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WRITTEN TESTIMONY
FOR STEVEN REYNOLDS
DIRECTOR,
DIVISION OF NUCLEAR MATERIALS SAFETY
REGION III
UNITED STATES NUCLEAR REGULATORY COMMISSION
TO THE
COMMITTEE ON VETERANS' AFFAIRS
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
UNITED STATES HOUSE OF REPRESENTATIVES
CONCERNING THE PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER

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INTRODUCTION

Chairman Mitchell, Ranking Member Roe, and Members of the Committee, I am honored to appear before you today to discuss the U.S. Nuclear Regulatory Commission's (NRC) regulatory role, actions, and findings to date regarding medical events at the U. S. Department of Veterans Affairs hospitals, particularly the Veterans Affairs Medical Center in Philadelphia, Pennsylvania (VA Philadelphia). I hope that my testimony will be helpful to the Committee's work.

NRC'S REGULATORY ROLE

The NRC is an independent agency created by Congress to license and regulate the civilian use of radioactive materials. The NRC issues licenses to facilities that authorize the safe and secure possession and use of radioactive material. In the nuclear medicine area, the NRC does not regulate the practice of medicine. NRC's regulations seek to ensure the adequate protection of those working with radioactive material, as well as the public and the environment, and that the patient receives the radiation dose intended and prescribed by the medical practitioner.

The NRC has a specific set of regulatory requirements for the medical use of radioactive materials. These regulations include the definition, criteria, and reporting requirements for medical events. Prior to 2002, the term "misadministration" was used in the regulations to describe these events. The NRC replaced the term "misadministration" with "medical event" as this term more correctly and simply conveys that the radioactive material or the radiation from the material, was not delivered as directed by the physician.

The NRC requires licensees to report a medical event because such an event indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. Actual harm to a patient, whether it is an injury from overexposure or inadequate treatment due to underexposure, must be determined through a separate analysis by a physician. In severe events, when the dose error is well over 20 percent too high or too low, such as the events that occurred at the VA Philadelphia, NRC inspection teams are supplemented with a medical consultant, who is a licensed physician. The medical consultant assesses the patient's risk of harm.

The agency's Region III office, based in Lisle, Illinois, provides regulatory oversight of the Department of Veterans Affairs' license. The VA was issued a master materials license (MML) in March 2003. An MML is issued only to Federal government agencies or departments and authorizes the use of radioactive material at multiple sites. The holder of the MML is responsible for ensuring that NRC requirements are met. Prior to issuance of the MML, the NRC issued a separate license to each VA site throughout the United States. The VA's license requires the VA to establish an internal, independent framework of oversight consistent with NRC regulations, and with inspection and enforcement policies, procedures, and guidance. Within this framework, the responsibility for patient safety and day-to-day oversight of VA medical procedures using radioactive materials lies with the VA's National Radiation Safety Committee. The VA's National Health Physics Program (NHPP) acts as the VA's regulatory organization and is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.

BACKGROUND OF THE VA MEDICAL CENTER IN PHILADELPHIA

VA Philadelphia began performing permanent implant prostate brachytherapy in 2002, using contracted doctors from the University of Pennsylvania Hospital. The NRC received a report of a potential medical event in 2003. The NRC conducted an inspection and examined the record of the event, as well as the procedures for prostate implants, and interviewed the physician involved but did not identify any violations of NRC regulations. In 2005, a similar potential medical event was reported to the VA's NHPP. The NRC was informed of the event and evaluated the performance of the NHPP inspectors by observing the NHPP inspection of the event. NHPP did not identify any violations at VA Philadelphia.

On May 18, 2008, the NRC received notification of a potential medical event from the VA that a patient undergoing treatment for prostate cancer at the VA Philadelphia received a dose that was over 20 percent lower than what was prescribed.

In response to this prostate underdose at VA Philadelphia, the NHPP conducted an inspection at the facility in May 2008. Based on the preliminary inspection findings, the NHPP requested VA Philadelphia to review more prostate brachytherapy treatments. Ultimately, all 116 prostate brachytherapy treatments performed since the inception of the program were reviewed by the VA.

NRC'S RESPONSE TO DATE

NRC closely followed the initial actions of the VA Philadelphia and the NHPP and, based on additional potential events, determined that it was necessary to accelerate our direct involvement.

