

From: Sandra Gabriel
To: Daniel Galmarini
Date: Thu, Nov 9, 2006 5:30 PM
Subject: Additional info. for NRC license amendment request for Woodbury, NJ facility, mail control 139593

Licensee: 21st Century Oncology, Inc., Woodbury, NJ facility
License No.: 09-31141-01
Docket No.: 03037177
Mail Control No.: 139593

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

This is in response to your October 11, 2006 request to name Ashraf Youssef, M.D. as authorized user (AU) and Wadie Tawadrous, M.S. as authorized medical physicist (AMP) for HDR use at your Woodbury, New Jersey facility. The submitted information is insufficient to demonstrate that these individuals comply with the requirements of 10 CFR 35.960 and 35.51.

At the present time, the NRC listing of recognized certification boards and dates does not include ABR certification in Radiation Oncology from 1999 or in Therapeutic Radiological Physics from 2006 (both will be recognized for certificates dated June 2007 or later). The most expeditious way to name Dr. Youssef as AU and Mr. Tawadrous as AMP would be to provide documentation that they have each been listed on an NRC or Agreement State license for the same authorization within the past 7 years. Otherwise you will need to document that each qualifies based on training and experience.

1) Our records show that Dr. Youssef has previously been listed on NRC licenses as AU for 35.400, but not for HDR. If he has not previously been named on a license as AU for HDR, it will be necessary to show that he meets the requirements of 10 CFR 35.690(b)(3) and (c).

a) 35.690(c) relates to training in device operation, safety procedures, and clinical use. You provided a copy of a Nucletron training certificate titled "Physician Training-Overview for HDR Brachytherapy." Please provide an outline of the topics addressed in this training and confirm that they included device operation, safety procedures, and clinical use.

b) To meet the requirements of 35.690(b)(3), it is necessary for Dr. Youssef to perform some clinical HDR cases under the supervision of a preceptor AU. Please provide a written attestation, signed by a preceptor HDR authorized user, stating that Dr. Youssef "has satisfactorily completed the requirements in 10 CFR 35.960(b)(1), (b)(2), and (c) and has achieved a level of competency sufficient to function independently as an HDR authorized user". Also provide the number of the NRC license listing the preceptor as an HDR AU or a copy of the Agreement State license or broad license permit showing this listing.

2) If Mr. Tawadrous has not previously been named on a license as AMP for HDR, it will be necessary to show that he meets the requirements of 10 CFR 35.51(b)(1), (b)(2), and (c). Please provide the following:

a) Documentation that Mr. Tawadrous holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university (provide a copy of diploma or transcript, showing date of degree and field of major study)

b) Documentation of one year of full-time training in medical physics and one year of full-time supervised medical physics work experience conducted in clinical radiation facilities that provide high-energy, external beam therapy (megavoltage photons and electrons) and brachytherapy services, including:

(i) Dates, location, and activities of the one year of full-time training, for example, formal

medical physics courses, texts read and reviewed with supervisor, laboratory exercises performed.

(ii) Dates, location, and activities of the one year of full-time medical physics work experience supervised by an individual who meets the requirements of AMP. Provide the name of the supervising AMP and NRC license number or copy of the Agreement State license or broad license permit showing this listing.

(iii) Confirmation that training and experience included performing sealed source leak tests and inventories; performing decay corrections; performing full calibration and periodic spot checks of external beam treatment units and HDR units; and conducting radiation surveys around external beam treatment units and HDR units.

c) Documentation of training in HDR hands-on device operation, safety procedures, and clinical use [The Nucletron training certificate you submitted was for a course in "Brachytherapy Treatment Planning, Version 14.3," but did not cover the other topics listed in 35.51(c)]; and

d) A written attestation, signed by a preceptor HDR AMP who is familiar with Mr. Tawadrous' HDR training, stating that Mr. Tawadrous "has satisfactorily completed the requirements in 10 CFR 35.51(b)(1) and (c) and has achieved a level of competency sufficient to function independently as an authorized medical physicist for HDR." Also provide the number of the NRC license listing the preceptor as an HDR AMP or a copy of the Agreement State license or broad license permit showing this listing.

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 139593. 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 country from November 14-28, returning to the office on November 29.

Thank you for your assistance.

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

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