November 17, 2009

EA-09-038
NMED No. 080296

Gary Williams, M.S., Interim Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-34325/2009-001(DNMS), PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER

Dear Mr. Williams:

On June 22-26, August 27-28 and October 14-16, 2009, the U.S. Nuclear Regulatory Commission (NRC) inspectors conducted a reactive inspection at the Department of Veterans Affairs (DVA), Master Materials License (MML), Philadelphia Veterans Affairs Medical Center (PVAMC, permittee). The inspection included a review of the final dose assessments for all of the patients who received prostate brachytherapy treatments; and a review of the facts, circumstances, root and contributing causes regarding 97 medical events that occurred between February 25, 2002, and June 5, 2008, and the status of your proposed corrective actions. The enclosed report presents the results of this inspection. The NRC also contracted a medical consultant, Ronald E. Goans, M.D., Ph.D., MPH, to review the medical significance of a selected number of these medical events. Dr. Goans' report is enclosed.

Based on the results of this inspection, one apparent violation was identified involving the licensee's failure to notify the NRC the next calendar day after discovery of a medical event as required by Title 10 Code of Federal Regulation (CFR) 35.3045(c). The NRC has previously identified six additional apparent violations in NRC Inspection Report No. 030-34325/2008-029(DNMS), dated March 30, 2009. The NRC re-characterized one of these apparent violations into two separate violations related to the licensee's failure to develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive. In total, eight apparent violations have been identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/ enforcement/enforce-pol.html. The apparent violations involve the failure to: (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2); (2) develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive as required in 10 CFR 35.41(b)(2); (3) develop procedures that address verifying that the administration is in accordance with the written directive as required in 10 CFR 35.41(b)(2); (4) train supervised individuals regarding identification and reporting requirements for medical events as required in 10 CFR 35.27(a)(1); (5) instruct a non-supervised individual regarding identification and reporting of medical events as required in 10 CFR 19.12(a)(4); (6) report by telephone to the

NRC the next calendar day numerous medical events as required by 10 CFR 35.3045(c); (7) record total dose on a written directive as required by 10 CFR 35.40(b); and (8) provide complete and accurate information in accordance with 10 CFR 30.9 in several 15-day written reports to the NRC as required in 10 CFR 35.3045(d). The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the preliminary inspection exit meetings on June 26, August 28 and October 16, 2009. A final exit meeting informing you of the apparent violations was conducted via telephone on November 2, 2009.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review.

An open predecisional enforcement conference to discuss these apparent violations has been scheduled for December 17, 2009, at 1:00 p.m. (EST). The meeting will be held in the Commissioners' Conference Room on the first floor of the NRC's Headquarters building at One White Flint North, 11555 Rockville Pike, Rockville, Maryland. This conference will be open to public observation in accordance with Section V of the NRC Enforcement Policy.

In addition to the apparent violations, the NRC identified a number of concerns that contributed to the medical events. Overall, the concerns involve inadequate management oversight of the prostate brachytherapy program by the Radiation Safety Officer and the Radiation Safety Committee. Specifically, the NRC noted a lack of a safety culture which resulted in safety concerns going unreported, and a non-rigorous and informal assessment of patient doses, which did not demonstrate a commitment to performance improvements.

As stated in the enclosed NRC Regulatory Issue Summary 2005-18, "Guidance for Establishing and Maintaining a Safety Conscious Work Environment," a strong safety culture is described as the "necessary full attention to safety matters." A strong safety culture is also described as having a "safety-first focus." Attributes include the safety-over-production principle, procedural adherence, and conservative decision-making. Therefore, in addition to discussing the apparent violations, you should also be prepared to discuss the specific actions that have been or will be taken to address the concerns identified in Section 7.2 of the enclosed inspection report. Furthermore, we request that you address the roles, the responsibilities, and the performance of the Radiation Safety Officer, the Radiation Safety Committee (RSC), the contract medical physicists, and the authorized user physicians during the period when these medical events occurred, including how and why these individuals and the RSC failed to recognize precursors that could have prevented or minimized the number of medical events.

The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. The NRC specifically wishes to ensure that we have a common understanding of the facts, the root causes, and reasons for the missed opportunities to identify the medical events. During this

conference, we also request that you discuss the seriousness of the injuries to the patients, including, but not limited to: (1) the potential for continuing medical issues; (2) the potential increased risk of recurrence of cancer; and (3) the need for continuing patient follow up. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

We appreciate your cooperation and will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 37-00062-07

Enclosures:
1. Inspection Report 030-34325/2009-001 (DNMS)
2. Medical Consultant's Report
3. NRC Regulatory Issue Summary 2005-18
4. NRC Information Notice 96-28

cc w/encls: Richard Citron, Medical Center Director-VA Medical Center-Philadelphia
Mary E. Moore, M.S., M.Ed., Radiation Safety Officer-VA Medical Center-Philadelphia
Nelson Miranda, Director, VA Office of the Inspector General

