

 **The Hospital of
Central Connecticut**

at New Britain General and Bradley Memorial

100 Granville Street
New Britain, CT 06050
860-234-5011

81 Meriden Avenue
Southington, CT 06489
860-236-5000

www.thccc.org
Laurence A. Tanner, President

January 19, 2009

br 1

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

03001250

Dear Sir or Madam:

Attached is an amendment request on our facilities NRC license (license number: 06-02388-01).

The Hospital of Central Connecticut is requesting the following changes to our NRC license.

- Add LaDonna Dakofsky, M.D. as an authorized user (Iridium-192 for uses in a High Dose Rate Remote Afterloader Unit). Attached is NRC Form 313A (AUS) in support of this change.

If you have any technical question regarding this amendment request, please do not hesitate to contact me at (860) 224-5520 or by e-mail at gp219@columbia.edu

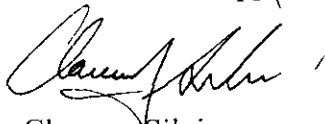
Prepared by:



George Pavlonnis, III M.S. DABR
American Board of Radiology Certified Medical Physicist

RECEIVED
REGION 1
JAN 23 PM 12:24

Reviewed and Approved by:



Clarence Silvia
Senior Vice President, The Hospital of Central Connecticut

143231

**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. 3150-3120
EXPIRES: 10/31/2008

Name of Proposed Authorized User: **LaDonna Dakofsky** State or Territory Where Licensed: **Connecticut**

Requested Authorization(s) (check all that apply):
 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)

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	University of Pennsylvania (SEE ATTACHED LETTER)	110	7/88 to 6/91
Radiation protection	University of Pennsylvania (SEE ATTACHED LETTER)	11	7/88 to 6/91
Mathematics pertaining to the use and measurement of radioactivity	University of Pennsylvania (SEE ATTACHED LETTER)	30	7/88 to 6/91
Radiation biology	University of Pennsylvania (SEE ATTACHED LETTER)	96	7/88 to 6/91

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:	
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		<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: 1,000	
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	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91
Preparing treatment plans and calculating treatment doses and times	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91
Using administrative controls to prevent a medical event involving the use of byproduct material	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91
Checking and using survey meters	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91
Selecting the proper dose and how it is to be administered	University of Pennsylvania (SEE ATTACHED LETTER)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	7/88 to 6/91

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	University of Pennsylvania PA-0131 (SEE ATTACHED LETTER)	7/88 to 6/91
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	
Neha Vapiwala, M.D. Residency Director	PA-0131	

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	Neal Goldberg, M.D. AU 3/10/08 to Present	n/a	n/a
Safety procedures for the device use	Neal Goldberg, M.D. AU 3/10/08 to Present	n/a	n/a
Clinical use of the device	Neal Goldberg, M.D. AU 3/10/08 to Present	n/a	n/a
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	
Neal Goldberg, M.D. Authorized User		06-2388-01	
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)

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	George Pavlonnis, AMP 4/1/08 to Present	n/a	n/a
Safety procedures for the device use	George Pavlonnis, AMP 4/1/08 to Present	n/a	n/a
Clinical use of the device	George Pavlonnis, AMP 4/1/08 to Present	n/a	n/a
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	
George Pavlonnis, Auth Medical Physicist		06-2388-01	
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.

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

35.690(a)(1).

OR

Training and Experience

I attest that **LaDonna Dakofsy** 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 LaDonna Dakofsy 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 LaDonna Dakofsy 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	Signature	Telephone Number	Date
Neal Goldberg, M.D.	<i>Neal Goldberg</i>	(860) 224-5520	01/19/2009

License/Permit Number/Facility Name
06-02388-01 / The Hospital of Central Connecticut



Environmental Health & Radiation Safety

January 14, 2009

LaDonna Dakofsky, M.D.
7 Sweetbriar Lane
Sandy Hook, CT 06482-1481

Dear Mr. Dakofsky:

In addition to the enclosed form, you may need to submit a letter from the University of Pennsylvania confirming that the signatory of the letter is an Authorized User as defined by the NRC regulations. Because the form attests only to your completion of the residency program here and not to your training on high dose-rate remote afterloaders, I am not certain whether this confirmation is necessary, but suggest you submit it with the form to head off later questions.

The enclosed form signed by Dr. Vapiwala should be sufficient to demonstrate that you completed three years of supervised clinical experience in radiation therapy as part of a training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education. Dr. Vapiwala is Director of the Residency Program for Radiation Oncology for the University of Pennsylvania School of Medical. The form also lists the classroom hours and supervised work experience hours you completed during your residency.

