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Saint Mary's
HOSPITAL

Office of the President
Chad W. Wable, FACHE

December 20, 2011

Br.1

Nuclear Regulatory Commission
Region I
Nuclear Materials Safety Branch
Division of Radiation Safety and Safeguards
475 Allendale Road
King of Prussia, PA 19406-1415

03001243

REFERENCE: License # **06-00679-01** Amendment

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REGION 1
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To Whom It May Concern:

A. New Radiation Safety Officer

Since our present Radiation Safety Officer, Dr. Robert Lehman, will be retiring soon; we wish to amend our license by adding Michael Kevin Malin, MD as the new Radiation Safety Officer.

Dr Malin is presently listed as an authorized user on our license. We have also *attached* a copy of his American Board of Radiology certification in Diagnostic Radiology, a copy of his certificate from Yale University School of Medicine documenting his training radioisotope handling, and a completed 313(a) RSO form.

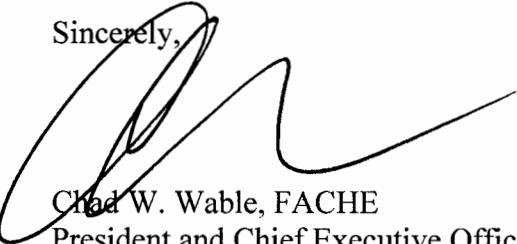
B. Removal of listed Authorized Users

Please remove the following individuals from our license:

1. Dwight Miller, MD
2. Raymond Gibney, MD
3. Bernard Percarpio, MD

Please let us know if you require any additional information and thank you for your prompt attention to this matter.

Sincerely,


Chad W. Wable, FACHE
President and Chief Executive Officer

Enc: American Board of Radiology Certification
Yale University School of Medicine Certificate
Form 313(a) RSO

56 Franklin Street, Waterbury, Connecticut 06706 (203) 709-6000 www.stmh.org

An affiliate of Saint Mary's Health System

576584
NMSS/RGN1 MATERIALS-002

The American Board of Radiology

*Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine*

Hereby certifies that

Michael Kevin Malin, M.B., B.Ch.

*Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of*

The American Board of Radiology

On this twelfth day of June, 1996

*Thereby demonstrating to the satisfaction of the Board
that he is qualified to practice the specialty of*

Diagnostic Radiology



Larry S. Amsterdam, MD Robert R. Hartley, MD M. Paul Capp, M.D.
President Secretary-Treasurer Executive Director

Yale University

Department of Diagnostic Radiology



SCHOOL OF MEDICINE
333 CEDAR STREET
P.O. BOX 208042
NEW HAVEN, CONNECTICUT 06520-8042

Certificate of Completion

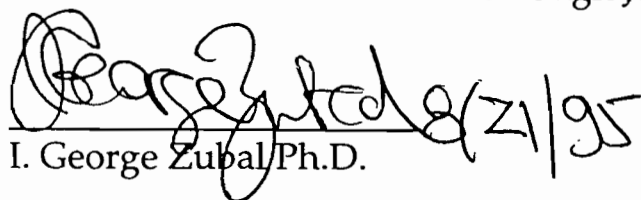
In recognition of having completed the clock hours of lecture or laboratory training as applies to Basic Radioisotope Handling Techniques and as applies to appropriate knowledge of the technical aspects of Nuclear Medicine imaging procedures, this certificate is hereby awarded to:

Dr. Michael K. Malin

for completing the course content of:

100 hours of Radiation Physics and Instrumentation
30 hours of Radiation Protection
20 hours of Mathematics pertaining to Radioactivity
20 hours of Radiation Biology, and
30 hours of Radiopharmaceutical Chemistry.

This program was conducted under the supervision of the General Nuclear Medicine Section at Yale University, Yale/New Haven Hospital, and Yale/Veterans Administration Hospital during the months of August, 1994 through July 1995.


I. George Zubal/Ph.D.

Technical Director, Section Nuclear Medicine, and
Program Coordinator

**RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.50]**APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Radiation Safety Officer

Michael Kevin Malin, 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**

- Provide a copy of the board certification.
- Use Table 3.c. to describe training in radiation safety, regulatory issues, and emergency procedures for all types of medical use on the license.
- 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**

- 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.
- Skip to and complete Part II Preceptor Attestation.

OR

☐ **3. Structured Educational Program for Proposed Radiation Safety Officer**

- Classroom and Laboratory Training

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation	See attached certificate		
Radiation protection	See attached certificate		
Mathematics pertaining to the use and measurement of radioactivity	See attached certificate		
Radiation biology	See attached certificate		
Radiation dosimetry	See attached certificate		
Total Hours of Training:		190.0	

(3-2009)

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.)+ _____ _____ _____		

+ 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
<p>This license authorizes the following medical uses:</p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> 35.100</div> <div style="width: 50%;"><input type="checkbox"/> 35.200</div> <div style="width: 50%;"><input type="checkbox"/> 35.300</div> <div style="width: 50%;"><input type="checkbox"/> 35.400</div> <div style="width: 50%;"><input type="checkbox"/> 35.500</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (remote afterloader)</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (teletherapy)</div> <div style="width: 50%;"><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</div> <div style="width: 50%;"><input type="checkbox"/> 35.1000 (_____)</div> </div>	

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	Robert M. Lehman, MD	1998 - Present
Radiation safety, regulatory issues, and emergency procedures for 35.300 uses	Robert M. Lehman, MD	1998 - Present
Radiation safety, regulatory issues, and emergency procedures for 35.400 uses	Robert M. Lehman, MD	1998 - Present
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>License/Permit Number listing supervising individual</p>												
<p>License/Permit lists supervising individual as:</p> <p> <input checked="" type="checkbox"/> Radiation Safety Officer <input type="checkbox"/> Authorized User <input type="checkbox"/> Authorized Nuclear Pharmacist <input type="checkbox"/> Authorized Medical Physicist </p> <p>Authorized as RSO, AU, ANP, or AMP for the following medical uses:</p> <table style="width: 100%;"> <tr> <td><input checked="" type="checkbox"/> 35.100</td> <td><input checked="" type="checkbox"/> 35.200</td> <td><input checked="" type="checkbox"/> 35.300</td> <td><input checked="" type="checkbox"/> 35.400</td> </tr> <tr> <td><input type="checkbox"/> 35.500</td> <td><input type="checkbox"/> 35.600 (remote afterloader)</td> <td><input type="checkbox"/> 35.600 (teletherapy)</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 35.600 (gamma stereotactic radiosurgery)</td> <td colspan="3"><input type="checkbox"/> 35.1000 (_____)</td> </tr> </table>		<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 (_____)		
<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 (_____)												

- 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 Michael Kevin Malin, MD 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 _____ 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 _____ 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 Michael Kevin Malin, 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 Saint Marys Hospital
Name of Facility
License/Permit Number: 067-00679-01

Name of Preceptor
Robert M. Lehman, M.D.

Signature


Telephone Number

203-709-6030

Date

12/15/2011

This is to acknowledge the receipt of your letter application dated

12/20/2011, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment (06-00679-01)
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

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** 576584.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.