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Nelson Miranda, Director, VA Office of the Inspector General

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Letter to G. Williams from Steven A. Reynolds dated November 17, 2009

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-34325/2009-001(DNMS), PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER

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REGION III

Docket No.:	030-34325
License No.:	03-23853-01VA
Report No.:	030-34325/2009-001(DNMS)
Licensee:	Department of Veterans Affairs (DVA)
Location Inspected:	Philadelphia Veteran Affairs Medical Center (PVAMC) Philadelphia, Pennsylvania [permittee under the DVA's Master Materials License]
Address:	3900 Woodland Avenue Philadelphia, Pennsylvania
Inspection Dates:	June 22-26, August 27-28 and October 14-16, 2009, with continued in-office review through November 2, 2009
Preliminary Exit Meetings:	June 26, August 28 and October 16, 2009
Final Exit Meeting:	November 2, 2009
Inspectors:	Cassandra F. Frazier, Senior Health Physicist Donna-Beth Howe, Ph.D., Health Physicist, FSME Deborah A. Piskura, Health Physicist Darrel G. Wiedeman, Senior Health Physicist
Accompanied by:	Ronald E. Goans, M.D., Ph.D., MPH, NRC Medical Consultant, on site August 27-28, 2009
Approved By:	Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

Enclosure 1

EXECUTIVE SUMMARY

Philadelphia Veterans Affairs Medical Center (PVAMC)
NRC Reactive Inspection Report No. 030-34325/2009-001(DNMS)

The Nuclear Regulatory Commission (NRC) conducted this reactive inspection on June 22-26, August 27-28, and October 14-16, 2009. The purpose of the inspection was to review the final dose assessments for all 114 patients who received prostate brachytherapy treatments at the PVAMC, review the licensee's corrective actions, and obtain the information required to close the open inspection item identified in Section 6.2 of NRC Inspection Report No. 030-34325/ 2008-29(DNMS) that involved the licensee's failure to report a medical event by the next calendar day. During this inspection, the inspectors reviewed patient pre- and post-treatment plans, written directives, and various patient treatment records, including patient data generated by the PVAMC and the National Health Physics Program (NHPP). This inspection also included a review of the licensee's final dose assessments for all of the patients who received prostate brachytherapy treatments at the PVAMC, the licensee's corrective actions, and obtain the information required to close the open inspection item identified in NRC Inspection Report No. 030-34325/2008-029(DNMS). The inspectors determined that a substantial programmatic breakdown of the prostate brachytherapy program occurred at the PVAMC due to the number and significance of the medical events.

Based on the results of this inspection, one apparent violation was identified involving the licensee's failure to notify the NRC the next calendar day after discovery of a medical event as required by 10 CFR 35.3045(c). The NRC has previously identified six apparent violations in NRC Inspection Report No. 030-34325/2008-029(DNMS). The apparent violations include the licensee's failure to: (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive; (2) develop procedures that address methods for verifying that administration is in accordance with the treatment plan and written directive; (3) instruct supervised individuals regarding identification and reporting requirements for medical events; (4) instruct a non-supervised individual regarding identification and reporting of medical events; (5) record total dose on a written directive; and (6) provide required information in several 15-day reports. The NRC re-characterized one of these apparent violations into two separate violations related to the licensee's failure to develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive.

Based on the results of this inspection, one new concern was identified. The assessment of patient doses lacked the rigor and formality required to demonstrate the licensee's commitment to performance improvements. The NRC previously identified four concerns in NRC Inspection Report No. 030-34325/2008-029(DNMS) that were contributing factors to the medical events that involve inadequate management oversight of the prostate brachytherapy program and lack of a safety culture.

The root causes of the medical events and the licensee's corrective actions were previously identified in NRC Inspection Report No. 030-34325/2008-029(DNMS). No new root causes were identified during this inspection. The inspectors identified three additional corrective actions during this inspection, which include: (1) performing verification computerized

tomographies (CTs) on patients who received prostate implants between February 25, 2002, and May 12, 2008, and re-evaluating the dose delivered to the prostate and the periprostatic tissue and/or the rectum; (2) referring eight patients to the VA Puget Sound Health Care System, Seattle for re-implantation procedures; and (3) removing one individual from performing brachytherapy treatments at VA facilities.

The NRC contracted a medical consultant to review additional medical events and determine if any adverse health consequences to the patients would be expected. During this inspection, the medical consultant reviewed 15 patient cases. The consultant noted that several patients experienced radiation proctitis, rectal bleeding possibly from high doses of radiation, and recurrence of cancer. The NRC medical consultant reviewed a total of 39 medical events (24 medical events were evaluated in NRC Inspection Report No. 030-34325/2008-29(DNMS)).

