DEPARTMENT OF VETERANS AFFAIRS
UNDER SECRETARY FOR HEALTH
WASHINGTON DC 20420

JAN 1 4 2010

Mr. Steven A. Reynolds
Director, Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: NRC License 03-23853-01VA; EA-09-038

Dear Mr. Reynolds:

This is in response to your letter dated December 24, 2009, that outlined the Nuclear Regulatory Commission's (NRC) expectations for follow-up to the pre-decisional enforcement conference for the Department of Veterans Affairs (VA) Medical Center in Philadelphia. The pre-decisional enforcement conference was held on December 17, 2009. This letter provides the consolidated position of the Veterans Health Administration.

I reviewed with the medical center the apparent violations in the NRC inspection report that was dated November 17, 2009, and the subjects discussed at the pre-decisional enforcement conference.

I accept the violations in the NRC report with two exceptions. I do not agree that the apparent violations related to 15-day written reports and the medical center's failure to properly complete a written directive should be considered for escalated enforcement.

I am enclosing VA's assessment of the apparent violations cited in the NRC inspection report. This enclosure provides context and clarification for the apparent violations that I request you consider before making a final enforcement determination. The enclosure also addresses concerns identified in your inspection report.

As a related issue for the previously reported medical events (while noting that a medical event does not necessarily reflect patient harm), a proposal will be submitted not later than January 29, 2010 to retract approximately three-fourths of those events. This proposal is based upon the finding that D90 is not a widely accepted criterion for regulatory evaluation. Furthermore, a blue ribbon panel of external experts has recommended medical event criteria for the treatment site, which are derived from an imaging review of seed localization, as compared to the intended treatment volume.

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The proposed new criteria follow from the NRC Advisory Committee on the Medical Use of Isotopes (ACMUI) 2005 recommendations that absorbed dose criteria, developed for clinical uses, provide dose data which are both imprecise and too subjective for regulatory reviews.

Thus, the D90 criteria that were previously used by the medical center for medical event reporting will be replaced by more appropriate criteria. Our review of the previously reported medical events under these new criteria better reflects the overall effectiveness of our brachytherapy treatments, since the ongoing reviews by clinical experts have not identified an overall increased rate of adverse outcomes for the patients.

The medical center continues to strengthen the radiation safety program and ensure future uses of radioactive materials achieve regulatory compliance. Further, the medical center understands the requirement to focus on a safety culture, to increase management oversight, and to avoid undue reliance on affiliates or outside consultants. Please contact me if you have any questions or comments.

Sincerely,

Gerald M. Cross, MD, FAAFP
Acting

Enclosure

The following paragraphs provide a status for the apparent violations and concerns in the Nuclear Regulatory Commission (NRC) inspection report dated November 17, 2009. Additional information is provided to help clarify circumstances for each of the apparent violations and concerns. The comments refer to the National Health Physics Program (NHPP) and VA Medical Center, Philadelphia.

1. Apparent violations related to lack of adequate and sufficient written procedures.

a. The three apparent violations are accepted as stated.

b. NHPP considers the violations to be similar and had cited the medical center as one violation under 10 CFR 35.41(a) and one violation under 10 CFR 35.41(b). For the NRC disposition of these apparent violations, NHPP recommends NRC combine the two violations that are under 10 CFR 35.41(b).

c. The primary corrective action was to suspend patient treatments using prostate seed implants.

d. The medical center sealed source policy has been based on an activity metric. Corrective actions are listed in the NRC inspection report that is dated November 17, 2009. The report refers to an earlier NRC report and an NHPP report.

e. The medical center does not plan to restart patient treatments with prostate seed implants. If restart is considered in the future, the medical center will undergo a restart process established by the National Radiation Safety Committee. This process includes implementation of standard procedures that address root causes identified during the NHPP inspection in 2008 and medical center internal reviews.

2. Apparent violation related to training for two supervised individuals.

a. The apparent violation is accepted as stated.

b. The medical center had identified some limited training documentation for various staff but does not offer those records as adequate and sufficient objective evidence that training was completed as normally expected for a radiation safety program.

(1) NRC requested submission of such records as follow-up to the pre-decisional enforcement conference on December 17, 2009.

(2) The medical center reference was to documents that had been sent to NRC on March 17, 2009, by facsimile, and to additional recently discovered documents.

