NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION
Office of Public Affairs Region III
2443 Warrenville Road
Lisle IL 60532

No. III-09-033
November 18, 2009

Contacts:
Viktoria Mitlyng 630-829-9662
Prema Chandrathil 630-829-9663
E-Mail: opa3@nrc.gov
Web site: www.nrc.gov

NRC COMPLETES INSPECTION OF MEDICAL ERRORS AT VETERANS AFFAIRS HOSPITAL IN PHILADELPHIA

A special inspection of multiple medical errors during prostate cancer treatments at the Philadelphia Veterans Affairs Medical Center (VA Philadelphia) has revealed eight apparent violations of Nuclear Regulatory Commission (NRC) regulations, the agency said on Wednesday. The agency will meet with VA officials Dec. 17 to discuss the issue before making any enforcement decisions.

Medical errors at VA Philadelphia involved the incorrect placement of iodine-125 seeds used to treat prostate cancer. The medical center's review of prostate cancer treatments had identified 98 medical errors out of the total of 116 treatments conducted on 114 veterans between 2002 and 2008.

"The health and safety of US veterans are of paramount importance to the agency," said Mark Satorius, regional administrator for NRC Region III Office, in Lisle, Ill. "The NRC mounted a comprehensive special inspection to determine what went wrong at VA Philadelphia. We discovered an absence of safety checks and balances. They must be in place to ensure safe and quality care for patients."

"The NRC expects licensees who use nuclear materials in medicine to do so responsibly. We hope learning from this experience will prevent such egregious errors in the future," Satorius added.

In its first phase, from July 2008 to February 2009, the NRC investigation reviewed the circumstances around the medical events, focusing on identifying programmatic weaknesses.

The second part of the inspection, from June 2009 – October 2009, focused on verifying the accuracy of radiation dose calculations provided to the NRC by VA Philadelphia.

The NRC inspection team reviewed final dose calculations for all 114 veterans treated at the facility (two patients received two treatments). Verifying radiation doses enabled the NRC to evaluate if the radiation dose prescribed matched the dose received. The accuracy of these records is vital for medical experts to assess the seriousness of injuries to patients, including the potential for continuing medical issues, increased risk of recurrence of cancer and the need for continuing patient follow up.

This issue first came to the NRC's attention in May 2008, followed by the discovery of more medical events at VA Philadelphia that involved delivery of a dose that was either 20 percent higher or lower than the prescribed dose or delivery to an unintended area.

The NRC hired a medical consultant to determine possible adverse health consequences to the patient that could be caused by medical errors. The consultant reviewed the dose records and other data of 39 patients; he stated that several patients experienced symptoms that could be related to the medical errors in their treatment, such as inflammation and damage to the lower parts of the colon, rectal bleeding and recurrence of cancer.

The NRC identified eight apparent violations. They are associated with the lack of procedures that would help ensure that each prostate cancer treatment adheres to the prescription written by the physician; absence of verification tools to ensure that the treatment was delivered as prescribed; failure to instruct personnel in identification and reporting requirements for medical events; failure to record the dose received by a patient on the doctors' prescription form; failure to make sure all written reports are complete and accurate; and failure to notify the NRC no later than the next calendar day after discovery of a medical event.

A predecisional enforcement conference between the NRC and the Department of Veterans Affairs (DVA) will be held on December 17, 2009, at 1 PM (EST), in the Commissioners' Conference Room, One White Flint North, 11555 Rockville Pike, Rockville, Md. This conference is being held to obtain information to assist the NRC in making an enforcement decision.

After the predecisional enforcement conference, the NRC will review the information received during the conference and the conclusions of the special inspection to determine what type of action will be taken against the Department of Veterans Affairs.

The reports documenting the findings of both parts of the special inspection and the reports of the medical consultant will be available through the NRC RIII Office of Public Affairs and at the NRC web site: http://www.nrc.gov/reading-rm/adams/web-based.html. The NRC will continue inspection efforts with the focus on other Veterans Affairs prostate cancer treatment programs and the National Health Physics Program.

###