REPORT DETAILS

1 Program Scope and Inspection History

The Department of Veterans Affairs (DVA) (licensee) holds a Master Materials License (MML), which authorizes the DVA to issue permits for the possession and use of licensed material, and ties the licensee to a framework of oversight consistent with the NRC regulations and inspection and enforcement policies, procedures, and guidance. The DVA National Radiation Safety Committee (NRSC) has the responsibility for providing oversight of the DVA's implementation of its MML and associated permittee activities. The NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP). The Philadelphia Veterans Affairs Medical Center (PVAMC, permittee) is a permittee under the DVA's MML.

The PVAMC is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included iodine-125 (I-125) brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with an activity of either 0.380 millicuries (mCi) or 0.509 mCi of I-125, based on the written directive prepared by the authorized user physician. The prostate brachytherapy program was implemented by two authorized user physicians who prepared the written directives with a prescribed prostate dose of either 145 Gray (Gy) (145 Sieverts (Sv)) or 160 Gy (160 Sv). Three contract medical physicists provided support services to the PVAMC and generated treatment plans for the prostate cases. Between February 25, 2002 and June 2, 2008, the permittee administered 116 prostate brachytherapy treatments to 114 patients (two patients received a second prostate brachytherapy treatment, which resulted in 116 treatments).

The NRC conducted this reactive inspection on June 22-26, August 27-28, and October 14-16, 2009. The purpose of the inspection was to review the final dose assessments for all 114 patients who received prostate brachytherapy treatments at the PVAMC, review the licensee's corrective actions, and obtain the information required to close the open inspection item identified in Section 6.2 of NRC Inspection Report No. 030-34325/2008-29(DNMS) that involved the licensee's failure to report a medical event by the next calendar day. The NRC previously identified six apparent violations in NRC Inspection Report No. 030-34325/2008-29(DNMS). During this inspection, the inspectors identified one additional apparent violation that involved the licensee's failure to notify the NRC the next calendar day after discovery of a medical event. In addition, one of the apparent violations identified in NRC Inspection Report No. 030-34325/2008-29(DNMS), which involved the licensee's failure to develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive, has been re-characterized as two separate violations in this report (see Section 6.2). In January 2009 and October 2009, the NHPP conducted follow-up inspections; the reports for these inspections have not been issued.

2 Assessment of Patient Doses

2.1 Inspection Scope

The inspectors reviewed the dose assessment information the licensee generated and collected on spreadsheets, which summarized dose data for all 114 patients who received permanent prostate implants at the PVAMC. The inspectors interviewed the Radiation Safety Officer (RSO), the chairman of the Radiation Safety Committee (RSC), the chief of the Radiation Oncology Service, and the licensee's contract medical physicist. The inspectors also reviewed selected VariSeed® treatment plans.

2.2 Observations and Findings

The PVAMC initially developed a spreadsheet that included the prostate dose for each patient in terms of D90 (dose to 90 percent of the prostate) based on the original computerized tomography (CT) data, which was typically obtained one day after the implant. Each patient was assigned a patient number designated as "XRT XXX." The information in the spreadsheet evolved over the course of several months as the permittee generated additional data for patient doses. The information collected included the doses to the rectum, the bladder and the periprostatic tissues. The permittee also generated prostate doses based on information obtained from new CTs performed on the patients in 2008. The 2008 CTs were contoured by a contract radiation oncologist, who also re-contoured selected original CTs. The PVAMC relied on the doses that were generated based on the re-contoured original CTs to identify medical events. The PVAMC contracted a part-time medical physicist to generate post-treatment plans based on the re-contoured original CTs and the 2008 CT data.

During the June 22-26 inspection, the inspectors reviewed dose data for 34 patients. The inspectors identified inconsistencies and conflicting information in the data. For example, when comparing the D90s generated from the original day one CT data and the 2008 CT data, the inspectors noted significant differences in the D90s. For example, patient number XRT 035, the original post plan showed a D90 of 144 Gy (144 Sv), and the 2008 post plan D90 showed 92 Gy (92 Sv). For patient number XRT 009 the original post plan D90 showed 125 Gy (125 Sv) and the 2008 post plan D90 showed 86 Gy (86 Sv). For patient number XRT 007 the original post plan D90 showed 105 Gy (105 Sv) and the 2008 post plan D90 showed 50 Gy (50 Sv). Additionally, the inspectors noted that the PVAMC did not have a standard procedure with established criteria to evaluate patient doses in a consistent manner. This resulted in delays and inconsistencies with the permittee's decision-making relative to the dose data used to identify medical events and doses to unintended organs and tissues. After several months, the permittee elected to rely on the doses that were generated based on the re-contoured original day one CTs to identify medical events, and not use the 2008 CT data. The permittee decided not to use the 2008 CT data to identify medical events because it determined that the data would not accurately reflect the original clinical outcome (placement of the seeds, tissue responding to the radiation, seed migration, etc.). The inspectors reviewed selected cases and patient treatment plans including the VariSeed® 3D View Reports, which depict the placement of the seeds within the

prostate and adjacent organs and tissues. The inspectors compared the original post-treatment plans with re-contoured original plans and 2008 treatment plans.

