



Danbury Hospital

July 13, 2010

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

Br.1

RECEIVED
2010 JUL 26 PM 2:14

RE: NRC License No. 06-08544-01 (Danbury Hospital)

To Whom It May Concern:

03001274

Danbury Hospital is requesting the following individuals to be added to the NRC license #06-08544-01 in the denoted category:

John Spera, M.D. as authorized user for the use of Ir-192 in a high dose rate after loader;

Vassiliki Potari, M.Sc. as authorized medical physicist for the use of Ir-192 in a high dose rate afterloader for calibrations, spot-checks and training.

Dr. Spera has participated in 4 specific cases (4 individuals) with a total of 10 treatments using a vaginal cylinder of various sizes. He is already listed under the license for parts 300 and 400 with 25 years experience. Under the auspices of Dr. Sanghavi, the authorized user listed on the license, he has participated in preparing the treatment plans, calculation of the treatment doses and times, selecting the proper dose and how to apply it. Under the guidance of David Wishko, Ph.D., the authorized medical physicist for the above license, Dr. Spera has reviewed the full calibration procedure and the periodic spot checks required before each treatment. He has used the administrative tools provided, (i.e. 2nd dose checks and manual time calculation) to prevent a medical event. He has participated in the yearly emergency procedure training conducted by a representative of Nucletron Corporation and has been instructed in the use and pre-checking of survey meters.

Vassiliki Potari, M.Sc., has participated in 4 HDR cases involving a total of 11 treatments utilizing a vaginal cylinder of various sizes. She has attended the training session provided by Nucletron Corp. and has participated in the treatment planning of each case. She has 10 years of experience using Cs-137 for low dose rate treatments. Under the auspices of David Wishko, Ph.D., Ms. Potari has participated in 2 source exchanges requiring full calibrations of the HDR unit in addition to spot-checks before each treatment. She has been trained by a Nucletron representative in emergency procedures in the event of an abnormal operation and is fully acquainted with the operation of a survey meter.

In addition, please delete Ian Crooks, M.Sc. and Lee Anne Zarger, M.S. from the license as authorized Medical Physicists.

Sincerely,


John M. Murphy, MD
President and Chief Executive Officer

gl
Enclosure

573214
NRC/REGM MATERIALS-002

**AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE
AND PRECEPTOR ATTESTATION
[10 CFR 35.51]**

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 3/31/2012

Name of Proposed Authorized Medical Physicist

Vassiliki Potari, M.Sc.

- Requested Authorization(s) (check all that apply)
- 35.400 Ophthalmic use of strontium-90 35.600 Teletherapy unit(s)
- 35.600 Remote afterloader unit(s) 35.600 Gamma stereotactic radiosurgery 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. Go to the table in 3.c. 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 Authorized Medical Physicist Seeking Additional Authorization for use(s) checked above**
- a. Go to the table in section 3.c. to document training for new device.
- b. Skip to and complete Part II Preceptor Attestation
- 3. Education, Training, and Experience for Proposed Authorized Medical Physicist**
- a. Education: Document master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.

Degree	Major Field
College or University	

b. Supervised Full-Time Medical Physics Training and Work Experience in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

Yes. Completed 1 year of full-time training in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AND

Yes. Completed 1 year of full-time work experience in medical physics (for areas identified below) under the supervision of _____ who meets the requirements for an Authorized Medical Physicist.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

b. Supervised Full-Time Medical Physics Training and Work Experience (continued)

If more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.

Description of Training/ Experience	Location of Training/License or Permit Number of Training Facility/Medical Devices Used+	Dates of Training*	Dates of Work Experience*
Medical Physics			
Performing sealed source leak tests and inventories			
Performing decay corrections			
Performing full calibration and periodic spot checks of external beam treatment unit(s)			
Performing full calibration and periodic spot checks of stereotactic radiosurgery unit(s)			
Performing full calibration and periodic spot checks of remote afterloading unit(s)			
Conducting radiation surveys around external beam treatment unit(s), stereotactic radiosurgery unit(s), remote after loading unit(s)			

Supervising Individual**

License/Permit Number listing supervising individual as an
authorized Medical Physicist

for the following types of use:

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

+ Training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services.

