



DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

OCT 12 2008

In Reply Refer To: 598/115HP/NLR

Steven Reynolds
Director, Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA

Dear Mr. Reynolds:

This letter is in follow-up to our telephone conference call today to discuss recent medical events that have been reported from four Veterans Health Administration (VHA) facilities. The medical events occurred for patients undergoing prostate brachytherapy procedures.

I recognize that standards are controversial among radiation oncology practitioners and societies. VHA is committed to ensuring that the Veterans receive the highest quality health care and I look forward to working with NRC in crafting a standard, so that VHA becomes a leader in the field of radiation oncology quality assurance.

By this letter, I am outlining VHA commitments for follow-up inspections and corrective actions to prevent recurrence of medical events. I agree to the specific commitments that are enclosed.

If you have any questions, please contact me (501) 257-1571.

Sincerely,

A handwritten signature in black ink, appearing to read "E. Lynn McGuire".

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

VHA Commitments for Prostate Brachytherapy Procedures

1. Complete inspections at all VHA facilities with active prostate brachytherapy procedures programs not later than January 30, 2009. Provide reports of the inspections to NRC.
2. Develop and implement standard procedures for prostate brachytherapy procedures programs to include, but not be limited to, the following:
 - a. Initial and periodic training for physician authorized users, medical physicists, dosimetrists, and Radiation Safety Officers and staff.
 - b. Training in medical events to include what is a medical event, how to identify a medical event, criteria to determine if specific patient circumstances are a medical event, and reporting requirements for a medical event.
 - c. Methods and procedures to verify seed placement is correct for determination of proper needle placements during prostate brachytherapy procedures, including appropriate imaging modality verifications.
 - d. Preparation and completion of written directives.
 - e. Methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post treatment dose analysis.
3. Review, evaluation, and resolution of data transfer problems that restricted post treatment dose analysis at VA Medical Center, Philadelphia, and G.V. (Sonny) Montgomery VA Medical Center, Jackson.
4. Identification and corrective action to prevent recurrence for root or basic causes that resulted in medical events.
5. Provide NRC definitive criteria to suspend a prostate brachytherapy procedures program not later than November 17, 2008. Use the following criteria until definitive criteria are established.

Upon determination that an unacceptable number of inadequate treatments have been performed, either on the basis of external reviews or NHPP inspection, the program will be immediately suspended. A criteria of number of medical events greater than 20% will be used to determine unacceptable performance.

6. Complete inspection by NHPP before restarting an inactive or suspended prostate brachytherapy procedures program to confirm VHA standard procedures in paragraph 2 above had been developed and implemented at the facility being inspected. Provide notification to NRC before restarting a prostate brachytherapy procedures program. The inspection will confirm training for authorized user physicians, medical physicists, dosimetrists, Radiation Safety Officer and staff, and others involved in the program and use the NHPP audit checklist.
7. Complete inspection by NHPP before approving a new prostate brachytherapy procedures program to confirm standard VHA standard procedures in paragraph 2 above had been

developed and implemented at the facility being inspected. Provide notification to NRC before approving a new prostate brachytherapy procedures program. The inspection will confirm training for authorized user physicians, medical physicists, dosimetrists, Radiation Safety Officer and staff, and others involved in the program and use the NHPP audit checklist.