As previously noted, the inspectors identified an inconsistent approach and methodology in the assessment of doses. Based on the inspectors' review of the number of medical events reported, the inspectors identified one case, patient number XRT 072, that was reported twice. The actual number of medical events reported was 97 rather then 98 as reported by the licensee. In addition, seven patients did not have original CT data that could be retrieved for dose calculations. For example, patient numbers XRT 025, 031, 033, 076, 084,104, and 111 did not have final dose values identified. The licensee reported these cases as medical events in 2008, based on 2008 CTs.

The permittee provided updates on the status of certain patient cases. Five of the 114 patients treated had expired; however, the inspectors confirmed that the cause of death for these five patients was not related to their prostate brachytherapy treatments. The PVAMC offered to refer 18 of its patients to the VA Puget Sound Health Care System, Seattle facility for re-implantation. Eight patients received re-implants. The remaining ten patients, who declined a re-implant, received additional follow up through other treatment modalities.

During the August 27-28 inspection, the inspectors reviewed 60 additional patient cases and post-treatment plans. The inspectors noted inconsistencies in the doses for patient numbers XRT 080 and 102 where multiple re-contours and treatment plans were maintained that resulted in different D90s. The D90 values recorded in these treatment plans conflicted with the dose data recorded in the spreadsheet.

In September 2009, the PVAMC identified a new issue that could potentially affect the D90 which involved redundant seed count. The redundant seed count or Isocentric Reconstruction Root-Mean-Square (RMS) Error is an error factor which can affect the D90s in the automatic seed finding feature of the VariSeed® software for counting seeds from imported CT images into the computer for post-treatment planning. The RMS error accounted for ambiguities in seed placement and identification of the seeds in the CT images. The contract physicist re-planned each patient case to correct for redundant seed counts and completed the treatment planning in October 2009. The inspectors reviewed 11 patient records to assess the redundant seed count issue. The inspectors noted that for four patients (numbers XRT 012, 026, 041 and 083), the final D90 increased to within 80 percent of the respective prescribed dose of 160 Gy (160 Sv) (for patient numbers XRT 012, 041, and 083), and (145 Gy (145 Sv) (for patient number XRT 026). The D90s for the remaining patients did not change significantly. The licensee used the October 2009 treatment plans generated to account for the redundant seed count for the final patient dose data identified in their spreadsheet. This data was reviewed by the inspectors during the October 14-16 inspection. The licensee submitted the final patient dose data spreadsheet, entitled "Revised Prostate Brachytherapy Information for Philadelphia VAMC," to the NRC on October 19, 2009.

Based on the final data submitted, the inspectors identified 17 cases that met the NRC's internal abnormal occurrence criteria (patient numbers XRT 001, 006, 010, 013, 018, 019, 027, 037, 044, 057, 066, 078, 080, 088, 096, 098, and 102) where the dose to the periprostatic tissue and/or the rectum exceeded the value for a medical event. In all cases the prescribed dose to the prostate was 160 Gy (160 Sv) and the dose delivered to the prostate was in the range of 39 Gy (39 Sv) to 111 Gy (111 Sv). The dose to the periprostatic tissue ranged between 248 Gy (248 Sv) and 588 Gy (588 Sv). Patient number XRT 018 (who had two implant procedures) received a prostate dose of 203 Gy (203 Sv), a rectal dose of 318 Gy (318 Sv), and a periprostatic tissue dose of 355 Gy (355 Sv) as a result for both implants.

Each of these 17 cases were medical events because: (1) the region of the patient's periprostatic tissue or rectum where the seeds were placed received a dose that was greater than 0.50 Sv and was 50 percent greater than the expected dose the area would have received if the treatment had been administered in accordance with the written directive and treatment plan; and (2) the prostate received 20 percent less than the prescribed dose of 160 Gy (160 Sv) (except for patient number XRT 018) and the dose differed from the prescribed dose by more than 0.50 Sv.

2.3 Conclusions

The inspectors noted an inconsistent approach and methodology in the license's assessment of doses to the prostate as well as to other organs and tissues. This resulted in delays and uncertainties in the final dose assessments. The inspectors identified 17 of the 97 cases that were reported as medical events which involved unintended doses to other organs or tissues that exceeded more than 0.50 Sv and the doses were 50 percent greater than the expected dose the area would have received if the treatment had been administered in accordance with the written directive and treatment plan. These 17 cases met the NRC's internal abnormal occurrence criteria. Final dose data was not available for seven patients.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors reviewed the information that was available to the authorized user physicians, the medical physicists and the radiation oncology staff. In addition, the inspectors interviewed the RSO and the contract medical physicist to determine what event notifications had been made. The inspectors also reviewed the event notifications to the NRC Operations Center on May 16, 2008, (Event Number 44219), and subsequent updates, which included the August 12, 2009, event notification to the NRC Operations Center; and reviewed the licensee's 15-day written reports submitted to the NRC dated June 21; July 8, 15, 21, 22, 30, and 31; August 4 and 7, 2008; and August 26, 2009.

