

March 11, 2010
EN 10-014

OFFICE OF ENFORCEMENT
NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION

Licensee: Department of Veterans Affairs (DVA)
Docket No.: 03034325

EA-09-038

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$227,500

This is to inform the Commission that a Notice of Violation (Notice) and Proposed Imposition of a Civil Penalty in the amount of \$227,500 will be issued on or about March 17, 2010, to the Department of Veterans Affairs (DVA), a master materials licensee, for numerous medical events which occurred at the Philadelphia Veterans Affairs Medical Center (PVAMC). The Notice of Violation contains:

- Two Severity Level II violations of 10 CFR 35.41(a)(2) to address multiple medical events¹ which occurred over the course of a six year period, due to an inadequate prostate 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 Severity Level II violation of 10 CFR 35.41(b)(2) for multiple examples in 2007 where the licensee did not perform post-treatment verifications due to malfunctioning equipment and continued to treat patients knowing that the equipment was malfunctioning.
- A second violation of 10 CFR 35.41(b)(2), characterized at Severity Level III, as it involved a single instance where the wrong dose seeds were ordered and implanted in a patient. Because this case stemmed from a separate root cause, it was not combined with the previous violation of 35.41(b)(2).

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.

- A Severity Level III problem for failure to train staff and authorized users in reporting of medical events as required by 10 CFR 35.27(a)(1) and 10 CFR 19.12(a)(4). These violations were combined into a single problem because the same root cause led to the lack of training for the staff, who performed the brachytherapy procedures.
- Finally, the staff cited a Severity Level III violation of 10 CFR 35.3045(c) for failure to notify the NRC when sufficient information existed to show that a medical event occurred.
- Two Severity Level IV violations are also cited. Specifically, a violation of 10 CFR 35.40(b)(6)(ii) is cited for a single failure to specify the implant treatment site, total source strength and exposure time (or total dose), number of sources, and the radionuclide on the written directive, during the period after source implantation but before completion of the procedure. Further, the DVA failed to provide complete information when it submitted required written reports to the NRC regarding its medical events. Specifically, DVA reports failed to provide the information required pursuant to 10 CFR 35.3045(d).

The staff considered whether credit was warranted for Identification and Corrective Action in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The DVA has been the subject of escalated enforcement action within the last two years,² therefore the staff considered whether Identification credit was warranted. Credit was not warranted for Identification because the staff determined that, although DVA identified many of the same violations, NRC inspectors identified the overall substantial programmatic breakdown and provided considerable intervention to ensure that the licensee evaluated the significance of the violations. Further, the staff determined that credit was warranted for Corrective Actions which included, but were not limited to, (1) suspending the PVAMC brachytherapy program and not permitting restart without approval by the DVA's MML oversight program, (2) revising the PVAMC procedures, and (3) providing training to PVAMC staff and contractors on NRC's reporting requirements. The staff recognized, however, that routine application of the Enforcement Policy did not provide an appropriate emphasis to the DVA regarding the significance of PVAMC's particularly poor performance over the course of multiple years which led to numerous medical events occurring, without being identified, reported or corrected. Therefore, the staff determined that use of discretion to escalate the civil penalty was appropriate. The approach agreed to by the staff was to apply a single maximum statutory daily civil penalty amount to each of the Severity Level II violations and to apply a base civil penalty to the two Severity III violations and the Severity Level III problem. Therefore, to emphasize the importance of performing brachytherapy procedures in accordance with the written directive, evaluating the acceptability of the procedures, and training personnel on NRC requirements, the NRC staff proposes imposition of a Civil Penalty in the amount of \$227,500 for the two Severity Level II violations, two Severity Level III violations and the single Severity Level III problem.

² The NRC issued a SL III violation with proposed civil penalty of \$6500 on April 10, 2009, to the DVA based on actions at the Iowa City Medical Center (EA-08-353). The NRC imposed the civil penalty in an Order dated August 14, 2009. The licensee paid the civil penalty on August 28, 2009.

It should be noted that the licensee has not been specifically informed of the enforcement action. The schedule of issuance and notification is:

Mailing of Notice	March 17, 2010
Telephone Notification of Licensee	March 17, 2010

The Commonwealth of Pennsylvania will be notified.

The licensee has thirty days from the date of the Notice in which to respond. Following NRC evaluation of the response, the civil penalty may be remitted, mitigated, or imposed by Order.

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