U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

FACT SHEET

Office of Public Affairs
Phone: 301-415-8200
Email: opa.resource@nrc.gov

NRC'S Response to Medical Events at the Veterans Affairs Medical Center in Philadelphia, Pa.

Overview

The U.S. Nuclear Regulatory Commission (NRC) proposed a civil penalty in the amount of $227,500 against the Department of Veterans Affairs (DVA) on March 17, 2010 for eight violations of NRC requirements that resulted in nearly 100 medical errors.

The NRC responded aggressively and decisively as soon as the agency became aware of the potential problems at the Veterans Affairs (VA) hospital in Philadelphia. The health and safety of this nation's veterans is of paramount importance to the NRC, and the agency committed all necessary resources to identify and address the failures at the VA hospital in Philadelphia as well as other DVA hospitals to prevent recurrence.

The VA hospital in Philadelphia had failed to report 97 medical errors out of 116 prostate cancer treatment procedures performed between 2002 and 2008. The medical errors involved the incorrect placement of iodine-125 seeds. The Philadelphia brachytherapy program has been suspended since June 2008. At this time, there are no plans to restart the program.

For close to two years, the NRC had conducted extensive inspections to determine how 97 out of 116 procedures could have been executed incorrectly. As new information came to light the NRC expanded it efforts to obtain a clear picture of what went wrong and ensure a thorough review. A team of NRC inspectors was dedicated to getting to the bottom of the problems at the VA hospital in Philadelphia. They reviewed the circumstances surrounding the cases; looked at physicians' reports, treatment plans, and dose calculations; conducted interviews with VA staff; and analyzed the information they had collected. An independent medical consultant was hired to evaluate the impact of these medical errors on the health of the patients. The NRC team of inspectors returned many times to the VA hospital in Philadelphia to clarify issues and gather additional information. After more than 2,000 inspection hours, the NRC team was able to piece together the big picture of the failures that resulted in an unprecedented number of medical errors.

NRC inspectors found a substantial programmatic breakdown in the VA Philadelphia brachytherapy program. The doctors, medical physicists, and radiation safety staff allowed a substandard approach to brachytherapy treatments, which resulted in medical errors; they allowed a patient dose assessment process that lacked rigor and consistency; and did nothing to address the failure to communicate concerns about the quality of procedures, or perform safety checks due to assumptions that someone else was performing them. NRC inspectors concluded that the overall program at the VA hospital in Philadelphia lacked focus and commitment to safety.

After the NRC team had a clear picture and a firm understanding of where the breakdowns were the agency issued eight apparent violations. The NRC held a public enforcement conference in Washington D.C. to provide the DVA with an opportunity to present any additional information to the agency before a final decision was made.

Summary of Findings

- Two violations deal with multiple medical events[1] which occurred over the course of a six year period, due to an inadequate brachytherapy implant program. The violation is separated into two parts to address those violations within the Statute of Limitations and those where the Statute of Limitations had already expired.

- A violation for multiple examples in 2007 where the VA Philadelphia did not perform post-treatment plan verifications due to malfunctioning equipment and then continued to treat patients knowing that the equipment was malfunctioning.

- A violation for a single instance where the wrong dose of radioactive seeds were ordered and implanted in a patient.

- Failure to train staff and authorized users in reporting of medical events as required by NRC regulations. These problems were combined into a single violation because the same issues led to the lack of training for the staff, which performed the brachytherapy procedures.

- A violation for failure to notify the NRC when sufficient information existed to show that a medical error occurred.

- A violation for a failure to specify the implant treatment site, total radioactive seed dose, number of seeds, and the radionuclide on the written treatment plan, during the period after source implantation of the seeds but before completion of the procedure.

A failure by the DVA to provide complete information, required by NRC regulations, when it submitted required written reports to the NRC regarding its medical events.

Background

Department of Veterans Affairs - Holds a master materials license, issued by the NRC March 2003. A master license is issued to a federal organization and authorizes the use of radioactive material at multiple sites. A master materials license authorizes the VA to issue permits for the possession and use of licensed material at its hospitals and medical centers, and ties the licensee to a framework of oversight consistent with NRC regulations, inspection, licensing, enforcement policies, procedures, and guidance.