3.2 Observations and Findings

The NRC inspectors reviewed the information that was available to the licensee to make a determination that a medical event occurred. The inspectors identified that sufficient

information was available to the licensee at the completion of the prostate treatments to make a determination that a medical event occurred. Specifically, the permittee's VariSeed® post-treatment plans, including the treatment summaries and the 3-D images, provided sufficient data to the authorized user physicians and the permittee's contract medical physicists to make the determination that the implant was not in accordance with the written directive. Specifically, a medical event occurred for patient number XRT 006 with an implant date of January 9, 2006, which was not reported as a medical event until July 8, 2008. Patient numbers XRT 008, 068, 072, and 102 with implant dates of May 12, 2008, May 1, 2006, July 9, 2007, February 26, 2008, respectively, were also medical events; however, the licensee did not report these cases until July 22, 2008, a period greater than one calendar day. 10 CFR 35.3045(c) requires licensees to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of a medical event. The licensee's failure to notify the NRC, no later than the next calendar day after discovery of a medical event is an apparent violation of 10 CFR 35.3045(c).

Between May 16 and October 2, 2008, the licensee reported 92 medical events that involved I-125 prostate brachytherapy implants that occurred between February 25, 2002, and May 12, 2008. The inspectors identified one medical event that was reported twice (patient number XRT 072). Therefore, the actual number of medical events reported as of October 2, 2008 was 91. Six additional medical events were reported to the NRC on August 12, 2009 (patient numbers XRT 059, 061, 069, 081, 083, and 110). These medical events were reported because the dose to the prostate was less than 80 percent of the prescribed dose based on the post-treatment plans generated from the re-contoured original day one CTs, and not the 2008 CTs. The PVAMC radiation oncology staff notified all six patients involved in the medical events and the referring physicians were also notified.

The licensee has reported a total of 97 medical events. The licensee submitted their 15-day reports in separate letters in accordance with 10 CFR 35.3045(3)(d)(iv)(v) and (vi). On October 19, 2009, the licensee submitted its spreadsheet summarizing the final patient data to the NRC.

3.3 Conclusions

The inspectors closed the Open Item previously identified in Section 6.3 of NRC Inspection Report No. 030-34325/2008-029(DNMS). The inspectors identified one apparent violation associated with the failure to notify the NRC no later than the next calendar day after discovery of a medical event as required by 10 CFR 35.3045(c).

4 Licensee Corrective Actions

4.1 Inspection Scope

The inspectors interviewed selected licensee personnel concerning their proposed corrective actions. The inspectors also reviewed the corrective actions described in the Administrative Board of Investigations (ABI) report dated September 5, 2008, corrective actions identified in the NHPP's inspection report dated October 16, 2008, and the

corrective actions identified in the PVAMC's response to the NHPP inspection report dated December 29, 2008.

4.2 Observations and Findings

The inspectors identified three additional corrective actions during this inspection that include: (1) performing verification CTs on patients who received prostate implants between February 25, 2002, and May 12, 2008, and re-evaluating the dose delivered to the prostate and the periprostatic tissue and/or the rectum; (2) referring eight patients to the VA Puget Sound Health Care System, Seattle for re-implantation procedures; and (3) removing one individual from performing brachytherapy treatments at VA facilities.

The licensee's other corrective actions were previously identified in NRC Inspection Report No. 030-34325/2008-029(DNMS). The licensee suspended its prostate brachytherapy program on June 11, 2008, and it remains suspended. The licensee ordered an external review by the ABI of the prostate brachytherapy program. The licensee's corrective actions included: (1) revising its procedures for the prostate brachytherapy treatments to include an evaluation and verification that the administered dose was in accordance with the written directive; (2) directions that require the radiation oncology staff to stop the procedure if there is any uncertainty associated with the treatment; (3) amending the PVAMC Sealed Source Radiotherapy policy to include: a) a comparison and evaluation of both treatment plans and associated calculations with the written directive; b) direction to allow prostate brachytherapy treatments to proceed only when the treatment planning computer is able to produce pre and post-treatment plans; and c) immediately reporting all deviations that exceed ten percent of the prescribed dose or dose fraction to the RSO and quality management staff; (4) instituting a medical center peer-review system for radiation oncology services and post-treatment evaluations; (5) providing radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events; (6) revising the contract for radiation oncology services to realign these services under the RSO; (7) instituting an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns; (8) suspending prostate brachytherapy treatments until all the corrective actions have been completed and they have been approved to re-start by the NHPP; and (9) conducting an external review of the prostate implant program, by physicians and medical physics consultants who were experts in performing prostate brachytherapy treatments, to evaluate the former prostate implant program and current program, and incorporating their recommendations into hospital policies and procedures. During this inspection the following additional corrective actions were identified: (10) performing verification CTs on all patients who received prostate implants between February 25, 2002, and May 12, 2008, and re-evaluating the dose delivered to the prostate and the periprostatic tissue and/or the rectum; (11) referring eight patients to the VA Puget Sound Health Care System, Seattle for re-implantation procedures; and (12) removing one individual from performing brachytherapy treatments at VA facilities.