(3) Based on this current understanding that the records do not support a conclusion that training documents were adequate, the medical center is preparing a 'roadmap' summary with the training documents for submission to NHPP and to be available to the NRC, if requested.

c. The medical center has concluded that the overall context of interactions with the board certified physician authorized users and the board certified medical physicists established that these staff had more than an adequate working understanding of regulatory requirements including those for identification and reporting of medical events.

d. As part of the corrective actions, the medical center has included all contract medical physicists and other contract personnel in facility-mandated training regarding NRC regulations and reporting requirements for radiation

oncology. The medical center has also initiated a schedule of regular training sessions of all radiation oncology staff in regulatory and local policy. Radiation oncology has reviewed and amended local policy and practice to incorporate chart review and peer reviews to address medical issues and safety concerns.

e. Training in the definition of a medical event occurred at multiple Radiation Safety Committee meetings and was provided to all radiation oncology staff. Such training is also a continuing educational function. The Radiation Oncology Department has included medical physicists as part of departmental quality assurance functions.

3. Apparent violation related to instructing a non-supervised individual.

a. The apparent violation is accepted as stated.

b. See comments in paragraph 2 above.

4. Apparent violation related to completion of a written directive.

a. The apparent violation is accepted as stated.

b. NHPP does not consider the violation, if viewed separately, to represent a basis for escalated enforcement.

c. The medical center acknowledges this violation as a one-time event as confirmed by the comprehensive review of all other procedures at the medical center.

d. The failure to complete the written directive was acknowledged by the authorized user as an oversight. Corrective action has been taken in that this authorized user has received training in proper procedure.

5. Apparent violation related to 15-day written reports.

a. The apparent violation is accepted as stated.

b. NHPP does not consider the violation, if viewed separately, to represent a basis for escalated enforcement.

c. The apparent violation is related to completeness and accuracy of information provided to NRC under 10 CFR 35.3045 (d).

d. NRC published in the *Federal Register* (Volume 67, No. 79, April 24, 2002), Statements of Consideration on reporting of a medical event under 10 CFR 35.3045. As quoted, "We reworded these paragraphs to read 'the effect, if any, on the individual' and 'what actions, if any, have been taken or are planned, to prevent recurrence.' The words 'if any' and 'are planned' were added because there might not be any effect or any actions taken at the time the event is reported."

e. The medical center communicated to the NRC as early as their first reactive inspection in June 2008 that the medical center had commenced a comprehensive evaluation of prostate seed implants. This effort entailed a comprehensive review for all patients to include their clinical status and prostate brachytherapy studies, internal reviews, and external reviews of the program.

f. The results of the multiple internal and external reviews were being assimilated and conducted during the time when 15-day reports were being sent. The information was critical to determination of *why the event occurred.* That fact-finding was ongoing was communicated to the NRC in relevant 15-day reports. Reporting causality prior to the completion of these reviews would have been premature and any information would be speculative rather than based on

fact. The medical center provided to NRC a copy of the Administrative Board of Investigation report. This report addressed root causes.

g. The *effect on individuals* was also an ongoing process that required individual assessment of each patient and critical evaluation of studies and reports. Information was reported to NRC that was known at the time of each 15-day report.

(1) As a corrective action, on August 6, 2009, the medical center provided NHPP with updated information for effects on individuals in reports that were characterized as addendums to the original 15-day reports.

(2) NHPP forwarded the reports to NRC by e-mail dated August 7, 2009. A follow-up conference call was held with NRC on August 13, 2009, to discuss the reports as well as other dose information provided in the e-mail of August 7, 2009.

(3) In response to the conference call and subsequent e-mail contact with NRC, NHPP sent a follow-up e-mail to NRC on August 18, 2009, to clarify that "NHPP endorses the clinical update information as reflected in the revised 15-day reports which we submitted *in toto* as received from the facility."

(4) NHPP's understanding was that the revised information in the sections of these reports labeled "Effects on Patients" was adequate and responsive to NRC needs for reporting effects on individuals.

h. The immediate and most definitive *action to prevent recurrence* was closure of the prostate seed implant program until a thorough evaluation had been completed and processes and procedures revised as needed. Each of the written reports noted that prostate seed implants had been suspended.

i. For future written reports, the medical center will provide more definitive details to comply with the explicit sections in the 10 CFR 35.3045(d) reporting requirements.

j. The medical center has provided NRC detailed information related to the ongoing tracking of previous patient who had prostate seed implants. This tracking continues as part of the medical center follow-up actions.

k. NHPP requests NRC consider the number of patient treatments that had to be reviewed and the prompt actions by the medical center to complete such reviews with an emphasis on clinical care as a mitigating factor to disposition this apparent violation.