[1] The DVA reported a total of 97 different medical events beginning on October 25, 2002, and continuing through May 12, 2008. At the time these medical events were first reported to the NRC, in May 2008, the Statute of Limitations had already expired on several cases. As the NRC and the DVA continued to review the extent of condition, additional cases passed beyond the Statute of Limitations. On October 22, 2009, following consultation with the Commission (SECY 09-0132), the NRC requested that the DVA grant a waiver to the Statute of Limitations. On November 6, 2009, the DVA agreed to a waiver of the Statute of Limitations for a period of one year for those cases where the Statute of Limitations had not already expired.

VA National Radiation Safety Committee - Has responsibility for providing oversight of the VA's implementation of its license and associated activities. The Committee has delegated the authority to manage the VA radiation safety program to its National Health Physics Program.

National Health Physics Program - Is the VA regulatory organization responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.

Nuclear Regulatory Commission - The agency's regional office based in Lisle, Ill., has regulatory oversight of the VA's master materials license, which includes the National Radiation Safety Committee and the National Health Physics Program. The NRC does not have the responsibility for day-to-day oversight of VA medical procedures with radioactive materials because that entails examining patient records without cause, raising privacy issues. That responsibility lies with the VA's National Radiation Safety Committee and the National Health Physics Program. Failing to report a medical mistake is a violation of NRC regulations.

Timeline of Events

February 2002- Philadelphia Veterans Affairs Medical Center (VA Philadelphia) starts prostate cancer treatment (brachytherapy) program under NRC Agreement State Program

March 2003- A master materials license (MML) is issued to the Department of Veterans Affairs (DVA) by NRC. The VA Philadelphia operates under the DVA MML

May 2008- The DVA starts identifying and reporting medical errors at VA Philadelphia to the NRC. By December 2008 the DVA has reported a total of 97 medical errors to the NRC

June 2008- VA Philadelphia brachytherapy program is suspended

July 2008 to February 2009- NRC conducts a special inspection at VA Philadelphia in response to the multiple medical errors involving brachytherapy treatments. The results of this inspection are documented in the NRC Special Inspection Report issued March 30, 2009 (ML090900382)

September 2008- NRC requests assistance of a medical consultant. The results of these inspections are documented in two reports (ML083650335) and (ML093020636)

October 2008- As a result of other VA facilities identifying similar medical errors, the NRC issues a Confirmatory Action Letter (CAL) to the VA confirming corrective actions will be implemented prior to restarting the brachytherapy programs (ML082880717)

May 2009- NRC issues a Demand for Information to Dr. Kao to obtain specific commitments regarding his current and future involvement in NRC regulated activities (ML091460732)

June 2009- October 2009- NRC expands its ongoing special inspection and begins the second part of the inspection which focuses on verifying the accuracy of radiation dose calculations provided to the NRC by VA Philadelphia between February 2002 and June 2008. The results of this inspection are documented in the NRC Inspection Report which was issued November 17, 2009 (ML093210599)

December 2009- NRC holds a pre-decisional enforcement conference with the DVA to provide them with an opportunity to present any additional or new information to the NRC before a final decision is made.

March 2010- NRC proposes a $227,500 fine against the DVA (ML100710692)

The VA Philadelphia brachytherapy program remains suspended with no future plans for restart. If the DVA wants to restart the program they must effectively address all problems identified by the NRC.

Inspection Details

Immediately after the NRC was notified in May 2008, the agency took action and maintained close oversight of the VA and National Health Physics Program inspection of the medical errors. Shortly after, the NRC conducted its own thorough inspection at the facility. Based on the preliminary findings and the continued number of medical errors reported, the NRC launched a Special Inspection at the hospital in September 2008. In October 2008, the NRC issued a Confirmatory Action Letter (CAL). The CAL documents the commitments made by the VA to identify and address the problems that have led to these medical errors at VA hospitals and to prevent their recurrence.