4.3 Conclusions

The inspectors determined that the licensee's proposed corrective actions were adequate to prevent recurrence of the medical events and the apparent violations, with one exception. The licensee did not provide corrective actions that address the apparent violation to provide complete and accurate information in its 15-day written reports.

5 NRC Medical Consultant's Site Visit and Review

5.1 Inspection Scope

The medical consultant reviewed written directives and treatment plans, on site, with the inspectors on August 27 and 28. The medical consultant summarized his findings in the attached report. The inspectors reviewed the medical consultant's report to determine if any adverse health consequences were identified as a result of the medical events.

5.2 Observations and Findings

The NRC contracted a medical consultant, Ronald E. Goans, M.D., Ph.D, MPH, to review an additional 15 medical events to determine if any adverse health consequences to the patients were expected. The NRC medical consultant reviewed a total of 39 medical events (24 were evaluated in NRC Inspection Report No. 030-34325/2008-029(DNMS)). During the site visit, the consultant reviewed numerous written directives and treatment plans with the inspectors and the licensee's consulting medical physicist. The medical consultant reviewed the permittee's spreadsheet summarizing the treatments and he provided a statistical analysis of the data. The consultant's report noted that "the seed placement in the cases reviewed was quite erratic and not consistent with current medical standards." The consultant generally agreed with the PVAMC's dose estimates to the patients. However, his report stated that patients experienced radiation proctitis (patient numbers XRT 009, 040 and 053), and rectal bleeding possibly from high doses of radiation (patient numbers XRT 015 and XRT 104), and recurrence of cancer (patient numbers XRT 001, 042, 053 and 085).

5.3 Conclusions

The consultant generally agreed with the PVAMC's dose estimates to the patients. However, he indicated that erratic seed placement caused a number of patients to have elevated doses to the rectum, bladder, or periprostatic tissue. The consultant identified specific patients with rectal bleeding where the increased dose to the patients' colon, which resulted from erratic seed placement, may have been a contributing factor to the condition. In addition, several cases of radiation proctitis were identified along with several cases of recurrence of cancer.

6 Apparent Violations Identified In Previous Inspection Report

6.1 Inspection Scope

The inspectors summarized the apparent violations described in NRC Report 030-34325/2008-029 (DNMS) during the telephone exit meeting on November 2, 2009.

6.2 Observations and Findings

Based on the inspection findings described in NRC Report 030-34325/2008-029 (DNMS), the inspectors identified six apparent violations of NRC requirements associated with the permittee's brachytherapy program. The NRC re-characterized the previous apparent violation of 10 CFR 35.41(b) (2) into two separate violations. An open item was identified regarding medical event reporting in Section 6.2 of NRC Report No. 030-34325/2008-029 (DNMS). The inspectors reviewed additional information during this inspection to close this item, and identified an apparent violation that is described in Section 3.2 of this report. The apparent violations described in NRC Report 030-34325/2008-029 (DNMS) include:

(1) Title 10 CFR 35.41(a) (2) requires that for any administration requiring a written directive, the licensee develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Between February 25, 2002, and May 12, 2008, the licensee did not develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, Procedure 00-76, "Sealed Source Radiotherapy," dated November 2005, with previous revisions in 1999 and 2002, did not require that the dose to the treatment site be verified to ensure that the administered dose was in accordance with the written directive. The inspectors determined that 97 prostate brachytherapy treatments were administered between February 25, 2002, and May 12, 2008, where the administered dose was not in accordance with the written directive. The licensee's failure to develop and implement adequate procedures to provide high confidence that 97 prostate implants were performed in accordance with the written directive is an apparent violation of 10 CFR 35.41(a)(2).

(2) Title 10 CFR 35.41(b)(2), requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive. Between November 2006 and December 2007, the licensee's procedure did not address verifying that the administration was accordance with the applicable treatment plan and written directive. Specifically, Procedure 00-76, titled "Sealed Source Radiotherapy," dated November 2005, did not address alternate methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. The inspectors determined that the permittee administered 16 prostate brachytherapy treatments between November 2006 and December 2007, without performing

post-treatment verifications until sometime in December 2007 to January 2008. The licensee's failure to verify that the administration is in accordance with the treatment plan for 16 prostate brachytherapy treatments between November 2006 and December 2007 is an apparent violation of 10 CFR 35.41(b)(2).

