

October 22, 2009

EA-09-038

Gary Williams, Interim Director  
National Health Physics Program (115 HP/NLR)  
Department of Veterans Affairs  
Veterans Health Administration  
2200 Fort Roots Drive  
North Little Rock, AR 72114

SUBJECT: STATUTE OF LIMITATIONS WAIVER REQUEST FOR APPARENT  
VIOLATIONS INVOLVING PROSTATE BRACHYTHERAPY TREATMENT AT  
PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER

Dear Mr. Williams:

By letter dated March 30, 2009, the U.S. Nuclear Regulatory Commission (NRC) notified the Department of Veterans Affairs (DVA) of the results of a special inspection conducted in response to multiple reported medical events involving prostate brachytherapy treatments at DVA's Philadelphia Veterans Affairs Medical Center (PVAMC). Based on the results of the inspection, a number of apparent violations were identified that are being considered for escalated enforcement action. The March 30 letter noted that the NRC had not made a final enforcement determination in these matters, and that the number and characterization of the apparent violations could change based on further review.

Based on our review of the circumstances of this case, a number of the reported medical events appear to have occurred outside the 5 year Federal statute of limitations (SOL) period, and the SOL for violations associated with several additional cases will expire in the next few months. Because the NRC is continuing to review data provided by DVA and by our medical consultant, it is likely that the 5 year SOL for these additional cases will expire before the NRC makes a final enforcement decision.

In order for the NRC to defer its decision on initiating enforcement action until the completion of our assessment of the significance of these medical events, the NRC requests that DVA waive the 5 year SOL for NRC enforcement action in this matter. The NRC requests that DVA waive the SOL for a period of 1 year for each of those cases where the SOL has not already expired. By waiving the SOL, the NRC would be able to review information provided by DVA and by our medical consultant, and arrive at a more fully-informed enforcement decision. Should you agree to waive the 5 year SOL, your right to request a hearing on the imposition of civil penalties or any other Order in this matter would be preserved. In addition, your agreement to waive the 5 year SOL does not in any way constitute or imply an agreement with the apparent violations associated with these medical events.

The NRC requests that DVA consider this request and inform my office in writing of your decision, with a copy to Mr. Mark Satorius in our Region III office, within 20 days of receipt of this letter. Should you determine not to waive the 5 year SOL, the NRC will proceed based on the information available to us at this time.

If you have any questions regarding this request to waive the 5 year SOL, please contact Mr. Greg Bowman, Senior Enforcement Specialist, at (301) 415-2939.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

Cynthia A. Carpenter, Director  
Office of Enforcement

Docket No.: 030-34325  
License No.: 03-23853-01VA  
Permit No.: 37-00062-07

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