The Confirmatory Action Letter commitments of the National Health Physics Program include:

- conducting inspections at all 13 VA hospitals authorized to perform prostate cancer treatments
- developing and implementing standardized procedures for prostate cancer treatments at all VA hospitals
- identifying causes of the medical events and implementing corrective actions
- suspending any prostate cancer treatment program where 20% or more of the treatments have been identified as medical events
- conducting an inspection to confirm that all necessary corrective actions have been taken prior to restarting any suspended cancer treatment program
- notifying the NRC when program restart is planned
- conducting an inspection of new prostate cancer treatment programs before they start to confirm they meet the enhanced standards

The NRC Special Inspection, Part 1, focused on:

- conducting on-site inspections at the VA hospital in Philadelphia and all of the VA hospitals authorized to perform prostate cancer treatments
- reviewing the circumstances surrounding the multiple medical events at the VA hospital in Philadelphia
- assessing prostate programs at the other VA facilities
- assessing the response of the National Health Physics Program to these events
- determining whether the problems at the VA center in Philadelphia could be affecting other medical facilities
- using a medical consultant to conduct an independent assessment of possible health effects on patients

The NRC Special Inspection, Part 2, focused on:

- assessing the final dose estimations for all 114 patients who received prostate brachytherapy treatments
- using a medical consultant to review the health significance of these events on patients
- conducting additional on-site inspections at the VA hospital in Philadelphia
- assessing the VA's corrective actions to prevent recurrence reviewing new information related to the multiple medical events at the VA hospital in Philadelphia

Ongoing Actions

The NRC's inspection efforts did not stop with the VA hospital in Philadelphia, the agency questioned the state of the other VA hospitals and expanded its inspections to other facilities. This top to bottom review looked at the quality of the implant, the extent to which equipment is available and used to check the radiation dose to patients after treatment, ensure procedures and policies are in place and how they determine and document problems.

NRC findings associated with these inspections will be documented in a report issued later this year. If the NRC determines there are problems, at the other VA hospitals with prostate treatment programs or with the National Health Physics Program (NHPP), the problems may warrant additional enforcement actions.

If the DVA decides to restart the program the VA hospital in Philadelphia will need to demonstrate to the NRC that it has addressed the eight violations and NRC's concerns regarding safety culture.

The NRC's focus will remain steadfast on ensuring that nuclear material for treating patients will be used in a safe manner.

Veterans Affairs Hospitals with a Prostate Treatment Program

Samuel S. Stratton VA Medical Center, Albany, N.Y.
VA Medical Center Philadelphia, Pa.*
VA Boston Healthcare System, Boston, Mass.
VA N.Y. Harbor Healthcare System, Brooklyn, N.Y.
VA Medical Center, Cincinnati, Ohio
VA Medical Center, Durham, N.C.
G.V. (Sonny) Montgomery VA Medical Center, Jackson, Miss.*
VA Greater Los Angeles Healthcare System, Los Angeles, Calif.*
VA Medical Center, Minneapolis, Minn.
Hunter Holmes McGuire VA Medical Center, Richmond, Va.
VA Medical Center, San Francisco, Calif.
VA Puget Sound Health Care System, Seattle, Wash.
VA Medical Center, Washington, D.C.*

*Program Suspended

List of Important Documents

Document	Adams Accession Number
NRC Inspection Report dated 6/30/03 (2003 Event)	ML031820592
VA Medical Event Report dated 10/19/05 (2005 Event)	ML052970407
NRC Confirmatory Action Letter (CAL) 10/14/08	ML082880717
VA Final Patient Dose Assessment Data dated 10/29/09	ML093080147
NRC's Medical Consultant Report dated 12/22/08	ML083650335
NRC's Medical Consultant Report dated 10/12/09	ML093020636

NRC Inspection Report dated 3/30/09	ML090900382
NRC Inspection Report dated 11/17/09	ML093210599
NRC Notice of Significant Licensee Meeting 12/03/09	ML093360545
NRC Notice of Significant Licensee Meeting (revised) 12/08/09	ML093420061
NRC Demand For Information (Dr. Kao) 5/26/09	ML091460732
NRC Demand For Information Response (Dr. Kao) 5/28/09	ML091871017
VA Pre-decisional Conference (PEC) Slides (12/17/09 PEC)	ML093490891
NRC PEC Slides (12/17/09 PEC)	ML093490877
VA Response to PEC dated 1/14/10	ML100150326
VA Proposal to Retract Medical Events dated 1/29/10	ML100331994
Notification of Significant Enforcement Action EN 10-014; EA-09-038	ML100700572
Notice of Violation and Imposition of Civil Penalty EA-09-038	ML100710692

Select link to access Agencywide Documents Access and Management System (ADAMS) http://www.nrc.gov/reading-rm/adams.html.

March 2010