(3) Title 10 CFR 35.41(b)(2), requires, in part, that, as a minimum, the procedures required by 10 CFR 35.41(a) address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive. Between February 25, 2002, and May 12, 2008, the licensee's procedure did not address verifying that the administration was accordance with the applicable treatment plan and written directive. Procedure 00-76, titled "Sealed Source Radiotherapy," dated November 2005, did not address reviewing both the applicable treatment plan and the written directive. The inspectors determined that the licensee failed to review both the applicable treatment plan and the written directive for a brachytherapy treatment administered on May 5, 2008. Specifically, the treatment plan differed from the written directive, resulting in the implantation of I-125 seeds of an incorrect apparent activity which resulted in a medical event. The licensee's failure to develop procedures to verify that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive is an apparent violation of 10 CFR 35.41(b)(2).

(4) Title 10 CFR 35.27(a)(1) requires in part, that in addition to the requirements in 10 CFR 19.12, the licensee instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of 10 CFR Part 35, and license conditions with respect to the use of byproduct material. The inspectors determined that from February 25, 2002, to September 2008, two medical physicists, who were supervised individuals, were not instructed on the requirements for identifying and reporting requirements for a medical event by the permittee as required by 10 CFR 35.2 and 10 CFR 35.3045. The licensee's failure to instruct two medical physicists (supervised individuals) regarding the requirements for identifying and reporting medical events is an apparent violation of 10 CFR 35.27(a)(1).

(5) Title 10 CFR 19.12(a)(4) requires, in part, that all individuals who are likely to receive in a year an occupational dose in excess of 100 mrem, be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses. As of July 2008, an authorized user physician, who received an occupational dose in excess of 100 millirem in each year from 2002 to 2008, was not instructed on his responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations. The licensee's failure to provide instruction regarding identification and reporting requirements for medical events to an authorized user physician that received a dose in excess of 100 mrem in a year is an apparent violation of 10 CFR 19.12(a)(4).

(6) Title 10 CFR 35.40(b)(6)(ii) requires, in part, that the written directive specify, after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources, and total source strength and exposure time (or total dose). The inspectors identified a written directive dated May 5, 2008, that did not specify, after implementation but before completion of the procedure, the radionuclide, treatment site, number of sources and total dose was not recorded. Specifically, the procedure was completed on May 5, 2008, and the written directive did not specify the number of source seeds implanted or either the total source strength and exposure time or the total dose until May 28, 2008. The licensee's failure to record number of sources and total dose after implantation, but before completion of the procedure, on the written directive is an apparent violation of 10 CFR 35.40 (b) (6).

(7) Title 10 CFR 30.9(a) requires, in part, that information provided to the Commission by a licensee be complete and accurate in all material respects. Title 10 CFR 35.3045(d) requires, in part, that a licensee submit a written report to the appropriate NRC Regional Office within 15 days after discovery of a medical event. It further requires that the written report include: (1) why the event occurred; (2) the effect, if any, on the individual(s) who received the administration; and (3) what actions, if any, have been taken or planned to prevent recurrence. Based on the inspectors' review, the reports submitted to the NRC on June 21, July 8, 15, 21, 22, 30, 31, and August 4 and 7, 2008, did not describe: (1) why the event occurred; (2) the effect on the individuals who received the administration; and (3) what actions were taken or planned to prevent recurrence. Specifically, for these three areas, the reports merely indicated that the cause was still under investigation, the effects were still under investigation and that the program was suspended until long-term actions to prevent recurrence could be determined. This incomplete information was material to the NRC because it affected the NRC's ability to timely determine the significance of the events and the adequacy of the licensee's, rather than just the permittee's, corrective actions. The licensee's failure to provide complete and accurate information in its written reports is an apparent violation of 10 CFR 30.9/35.3045(d).

6.3 Conclusions

The inspectors identified seven apparent violations regarding failure to: (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive; (2) develop procedures that address methods for verifying that administration is in accordance with the treatment plan and written directive; (3) develop procedures that address verifying that the administration was in accordance with the written directive; (4) instruct supervised individuals regarding identification and reporting requirements for medical events; (5) instruct a non-supervised individual regarding identification and reporting of medical events; (6) record total dose on a written directive; and (7) provide complete and accurate information in its written reports.

7 Areas of Concern

7.1 Inspection Scope

The inspectors identified an additional area of concern regarding the licensee's assessment of patient doses during this inspection. The inspectors also summarized the areas of concern described in NRC Report 030-34325/2008-029 (DNMS) during the telephone exit meeting on November 2, 2009.

