January 18, 2010

The Honorable Arlen Specter
United States Senate
Washington, D.C. 20510

Dear Senator Specter:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of December 1, 2009, in which you expressed concerns about issues that were raised in a November 15, 2009, article published in the *Philadelphia Inquirer* regarding the prostate brachytherapy program at the Philadelphia VA Medical Center (PVAMC).

The NRC sets the rules under which licensees such as the Department of Veterans Affairs (DVA) use radioactive materials. As a regulating agency, the NRC is responsible for developing the rules and requirements that, when followed, ensure the safe use of radioactive material in medical treatments. In addition, we have an obligation to oversee the use of radioactive material by implementing inspection and enforcement programs. Our regulations require that patients receive the treatment prescribed by their physicians. The NRC regulations also require that authorized physicians have appropriate training in the use of radioactive material and applicable NRC regulations. The NRC does not, however, regulate the practice of medicine.

Prior to the summer of 2008, when the NRC learned of the multiple medical events at the PVAMC, the DVA reported two treatments as possible medical events, one in February 2003, and the other in October 2005. Generally speaking, a medical event is the result of the actual treatment to the patient being significantly different than what the physician prescribed. Immediately following notification of these events, the NRC conducted an inspection for the 2003 treatment and accompanied the DVA's National Health Physics Program (NHPP) inspector during the inspection of the 2005 treatment. Both of these inspections were limited in scope to the circumstances surrounding the apparent medical events, and complemented the NRC's and NHPP's periodic, broader programmatic inspections of the licensed activities. In both cases, a large fraction of seed implants were placed in the patients' bladders instead of their prostates. The seeds were removed from the patients' bladders while the patients remained in the operating room, and the physician revised the prescription (written directive) to indicate the actual number of seeds implanted in the patients' prostates and the misplaced seeds removed from the patients' bladders. The NRC (for the 2003 treatment) and the DVA's NHPP (for the 2005 treatment) evaluated the circumstances of these events and determined that they did not constitute medical events as defined by Title 10 *Code of Federal Regulations* (CFR) 35.3045 or violations because the misplaced seeds were removed from the patients' bladders while the patient remained in the operating room, and the physician revised the prescription (written directive) to indicate the actual number of seeds implanted in the patients' prostates. Therefore, an accurate count of the number of seeds and the radioactive dose applied to the prostate were recorded.

Based on the information gained during the inspections of the 2003 and 2005 events, there was not sufficient evidence to identify programmatic weaknesses in the prostate brachytherapy program at the PVAMC and thus to recommend program suspension. It is the responsibility of the DVA, under the terms of its NRC-issued Master Materials License, to identify problems in medical treatments using radioactive material, to report those problems, and take necessary corrective action.

After being notified in 2008 of multiple medical events, the NRC promptly dispatched an inspection team to the PVAMC and issued a Confirmatory Action Letter to the DVA dated October 14, 2008, that affirms DVA's commitments to institute additional safety measures at all of the DVA facilities that conducted brachytherapy procedures. The NRC inspections were conducted onsite at the PVAMC on July 23-25, 2008; September 9-12, 2008; June 22-26, 2009; August 27-28, 2009; and October 14-16, 2009. The results of NRC inspections are documented in inspection reports issued March 30, 2009, and November 17, 2009. The NRC has still-unresolved concerns regarding the DVA's compliance with NRC safety requirements. On December 17, 2009, the NRC held a predecisional enforcement conference to discuss the multiple medical events and the associated eight apparent violations identified at the PVAMC. The NRC expects the DVA to address these concerns and implement necessary corrective actions to comply with 10 CFR Part 35 prior to resuming prostate brachytherapy at PVAMC. Enforcement action by the NRC is still pending.

As a result of recent events involving therapeutic use of byproduct material, along with advice from the Advisory Committee on the Medical Uses of Isotopes, the NRC has reconsidered the appropriateness and adequacy of the regulations for medical events and written directives. Among the issues identified was the lack of clarity as to when and how certain information is to be entered into the written directive. Rulemaking is in progress to amend the NRC's regulations regarding reporting of medical events involving permanent implant brachytherapy to address this and related issues.

In addition to the comprehensive review of the events at the PVAMC, the NRC has conducted extensive reviews of the DVA's oversight of prostate brachytherapy across the country and assessments of those reviews are ongoing. We have also initiated steps to enhance our oversight of all NRC materials licensees, including increasing our focus on the safety culture at medical facilities, increasing the focus on medical facilities' oversight of contracted medical professionals, and increasing the focus on extent of condition reviews. In addition, we will soon begin an internal review of the NRC's response to the events at the PVAMC. The assessment of those reviews will be used to determine what, if any, changes should be made to the NRC's oversight of brachytherapy procedures performed by all NRC licensees.

As always, the NRC will continue to monitor events for trends and take action when there are issues that may impact patient safety.

The NRC staff is available to provide a briefing for you or your staff, if you desire. If this would be helpful, please have your staff contact Rebecca Schmidt, Director, Office of Congressional Affairs, at 301-415-1776.

Sincerely,

/RA/

Gregory B. Jaczko