6. Apparent violation related to medical event reporting within 24 hours after discovery.

a. The apparent violation is accepted as stated.

b. The medical center did report medical events within 24-hours of discovery during the reviews in 2008. The failure to discover and report medical events during 2002 to 2008 was related to program deficiencies outlined in NRC and NHPP inspection reports.

7. Root causes and corrective actions.

a. The description of root or basic causes in the NRC and NHPP inspection reports and those identified by the medical center Administrative Board of Investigation report are accepted.

b. The corrective actions are noted above.

c. NHPP completed a 6-month follow-up inspection at the medical center to review corrective actions related to escalated enforcement. NRC accompanied NHPP for this inspection. This NHPP inspection closed the previous violations and did not identify any violations related to other uses of radioactive materials at the medical center.

8. Failure by key staff to achieve regulatory compliance and provide oversight.

a. Key staff and groups including the Radiation Safety Committee, Radiation Safety Officer, authorized users, and medical physicists did not achieve regulatory compliance for seed implant procedures that were performed from 2002 to 2008.

b. In general, the individual roles and responsibilities expected for key staff are part of the training and experience gained during professional qualification. An assumption that professional qualifications and experience are adequate, absent a fully documented radiation safety training program, contributed to the medical events occurring, to precursors not being identified, and to lack of discovery of medical events when adequate evidence was available

c. NRC and NHPP inspection reports have listed root causes which are applicable to actions by the key staff, including the Radiation Safety Committee.

d. The medical center Administrative Board of Investigation identified root causes that included lack of training, peer reviews, procedures to ensure reporting of medical events, Radiation Safety Committee oversight, and a safety culture.

e. Overall, the failure by the authorized users and medical physicists to identify and report the poor quality of prostate seed implants to the Radiation Safety Officer is rather perplexing and demonstrates a lack of a safety culture.

f. As a corrective actions, the medical center safety culture has been strengthened and stressed as paramount for future uses of radioactive materials. Finally, key staff have been held accountable and multiple administrative actions taken.

9. Concerns related to interface for computer systems.

a. The concerns are accepted as stated.

b. The medical center self-identified a lack of interface for the period from November 2006 through November 2007. The interface interruption timeframe affected a total of 18 scans for 18 patients, however, one scan for one patient was appropriately completed. The lack of effective corrective actions and oversight represented a failure to focus on a safety culture and willingness to stop work if needed for regulatory compliance.

c. An internal investigation identified newly issued security guidelines and lack of a specific department assigned for oversight for the treatment planning systems as the causes for the lack of connection.

d. The medical center has established a coordinated approach to address any new interface problems between information technology and biomedical engineering .

10. Concern related to annual audit for Radiation Safety Program.

a. The concern is accepted as stated.

b. The annual audits were provided to the Radiation Safety Committee in October 2008. The use of working documents and discussions absent a more

formal documentation of the audit results represented lack of rigor in radiation safety program management.

11. Concern related to safety culture.

a. The concern is accepted as stated.

b. The medical center also identified a need to strengthen the safety culture. See the comments in paragraph 8 above.

c. The medical center has an active open-door policy which is encouraged through postings in all areas of the medical center including Radiation Oncology Service. The new employee orientation, annual mandatory review, and annual safety exposition have participation by radiation safety staff.

d. The medical center displays Annual Patient Safety Goals throughout the medical center and staff are issued a patient safety handbook. The medical center has patient safety staff as part of the quality management office.

12. Concern related to rigor and formality of dose assessments.

a. The concern is accepted as stated.

b. The medical center continued extensive efforts to re-evaluate the post-treatment dose analysis results to establish correct and accurate results using a variety of metrics. The efforts ultimately resulted in a time-consuming process that was especially difficult since scientific methodology to evaluate dose to organs and tissues outside the prostate was not readily available in the scientific literature and had to be developed.

c. The medical center chose to collaborate with independent and objective subject matter experts to evaluate the clinical adequacy and regulatory compliance of the pre- and post-treatment plans and care delivered.

d. The iterative scientific process for the dose evaluations hampered development of an adequate and specific timeframe from the management perspective to complete the evaluations.