By this letter, I confirm that Dr. Vapiwala is an Authorized User under the Pennsylvania License of Broad Scope No. PA-0131 for uses listed PA Code 25.228 (linear accelerator), 10 CFR 35.400 (low dose-rate brachytherapy), and 10 CFR 35.600 (high dose-rate brachytherapy). The NRC regulations are incorporated into the Pennsylvania regulations by reference.

If the NRC license reviewer needs a copy of our DEP License, I would ask that person to contact me directly at 215-898-2106 or email me at keith@ehrs.upenn.edu.

Sincerely,

A handwritten signature in cursive script, appearing to read "Keith D. Brown".

Keith D. Brown, Ph.D., CHP
Medical Health Physicist

Documentation of Radiation Oncology Residency Training for Linear Accelerator and Manual Brachytherapy For Physicians Who Completed the Residency at Penn

Applicant Name: LaDonna (Jung) Dakofsky

State(s) where licensed to practice medicine: CT

Residency at : University of Pennsylvania

Dates of Residency: July 1988 to June 1991

- Residency approved by
- Residency Review Committee for Radiation Oncology of the ACGME
 - Royal College of Physicians and Surgeons of Canada
 - Committee on Postdoctoral Training of the American Osteopathic Association

Classroom and Laboratory Training:

Description of Training	Clock Hours (must total 200 hours or more)
Radiation physics and instrumentation	110
Radiation Protection	11
Mathematics pertaining to the use and measurement of radioactivity	30
Radiation Biology	96

Supervised Work Experience:

	Clock Hours (must total 700 hours or more):
Total hours of experience during residency in planning treatments, using radioactive sources and radiation producing machines to treat patients, ensuring correct delivery of radiation, and handling radioactive material	1000

Supervised clinical work experience in linear accelerator use included the following required topics:

<input checked="" type="checkbox"/>	Reviewing full calibration measurements and periodic spot checks of linear accelerators
<input checked="" type="checkbox"/>	Preparing treatment plans and calculating treatment doses and times for linear accelerator treatments
<input checked="" type="checkbox"/>	Using administrative controls to prevent a medical event involving a linear accelerator
<input checked="" type="checkbox"/>	Implementing emergency procedures to be followed in the event of the abnormal operation of the linear accelerator or console
<input checked="" type="checkbox"/>	Checking and using survey meters
<input checked="" type="checkbox"/>	Selecting the proper dose and how it is administered

Supervised clinical work experience in the use of manual brachytherapy sources included the following required topics:

<input checked="" type="checkbox"/>	Preparing, implanting, and safely removing brachytherapy sources
<input checked="" type="checkbox"/>	Using administrative controls to prevent a medical event involving use of radioactive material
<input checked="" type="checkbox"/>	Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
<input checked="" type="checkbox"/>	Using emergency procedures to control byproduct material
<input checked="" type="checkbox"/>	Maintaining running inventories of material on hand
<input checked="" type="checkbox"/>	Checking survey instruments for proper operation

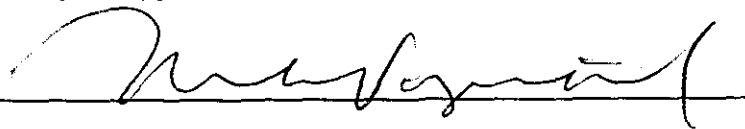
Device Specific Training for Linear Accelerator

Training included the following required topics:

<input checked="" type="checkbox"/>	Device operation
<input checked="" type="checkbox"/>	Safety procedures
<input checked="" type="checkbox"/>	Clinical Uses

Certification:

I attest that the above named physician has completed the training documented above. I further attest that I am an Authorized User under the NRC or Agreement State license at the site of the residency program named above to treat patients using a linear accelerator and manual low dose-rate brachytherapy sources.

Signature:  Date: _____

Printed Name: Neha Vapiwala, M.D., Residency Director

Telephone Number: 215-662-3694

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

LaDonna Jung Bakofsky

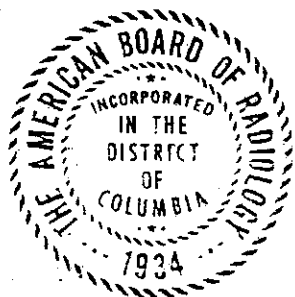
*Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of*

The American Board of Radiology

On this tenth day of June, 1993

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

Radiation Oncology



Lee F. Rogers
President

Justin J. Paton
Secretary-Treasurer

Forrest L. Fullbrook, M.D.
Executive Director



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

1/19/2009, and to inform you that the initial processing which includes an administrative review has been performed.

Memor. 06-02388-01
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** 143231.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.