First, the NRC conducted an independent inspection at VA Philadelphia in July 2008. Second, based on the NRC's preliminary inspection findings and the growing number of potential medical events, the NRC launched a Special Inspection in September 2008. The NRC's ongoing Special Inspection was tasked to:

- conduct further on-site inspections at the VA Philadelphia;
- conduct on-site inspections at all of the VA hospitals authorized to perform prostate brachytherapy treatments;
- review the circumstances surrounding the multiple medical events at the VA Philadelphia;
- assess prostate brachytherapy programs at the other VA facilities;
- assess the performance of the NHPP;
- determine whether the problems at the VA Philadelphia could be affecting other medical facilities; and
- conduct, with the assistance of a medical consultant, an independent assessment of possible health effects on patients who had received the wrong doses.

Third, in October 2008, the NRC issued a Confirmatory Action Letter to the VA, which confirms commitments made to the NRC by the VA to identify, address, and prevent the problems that have led to these medical events, including the following actions:

- conduct NHPP inspections at all 13 VA hospitals authorized to perform prostate brachytherapy treatments;
- develop and implement standardized procedures for prostate brachytherapy treatments at all VA hospitals;
- identify causes of the medical events and implement corrective actions;
- suspend any prostate brachytherapy treatment program where 20 percent or more of the treatments have been identified as medical events;
- conduct an inspection to confirm that all necessary corrective actions have been taken prior to restarting any suspended brachytherapy treatment program; and
- conduct an inspection of new prostate brachytherapy treatment programs prior to start up to confirm they meet the enhanced standards.

Because the physician conducting many of the prostrate brachytherapy treatments also worked at a local hospital, the Commonwealth of Pennsylvania and the local hospital were notified.

The NRC will verify through inspections that the commitments in the Confirmatory Action Letter have been successfully completed. The VA has agreed not to restart prostate brachytherapy treatment programs at five sites, including the VA Philadelphia, until all commitments have been met.

Fourth, on March 30, 2009, the NRC issued a Special Inspection Report on the medical events at the Philadelphia VA that identified six apparent violations of NRC regulations: (1) the failure to develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive; (2) the failure to develop procedures that address methods for verifying that administration is in accordance with the treatment plan and written directive; (3) the failure to train supervised individuals regarding identification and reporting requirements for medical events; (4) the failure to instruct a non-supervised individual regarding identification and reporting of medical events; (5) the failure to record total dose received by a patient on a written directive; and, (6) the failure to provide required information in several 15-day reports to the NRC. In addition to these apparent violations, the NRC identified concerns involving inadequate management oversight by the Radiation Safety Officer

and the Radiation Safety Committee at VA Philadelphia, and a pattern of unreported safety concerns.

Finally, in response to a Demand For Information issued to him by the NRC, the physician who performed the majority of the brachytherapy treatments at the VA Philadelphia, confirmed that he is currently not performing these treatments at any facility – VA or otherwise. He has also confirmed that he would give prior notification to the NRC if and when he resumes these treatments.

FUTURE NRC ACTIONS

The NRC is continuing to review the events at VA Philadelphia. We plan to issue separate Special Inspection reports that will address the findings of the inspections conducted at VA Philadelphia and at the other VA facilities authorized to perform prostate brachytherapy treatments, and the NHPP's performance at the conclusion of these inspection activities. As part of our response, the agency will consider what enforcement actions are warranted in these cases. The NRC will also notify all facilities administering this type of treatment about findings from these inspections that may inform their practice and where there may be common implications for the medical community and other stakeholders. These actions will be publicly available.

The NRC will apply the findings of our evaluations to our own regulatory practices. In this case, two areas that we have identified so far as needing increased NRC attention are licensee oversight of contract doctors and the safety culture at materials licensees. We will continue to look critically at our licensing and inspection program to determine what enhancements are needed. The NRC is also assessing whether any specific changes may be needed to strengthen our regulatory oversight of the VA's MML with respect to both the VA's internal regulatory framework and the NRC's regulatory practices.

Prior to the current events at the VA, the NRC had been evaluating, with input from the nuclear medicine community and other stakeholders, a proposed change to our regulations that may prohibit physicians from changing written treatment orders after the procedure begins. The issue of changing these orders during procedures was identified as a concern in the practice at the VA Philadelphia.

CONCLUSION

The NRC takes these medical events very seriously and continues our in-depth inspection. Once we have completed this work, we will evaluate the VA's response to our findings and determine what enforcement actions are warranted. Thank you for the opportunity to testify here today. I would be pleased to respond to your questions.