



NRC NEWS

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NRC PROPOSES \$227,500 FINE AGAINST DEPARTMENT OF VETERANS AFFAIRS

The Nuclear Regulatory Commission has proposed a \$227,500 fine against the Department of Veterans Affairs (DVA) for violations of NRC regulations associated with an unprecedented number of medical errors identified at the Veterans Affairs Medical Center in Philadelphia (VA Philadelphia).

Medical errors at VA Philadelphia involved the incorrect placement of iodine-125 seeds to treat prostate cancer. Out of 116 procedures performed between 2002 and 2008, 97 were executed incorrectly.

“This substantial fine emphasizes the high significance of violations at the Philadelphia Veterans Affairs Medical Center that resulted in close to 100 of our nation’s veterans receiving substandard treatments,” said Mark Satorius, regional administrator for the NRC’s Region III office in Lisle, Ill. “The lack of management oversight, the lack of safety culture to ensure patients are treated safely, the potential consequences to the veterans who came to this facility and the sheer number of medical events show the gravity of these violations.”

This is one of the largest fines ever proposed by the NRC for medical errors. The principal violations, assessed at \$208,000, are associated with the lack of written procedures to provide high confidence that each treatment was implemented as prescribed and the lack of a procedure to verify that the treatment was implemented correctly. Additional violations, assessed at \$19,500, involve the wrong dose of radioactive seeds being ordered and implanted into a patient on May 5, 2008, because no procedure existed to verify correct implementation of treatment; the lack of training in the NRC’s definition of a medical event and associated reportability requirements; and the failure to report medical events to the NRC no later than the next calendar day.

The NRC responded aggressively and decisively when medical errors at the VA hospital in Philadelphia came to light in May 2008. The NRC dedicated a special team of inspectors to conduct extensive in-depth inspections to determine how 97 of 116 treatments could have been

executed incorrectly. In addition, the NRC hired an independent medical consultant to assess the impact of medical errors on patients. NRC inspectors determined a widespread programmatic breakdown had occurred within the cancer treatment program at VA Philadelphia. Inspection findings are documented in two inspection reports which can be accessed at the NRC web site: <http://www.nrc.gov/reading-rm/adams.html>. Use ML090900382 and ML093210599 as search terms.

The DVA took a number of corrective actions to address problems identified by the NRC at VA Philadelphia. They included suspending the VA Philadelphia prostate cancer treatment program; ordering external reviews; revising procedures; providing radiation safety training to oncology staff; instituting an internal quality assurance program; removing one individual from performing prostate cancer treatments at DVA facilities; and others. The VA Philadelphia prostate cancer treatment program will remain suspended and cannot be restarted without informing the NRC.

The NRC expanded its inspection efforts to other DVA facilities with prostate cancer treatment programs and the National Health Physics Program (NHPP), the DVA's regulatory arm responsible for the oversight of medical facilities. For the NRC to have confidence that other DVA facilities did not suffer from the severity of the problems found at VA Philadelphia, an expanded review of other DVA facilities was necessary. Even though NRC inspectors identified some concerns, they did not reach the level of the widespread programmatic breakdown that afflicted VA Philadelphia. In addition, the agency found it imperative to make an assessment regarding the NHPP's effectiveness as a regulator. The results of this inspection will be documented in a report to be issued later this year. If violations to NRC regulations are identified, the NRC will take appropriate enforcement actions.

The DVA has 30 days to either pay the proposed fine or challenge it.

The NRC's letter, its enclosures, and the DVA's response will be available to the public through the agency's public electronic reading room at: <http://www.nrc.gov/reading-rm/adams.html>. Help in accessing these documents is available from the NRC Public Document Room at 1-800-397-4209.

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