7.2 Observations and Findings

In addition to the apparent violations described in this report, the NRC inspectors identified five concerns involving the PVAMC's prostate brachytherapy program:

(1) The 2007 quarterly radiation staff audits consistently indicated that written directives were in full compliance with the requirements, yet during the same period the permittee experienced computer interface problems associated with their VariSeed® treatment planning computer and CT images. The PVAMC continued to treat patients during this period even though they were not capable of determining that the administered dose was in accordance with the written directive and pre-treatment plan. Additionally, the fourth quarter 2006 radiation staff audit indicated that there was a problem with the computer interface systems. However, during the next quarterly RSC meeting in March 2007, there was no discussion of the computer interface problem;

(2) The RSO reported to the RSC in September 2007, and again in December 2007, that post-treatment plans for prostate brachytherapy implants had not been completed due to the continuing image transfer problems associated with the CT images and the VariSeed® treatment planning system. The RSC did not assign an "action item" to resolve the issue and the RSC was aware that there was a three month backlog of prostate post-treatment plans and took no action to correct this issue. After the problem was resolved in November 2007, the prostate post-treatment plans used to determine the dose delivered to the patient were not performed;

(3) Annual audits of the radiation safety program that had been performed by the RSO for 2006 and 2007 were not finalized and provided to the RSC for review. In addition, there is no indication that the RSC requested the audits to review;

(4) The PVAMC lacked a safety culture for reporting radiation concerns to the appropriate individuals. As an example, interviews of two medical physicists indicated that they had concerns about the quality of an authorized user physician's implants being "suboptimal." One physicist indicated that he raised a concern to the authorized user physician in 2002 and no action was taken by the physician. The physicist continued to work with the authorized user physician between 2002 and 2008, and did not inform the RSO or management of his concerns. The other physicist raised his concern to a physician at an affiliate

institution that provided contracted radiation oncology services to the PVAMC, but never raised the concern with the PVAMC's radiation safety staff or management; and

(5) The PVAMC did not complete the final dose assessments for the 114 patients treated until October 2009, approximately one year after the last medical events were reported. In addition, the dose assessment lacked the rigor and formality required to demonstrate the licensee's commitment to performance improvements. The permittee did not have criteria established for assessing patient doses in a consistent manner. In addition, there was no apparent leadership or senior management direction to establish time tables and milestones for completing the patient dose assessments.

7.3 Conclusions

The inspectors identified five concerns that were contributing factors to the medical events that include: (1) inadequate quarterly audits of the brachytherapy program by the radiation safety staff; (2) the failure of the RSC to take action regarding computer interface problems; (3) the annual audits of the radiation safety program conducted by the RSO for 2006 and 2007 were not finalized; (4) a lack of safety culture; and (5) the lack of rigor, methodology, and management commitment in performing patient dose assessments.

8 Exit Meeting

The inspectors discussed the conclusions described in this report with the licensee during preliminary exit meetings conducted at the licensee's facility on June 26, August 28, and October 16, 2009, and a final telephone exit meeting on November 2, 2009. The licensee did not identify any information reviewed during this inspection as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

#Linda Aumiller, Director, Quality Management
*#Richard Citron, Medical Center Director
Pamela Devine, R.N., Clinical Nurse Specialist
#Barbara L. Forsha, Quality Management Officer, VISN 4
#Cynthia Heidt, R.N, Associate Director, Nursing
Rodger Holst, M.S., Health Physicist
#David Macpherson, M.D., Chief Medical Officer, VISN 4
*Amit Maity, M.D., Ph.D., Chief, Radiation Oncology Service
*#Joel Maslow, M.D., Ph.D, Chairman, RSC
*#Mary Moore, M.S., Radiation Safety Officer
*#Margaret O'Shea Caplan, Associate Director, Finance
#Paula Salanitro, M.S. Medical Physicist (contractor)
#Al Sipple, Executive Assistant, Chief of Staff
#Dale Warman, Public Affairs Officer
*+Thomas Huston, Ph.D., CHP, Program Manager, NHPP
#Paul Yurko, M.S., Program Manager, NHPP
*+Gary E. Williams, M.S., Interim Director, NHPP
*Michael P. Hagan, M.D., Ph.D., Director, National Radiation Oncology Program
*Charles Anderson, M.D., Ph.D, Chairman, National Radiation Safety Committee
*Frank M. Miles, FACHE, Associate Chief Officer, Patient Care Services
*James C. Sinwell, Office of General Counsel

\# Participated in one or more of the onsite exit meetings on June 26, August 28, and/or October 16, 2009
\+ Participated in one or more of the onsite exit meetings by telephone on June 26, August 28, and/or October 16, 2009
* Contacted by telephone on November 2, 2009, for exit meeting

LIST OF ACRONYMS AND ABBREVIATIONS USED

ABI	Administrative Board of Investigation
CFR	Code of Federal Regulations
CT	Computerized Tomography
D90	Dose to 90 percent of the target organ
DVA	Department of Veterans Affairs
Gy	Gray
mCi	millicurie
MML	Master Materials License
NHPP	National Health Physics Program
NRSC	National Radiation Safety Committee
NRC	Nuclear Regulatory Commission
PVAMC	Philadelphia Veterans Affairs Medical Center
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
Sv	Sievert

Attachment