

Moore, Marleen M.

From: Lanzisera, Penny <Penny.Lanzisera@nrc.gov>
Sent: Thursday, October 11, 2012 12:17 PM
To: Moore, Marleen M.
Subject: Request for Additional Information

Licensee: Fletcher Allen Healthcare
License No. 44-10187-03
Docket No. 03003289
Mail Control 578082

Ms. Moore,

With regards to your request to add Dr. Bhav to your license for Therasphere use please confirm the following:

1. The 80 hours of physics training completed at Northwestern University in June 2000 included radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology.
2. The casework completed under Dr. Kikut was hands-on and included training on the operation of the delivery system and clinical use.

You may submit a response signed by Dr. Kikut and you to my attention either via email (pdf) or via fax (610-337-5269). Please reference Mail Control No. 578082 in your response. If we do not receive a response within 20 days, we will assume you no longer require the addition and void your request.

Sincerely,

Penny Lanzisera
U.S. NRC, Region I

Moore, Marleen M.

From: Ryu, Robert <RRyu@nmff.org>
Sent: Thursday, October 25, 2012 2:15 PM
To: Moore, Marleen M.
Subject: RE: Additional information needed regarding physics training for Dr. Anant Bhave

Yes, our physics curriculum does cover the requested topics as you've delineated.

Robert K. Ryu, MD FSIR
Professor of Radiology
Residency Program Director
Department of Radiology
Northwestern University Feinberg School of Medicine

676 N. St Clair St., Suite 800
Chicago, IL 60614
(312)695-3718
(312)695-5645 fax

From: Moore, Marleen M. [Marleen.Moore@vtmednet.org]
Sent: Thursday, October 25, 2012 9:47 AM
To: Ryu, Robert
Cc: Bhave, Anant D.
Subject: Additional information needed regarding physics training for Dr. Anant Bhave

Thank you for your letter for Dr. Bhave of May 15, 2012. The license amendment for Dr. Bhave for Theraspheres has taken longer than expected, and I now have received a request from the NRC for additional information. Could you confirm that the physics training included the requested topics "radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurements of radioactivity, and radiation biology"?

Marleen M. Moore, M.S.
Medical Physicist and Radiation Safety Officer Radiation Oncology Fletcher Allen Health Care
111 Colchester Ave
Burlington, VT 05401
phone 802-847-3506
fax 802-847-7413



*In alliance with
The University of Vermont*

October 23, 2012

Nuclear Materials Safety Section
Division of Radiation Safety and Safeguards
United States Nuclear Regulatory Commission Region I
2100 Renaissance Boulevard
King of Prussia, PA 19406

RE: Fletcher Allen Health Care
License # 44-10187-03
Mail Control No 578082

This is to attest that for the cases submitted for Dr. Bhav for use of Theraspheres, he actively participated in the planning and administration under my supervision. This included clinical use of the delivery system, which followed training in the operation of the system provided by M.D.S. Nordion.

Please contact me if there are further questions.

A handwritten signature in cursive script, appearing to read "Janusz Kikut".

Janusz K. Kikut, MD.
Director of Nuclear Medicine and PET/CT
Associate Professor of Radiology and Nuclear Medicine
University of Vermont College of Medicine