* 1 year of Full-time medical physics training and 1 year of full time work experience cannot be concurrent.

** If the supervising medical physicist is not an authorized medical physicist, the licensee must submit evidence that the supervising medical physicist meets the training and experience requirements in 10 CFR 35.51 and 35.59 for the types of use for which the individual is seeking authorization.

AUTHORIZED MEDICAL PHYSICIST TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

3. Education, Training, and Experience for Proposed Authorized Medical Physicist (continued)

c. 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
Hands-on device operation	4/13/10, 4/14/10, 4/27/10, 5/5/10, 5/18/10, 5/26/10, 6/1/10, 6/10/10, 6/23/10, 6/30/10, 7/7/10		
Safety procedures for the device use	4/13/10, 4/14/10, 4/27/10, 5/5/10, 5/18/10, 5/26/10, 6/1/10, 6/10/10, 6/23/10, 6/30/10, 7/7/10		
Clinical use of the device	4/13/10, 4/14/10, 4/27/10, 5/5/10, 5/18/10, 5/26/10, 6/1/10, 6/10/10, 6/23/10, 6/30/10, 7/7/10		
Treatment planning system operation	4/6/10, 4/7/10, 4/8/10, 5/18/10, 5/19/10, 5/20/10, 6/9/10, 6/10/10, 6/14/10		
Supervising Individual <i>If training is provided by Supervising Medical Physicist, (if more than one supervising individual is necessary to document supervised training, provide multiple copies of this page.)</i>		License/Permit Number listing supervising individual as an authorized Medical Physicist	
David S. Wishko, Ph.D.		06-08544-01	

for the following types of use:

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

If Applicable:

Authorization Sought	Device	Training Provided By	Dates of Training
35.400 Ophthalmic Use of strontium-90			

d. Skip to and complete Part II Preceptor Attestation.

AUTHORIZED MEDICAL PHYSICIST 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:

1. Board Certification

I attest that Vassiliki Potari, M.Sc. has satisfactorily completed the requirements in
Name of Proposed Authorized Medical Physicist
10 CFR 35.51(a)(1) and (a)(2).

OR

2. Education, Training, and Experience

I attest that _____ has satisfactorily completed the 1-year of full-time
Name of Proposed Authorized Medical Physicist
training in medical physics and an additional year of full-time work experience as required by 10 CFR 35.51(b)(1).

AND

Second Section

Complete the following:

I attest that Vassiliki Potari, M.Sc. has training for the types of use for which authorization
Name of Proposed Authorized Medical Physicist
is sought that include hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

AND

Third Section

Complete the following:

I attest that Vassiliki Potari, M.Sc. has achieved a level of competency sufficient to
Name of Proposed Authorized Medical Physicist
function independently as an Authorized Medical Physicist for the following:

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

AND

Fourth Section

Complete the following for preceptor attestation and signature:

I meet the requirements in 10 CFR 35.51, or equivalent Agreement State requirements for Authorized Medical Physicist for the following:

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

Name of Preceptor	Signature	Telephone Number	Date
David S. Wishko, Ph.D.		(203) 739-8093	07/19/2010
License/Permit Number/Facility Name			
06-08544-01 Danbury Hospital			

**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: 3/31/2012

Name of Proposed Authorized User

State or Territory Where Licensed

John Spera, M.D.

Connecticut

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:	
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:	
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	4/13/10, 4/14/10, 4/27/10, 5/5/10, 5/18/10, 5/26/10, 6/1/10, 6/10/10, 6/23/10, 6/30/10, 7/7/10		
Safety procedures for the device use	Nucletron Training - 2/2/2010		
Clinical use of the device	4/13/10, 4/14/10, 4/27/10, 5/5/10, 5/18/10, 5/26/10, 6/1/10, 6/10/10, 6/23/10, 6/30/10, 7/7/10 by AU		
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	
Seema Sanghavi, M.D.		0608544-01	
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)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

I attest that John Spera, 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 John Spera, 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	Signature	Telephone Number	Date
Dr. S Sanghavi, M.D.		(203) 739-8126	07/15/2010

License/Permit Number/Facility Name
06-08544-01

This is to acknowledge the receipt of your letter application dated

7/13/2010, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (06-08544-01) 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** 573214.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.