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Milford, DE 19963
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June 4, 2014

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Re: License No. 07-14850-01

To Whom It May Concern,

We, Bayhealth Medical Center, License Number 07-14850-01, wish to amend our radioactive materials license to reflect the following:

- We would like to add John Lahaniatis, M.D. as an authorized user for 35.600 HDR Remote Afterloader Use. Please see attached documentation. Dr. Lahaniatis is currently authorized for materials use 35.300 and 35.400.

If you have any questions regarding this amendment, please contact our radiation safety officer, Adam M. Henry at 1.866.755.2756 x703.

Regards,

Terry Murphy, FACHE
President / Chief Executive Officer

Br 1

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NMSS/RGN1 MATERIALS-002

**AUTHORIZED USER TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION**
(for uses defined under 35.400 and 35.600)
[10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: (05/31/2015)

Name of Proposed Authorized User

State or Territory Where Licensed

John Lahaniatis, MD

Delaware

Requested

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

Authorization(s)

35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)

(check all that apply)

35.600 Remote afterloader unit(s)

PART I -- TRAINING AND EXPERIENCE
(Select one of the three 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. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above

a. Go to the table in section 3.e. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation.

3. Training and Experience for Proposed Authorized User

a. Classroom and Laboratory Training 35.490 35.491 35.690

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			

Total Hours of Training:

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

b. Supervised Work and Clinical Experience for 10 CFR 35.490 (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)

Supervised Work Experience	Total Hours of Experience:		Confirm	Dates of Experience*
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility			
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking survey meters for proper operation			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing, implanting, and safely removing brachytherapy sources			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Maintaining running inventories of material on hand			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using emergency procedures to control byproduct material			<input type="checkbox"/> Yes <input type="checkbox"/> No	
Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility			Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association				
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User			

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User		

d. Supervised Work and Clinical Experience for 10 CFR 35.690

- Remote afterloader unit(s)
 Teletherapy unit(s)
 Gamma stereotactic radiosurgery unit(s)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Preparing treatment plans and calculating treatment doses and times		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Checking and using survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Selecting the proper dose and how it is to be administered		<input type="checkbox"/> Yes <input type="checkbox"/> No	

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Training and Experience for Proposed Authorized User (continued)

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: <input type="checkbox"/> Residency Review Committee for Radiation Oncology of the ACGME <input type="checkbox"/> Royal College of Physicians and Surgeons of Canada <input type="checkbox"/> Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	Varian GammaMed plus iX January 27-28, 2014 Sharon Thompson		
Safety procedures for the device use	Varian GammaMed plus iX January 27-28, 2014 Sharon Thompson		
Clinical use of the device	June 10,2013-May 5,2014, Khanh Nguyen, MD; Jan 27-28, 2014, Sharon Thompson		

Supervising Individual. (If training provided by Supervising Individual (if more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.) License/Permit Number listing supervising individual as an Authorized User

Khanh Nguyen, MD

07-14850-01 / 030-07565 / Bayhealth Medical Center

Authorized for the following types of use:

- Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

First Section

Check one of the following for each requested authorization:

For 35.490:

Board Certification

I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

I attest that John Lahaniatis, MD has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that John Lahaniatis, MD has received training required in 35.690(c) for device
Name of Proposed Authorized User
operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

I attest that John Lahaniatis, MD has achieved a level of competency sufficient to
Name of Proposed Authorized User
achieve a level of competency sufficient to function independently as an authorized user for:

Remote afterloader unit(s) Teletherapy unit(s) Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

35.400 Manual brachytherapy sources 35.600 Teletherapy unit(s)

35.400 Ophthalmic use of strontium-90 35.600 Gamma stereotactic radiosurgery unit(s)

35.600 Remote afterloader unit(s)

Name of Preceptor

Khanh Nguyen, MD

License/Permit Number/Facility Name

07-14850-01 / 030-07565 / Bayhealth Medical Center

Signature



Telephone Number

(302) 674-4401

Date

05/12/2014

file under Board ✓

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The American Board of Radiology

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Robert R. Hattery, M.D., Executive Director



June 7, 2004

John E Lahaniatis, MD



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47720 / RO / 21 , 22

Dear Dr. Lahaniatis:

I am pleased to inform you that you passed the oral examination held on June 6-7, 2004. The American Board of Radiology grants you its Certificate in Radiation Oncology. This is a ten-year time-limited certificate. The certificate will be sent to the above address in approximately three months. Your name will appear on the certificate as shown above. If you wish your name to appear differently, please notify the Board office within thirty days.

Your name and demographic information will be included in a Directory published by The American Board of Medical Specialties. It is your responsibility to notify other local and state or national organizations if appropriate.

The American Board of Radiology began issuing ten-year time-limited certificates in Radiation Oncology in 1995. The American Board of Medical Specialties (ABMS) and all of the 24 member boards have developed programs for Maintenance of Certification (MOC). The ABR MOC Program (ABR-MOCP) is designed to assist each diplomate with a ten-year time-limited certificate in fulfilling the requirements as defined by the ABR and ABMS for maintaining certification. The concept of continuous improvement is a significant principle that underpins the ABR-MOCP.

With issuance of your certificate, the ABR automatically considers you as being in the ABR-MOCP. However, it is your responsibility to initiate the program. Please download an enrollment application from the ABR website (www.theabr.org) after January 1, 2005 in order to enroll in the ABR-MOCP as an active participant. We will keep you informed about the ABR-MOCP via various communications. Please notify us in writing immediately of any change of address. You are encouraged to use the website in the future to compile your MOC documentation.

Personally and on behalf of the Board of Trustees of The American Board of Radiology, I wish to congratulate you for this distinguished achievement. You have accomplished one of the most significant milestones in your career.

Sincerely,

Robert R. Hattery, MD

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Lahaniatis, John E.

ABMS Primary Source Data

AMERICAN BOARD OF RADIOLOGY CERTIFICATION(S):

Radiation Oncology 06/07/2004 - 12/31/2014

Diplomate Self Reported Data

EDUCATION:

[REDACTED]

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This is to acknowledge the receipt of your letter application dated

6-04-14, and to inform you that the initial processing which includes an administrative review has been performed.

Amend: 07-14850-01
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** 584135.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.