2001-8/2003 *Nuclear Medicine Technologist*
Community Medical Center, Toms River, NJ
Senior technologist in a high volume general nuclear medicine department with a variety of scans such as Gallium scans, CERETEC labeled white blood cell scans, Total Body Iodine scans, and Iodine therapies. Equipment used at this facility was ADAC and Siemens imaging systems.

References

Michael Mink *Medical Physicist*
Diagnostic Radiology
BioMed Associates, Inc., Flemington, NJ
Phone# 908-788-9440

Vincent Immerso *Medical Physicist*
Diagnostic Radiology
BioMed Associates, Inc., Flemington, NJ
Phone# 908-788-9440

William Caubet *Medical Physicist*
Diagnostic Radiology
Community Medical Center, Toms River, NJ
Phone# 732-557-2036

SMD Superior Medical Diagnostics II, L.L.C

235 Franklin Ave. Nutley, NJ 07110
973 235-9090 Fax 973 235-0795

Memo To: John T. McLean, M.S., Radiation Safety Officer
From: John Galdi, Administrator
Subject: Delegation of Authority

You, John T. McLean, M.S., have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. 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 by radiation safety. You are required to notify management if staff do not cooperate and do 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 8 hours per month conducting radiation protection activities.

I accept the above responsibilities.

Signature of Management Representative

Signature of Radiation Safety Officer

This is to acknowledge the receipt of your letter/application dated

10/31/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (29-30730-01)

[X] There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

[ ] Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 143007.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader