

VIRTUA MEMORIAL HOSPITAL OF BURLINGTON COUNTY
175 Madison Ave
Mt. Holly, N.J. 08060

U.S. NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA

Attention: Tara Weidener

January 5, 2007

re: MATERIALS LICENSE 29-17610-01

Dear Tara:

We would like to reapply to adjust our radioactive materials license so as to add as an authorized user the following radiation oncologist:

JOHN WILSON, M.D.

for materials listed in 10 CFR 35.400 and for 35.600 HDR brachytherapy remote afterloader treatments. With respect to the latter Dr. Wilson has received an emergency training inservice on our Varian Gammamed Plus HDR unit from myself on 9/13/06 (see attached). Although Dr. Wilson has not yet completed his American Board of Radiology certification examinations (he is currently in the process), I have attached copies from his preceptors of an attestation letter and NRC forms 313A detailing his extensive didactic training and supervised usage experience with radioisotopes.

If there are any questions or additional material that you require, please contact me at 609-261-7074 at your convenience or by e-mail at pvisconti@virtua.org .

Respectfully,



Paula J. Visconti, Ph.D.
Radiation Safety Officer

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REGION I

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NMSS/RGN MATERIALS-002
REF 139455

**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: 10/31/2008

Name of Proposed Authorized User

John J. Wilson, MD

State or Territory Where Licensed

New Jersey and Pennsylvania

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	Hospital of the Univ of Penna	110	7/1/02-6/30/06
Radiation protection	Hospital of the Univ of Penna	11	7/1/02-6/30/06
Mathematics pertaining to the use and measurement of radioactivity	Hospital of the Univ of Penna	30	7/1/02-6/30/06
Radiation biology	Hospital of the Univ of Penna	96	7/1/02-6/30/06
Total Hours of Training:		247	

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.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Hospital of the Univ of Penna 37-00118-07	60	7/1/02-6/30/06
Checking survey meters for proper operation	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Preparing, implanting, and safely removing brachytherapy sources	Hospital of the Univ of Penna	350	7/1/02-6/30/06
Maintaining running inventories of material on hand	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Using administrative controls to prevent a medical event involving the use of byproduct material	Hospital of the Univ of Penna	50	7/1/02-6/30/06
Using emergency procedures to control byproduct material	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Total Hours of Work Experience		520	
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 checked="" 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	Hospital of the Univ of Pennsylvania	7/1/02-6/30/06	
Supervising Individual Eleanore Harris, MD Robert Lustig, MD	License/Permit Number listing supervising individual as an Authorized User 37-00118-07		

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)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Reviewing full calibration measurements and periodic spot-checks	Hospital of the Univ of Penna 37-00118-07	20	7/1/02-6/30/06
Preparing treatment plans and calculating treatment doses and times	Hospital of the Univ of Penna	300	7/1/02-6/30/06
Using administrative controls to prevent a medical event involving the use of byproduct material	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Checking and using survey meters	Hospital of the Univ of Penna	20	7/1/02-6/30/06
Selecting the proper dose and how it is to be administered	Hospital of the Univ of Penna	200	7/1/02-6/30/06
Total Hours of Work Experience		580	

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 checked="" 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	Hospital of the University of Penna	7/1/02-6/30/06
Supervising Individual Eleanor Harris, MD Robert Lustig, MD		License/Permit Number listing supervising individual as an Authorized User 37-00118-07

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	Eleanor Harris, MD Robert Lustig, MD 7/1/02-6/30/06		
Safety procedures for the device use	Eleanor Harris, MD Robert Lustig, MD 7/1/02-6/30/06		
Clinical use of the device	Eleanor Harris, MD RobertL Lustig, MD 7/1/02-6/30/06		
Supervising Individual. <i>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.)</i>		License/Permit Number listing supervising individual as an Authorized User 37-00118-07	
Authorized for the following types of use:			
<input checked="" type="checkbox"/> Remote afterloader unit(s) <input type="checkbox"/> Teletherapy unit(s) <input type="checkbox"/> 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.

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 John J. Wilson, MD 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 _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

I attest that John J. Wilson, MD 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 J. Wilson, 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 J. Wilson, 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 Robert Lustig, MD	Signature 	Telephone Number 215/349 8429	Date 1/18/07
License/Permit Number/Facility Name University of Pennsylvania Lic #37-00118-07			

VIRTUA MEMORIAL HOSPITAL
RADIATION ONCOLOGY

VARIAN GAMMAMED PLUS HDR UNIT

EMERGENCY PROCEDURES INSERVICE

THIS IS TO RECORD THAT ON THE DATE(S) INDICATED BELOW THE FOLLOWING PERSONNEL RECEIVED AN INSERVICE ON HOW TO HANDLE AN EMERGENCY SITUATION WITH THE GAMMAMED HDR UNIT IN ANY OF THE FOLLOWING CASES:

A PATIENT IN EXTREMIS SITUATION

AN ERROR IN CORRECT TREATMENT DELIVERY

A SOURCE RETRACTION FAULT

<u>NAME</u>	<u>POSITION</u>	<u>SIGNATURE</u>	<u>DATE</u>
<u>Kelly K. Fe</u>	<u>MD.</u>	<u>[Signature]</u>	<u>9/13/06</u>
<u>Tommy 2nd</u>	<u>Physicist</u>	<u>[Signature]</u>	<u>9/13/06</u>
<u>John Wilson</u>	<u>MD</u>	<u>[Signature]</u>	<u>9/13/06</u>
<u>Butzbach</u>	<u>MD</u>	<u>BUTZBACH</u>	<u>9/13/06</u>

[Signature]
Paula Visconti, Ph.D.
Radiation Safety Officer

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

1/5/2007, and to inform you that the initial processing which includes an administrative review has been performed.

ALWD. 29-17610-01 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 140070.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.