

NMSB1

April 8, 2008

U S Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA

ATTENTION: License Reviewers

03013049

RE: Materials License 29-17610-01

Dear Sir or Madam:

We would like to apply to adjust our radioactive materials license so as to add as an authorized user the following radiation oncologist: Catherine S. Kim, 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. Kim, in addition to receiving an emergency training inservice on our Varian Gammamed Plus HDR unit from myself on 12/28/07 (see attached), has fully participated under the supervision of our authorized users in numerous HDR treatments at this facility. She has also had full participation in multiple supervised LDR Cesium GYN procedures.

Although Dr. Kim has not yet completed her American Board of Radiology certification examinations (she is currently in the process), I have attached copies from her preceptors of an attestation letter and NRC forms 313A detailing her extensive didactic training and supervised usage experience with radioisotopes.

If there are any questions or additional materials 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., DABR
Radiation Safety Officer

2008 APR 14 PM 12:44

RECEIVED
REGION I

142309

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>Catherine Kim</u>	<u>Radiation Oncologist</u>	<u>Catherine Kim</u>	<u>12/28/07</u>
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

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



Jefferson Health System*

Department of Radiation Oncology

March 31, 2008

Thomas Jefferson University Hospitals

Thomas Jefferson University Hospital

Methodist Hospital Division

Jefferson Hospital for Neuroscience

Ford Road Campus

Methodist Hospital Nursing Center

RE: Catherine Kim, M.D.

To Whom It May Concern:

Dr. James Galvin (see below) is addressing the use of radioactive materials and linear accelerator training.

I am writing this letter of attestation to verify Dr. Kim's experience and training relative to functioning as an Authorized User of radioactive materials and electronically produced x-ray devices for medical purposes. Specifically, I would like to comment on her abilities to safely use afterloading, teletherapy and gamma stereotactic radiosurgery units, as well as manually placed brachytherapy sources. Referring to NRC regulations as presented in 10 CFR sections 35.690 and 35.490 as a template, I believe that she meets the requirements for a physician trained in radiation oncology that has not yet finished the process of obtaining certification from the American Board of Radiology. Using the section 35.690 requirements for teletherapy as a template for the use of linear accelerators to treat patients, I would like to affirm her ability to use this radiation therapy modality also. Dr. Kim received her training in the Department of Radiation Oncology here at Jefferson Medical College of Thomas Jefferson University and Thomas Jefferson University Hospitals, Inc. Ours is a four-year residency training program. Her laboratory and classroom training in the areas of radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, chemistry of byproduct materials, and the use of external beam irradiation devices totaled more than 200 hours.

I am listed as an Authorized Medical Physicist on the Materials License for Thomas Jefferson University Hospital. The number for that license is 37-00148-08.

If you have any questions about this letter of attestation, please do not hesitate to call me at 215-955-8855.

March 31, 2008
Re: Dr. Catherine Kim
Page 2

Dr. Maria Werner-Wasik (see below) is addressing her 36 months of supervised clinical experience.

Dr. Catherine Kim has successfully completed 36 months of supervised clinical experience which includes examining individuals and reviewing their case histories to determine their suitability for teletherapy, therapy, and selecting the proper dose and how it is to be administered, as well as post-administration follow-up and review of case histories.

If you require any additional information, please do not hesitate to contact me by calling 215-955-6700.

Sincerely,



James Galvin, D. Sc.
Professor
Division of Medical Physics



Maria Werner-Wasik, M.D.
Associate Professor and
Residency Program Director

MWW:JG:tm

**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

State or Territory Where Licensed

Catherine Kim

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

- Provide a copy of the board certification.
- 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.
- Skip to and complete Part II Preceptor Attestation.

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

- Go to the table in section 3.e. to document training for new device.
- 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	Thomas Jefferson Univ. Hospital Philadelphia, PA	100	07/01/03- 06/30/07
Radiation protection	Thomas Jefferson Univ. Hospital Phila., PA	10	07/01/03- 06/20/07
Mathematics pertaining to the use and measurement of radioactivity	Thomas Jefferson Univ. Hospital Phila., PA	12	07/01/03 - 06/30/07
Radiation biology	Thomas Jefferson Univ. Hospital	70	07/01/03- 06/30/07

Total Hours of Training:

192

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:	
Description of Experience Must include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys	Thomas Jefferson Univ. Hospital NRC License No. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
Checking survey meters for proper operation	Thomas Jefferson University Hospital NRC License No. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
Preparing, implanting, and safely removing brachytherapy sources	Thomas Jefferson Univ. Hospital NRC License No. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
Maintaining running inventories of material on hand	Thomas Jefferson Univ. Hospital NRC License No. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
Using administrative controls to prevent a medical event involving the use of byproduct material	Thomas Jefferson Univ. Hospital NRC no. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
Using emergency procedures to control byproduct material	Thomas Jefferson Univ. Hospital NRC License No. 37-00148-08	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	07/01/03-06/30/07
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	Thomas Jefferson Univ. Hospital NRC No. 37-00148-08		07/01/03-06/30/07
Supervising Individual Maria Werner-Wasik, M.D.	License/Permit Number listing supervising individual as an Authorized User 37-00148-08		

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 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	Location of Experience/License or Permit Number of Facility	Dates of Experience*
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	Maria Werner-Wasik, M.D. Associate Professor and Director of Residency Program 07/01/03-06/30/07		
Safety procedures for the device use	"	"	
Clinical use of the device	"	"	

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

37-00148-08

Signature: Maria Werner-Wasik

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.

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 Catherine Kim, M.D. 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 Catherine Kim, M.D. 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 Catherine Kim, M.D. 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 Catherine Kim, M.D. 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

Maria Werner-Wasik, M.D.

Signature



Telephone Number

215-955-6700

Date

03/31/08

License/Permit Number/Facility Name

Thomas Jefferson Univ. Hospital.

#37-00148-08

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

4/8/2000, and to inform you that the initial processing which includes an administrative review has been performed.

ATTEND. 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** 142309.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.