

From: Sandra Gabriel
To: Daniel Galmarini
Date: Sat, Apr 28, 2007 6:34 PM
Subject: Additional information for NRC license amendment request, mail control 140368

Licensee: 21st Century Oncology, Inc., Woodbury, NJ facility
License No.: 09-31141-01
Docket No.: 03037177
Mail Control No.: 140368

To: Daniel H. Galmarini, Director of Physics and RSO

Please send a return e-mail to confirm that you received this message.

This is in response to your April 6, 2007 resubmission of an amendment request to name Wadie Tawadrous, M.S. as authorized medical physicist (AMP) for HDR use at your Woodbury, New Jersey facility. The submitted information is not fully sufficient to demonstrate that Mr. Tawadrous meets the requirements of 10 CFR 35.51.

We responded to your original, October 11, 2006, request to name Mr. Tawadrous as AMP in an e-mail dated November 9, 2006. In that e-mail we noted that, unfortunately, the current NRC listing of recognized certification boards and dates does not include ABR certification in Therapeutic Radiological Physics from 2006 (this will be recognized for certificates dated June 2007 or later). We provided a listing of additional information needed to document Mr. Tawadrous' training and experience to meet the requirements of 35.51. Your current request included portions of this information, but a few additional items are still needed.

Please provide the following:

a) Documentation of Mr. Tawadrous' M.S. degree from Polytechnic University in Brooklyn, NY (provide a copy of diploma or transcript, showing date of degree and field of major study).

b) On page 2 of the submitted Form 313A(AMP), the "supervising individual" section was not completed. From the information on page 1 of the form, it appears that Dr. N. Ikoro may have been the supervising individual. Please confirm this. [We found in our files a recent copy of the City of New York Radioactive Materials license for The New York Methodist Hospital, which documents that Dr. Ikoro is an HDR AMP under this license.]

c) On page 3 of the submitted Form 313A(AMP), please clarify where the described HDR training was obtained and who supervised it. Was this done at The New York Methodist Hospital under Dr. Ikoro's supervision?

d) The HDR training on page 3 of the submitted Form 313A(AMP) refers to the GammaMed Plus unit. Please confirm that Mr. Tawadrous has also received training in hands-on device operation, clinical use, and emergency response for your Nucletron model 105.999 HDR unit. If he has received Nucletron vendor training in emergency procedures, please supply a copy of the training certificate (you already provided the certificate for Nucletron training in treatment planning).

e) The preceptor attestation on page 4 of the submitted Form 313A(AMP) was signed by Dr. S. Rafla. It is necessary for the attestation to be signed by an Authorized Medical Physicist, however Dr. Rafla is listed on The New York Methodist Hospital license as a physician Authorized User. Please resubmit the preceptor attestation, signed by any HDR AMP who can confirm that Mr. Tawadrous completed the required training and is competent to function independently as AMP. This could be signed by you or another of the AMPs on the NRC license for the Woodbury facility. I am attaching an electronic copy of the Form 313A(AMP) so that you can use a blank copy of the preceptor attestation page.

Please provide the requested information within 30 days, or we will assume that you do not wish to pursue this amendment request. You may respond by mail to the Region I office or by fax to my attention at 610-337-5269. In your response, please reference mail control 140368. If you respond by fax, you may wish to send an e-mail message to alert me that the fax has been sent.

Please feel free to contact me with any questions. Note that I will be out of the office from April 30 through May 4 and again from May 14 through May 17.

Thank you for your assistance.

Sandy Gabriel
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182

CC: lbarreca@rtsex.com

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

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized Medical Physicist

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			
Safety procedures for the device use			
Clinical use of the device			
Treatment planning system operation			

Supervising Individual

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.)

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)

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 _____ 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 _____ 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 _____ 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
License/Permit Number/Facility Name			