May 24, 2010

EA-10-081
CAL 3-08-004
NMED Nos. 080606, 080613, 080646, 080803, 090079, 090120, and 090244

Robert A. Petzel, M.D.
Under Secretary for Health
U.S. Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, D.C. 20420

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-34325/2008-030(DNMS) - DEPARTMENT OF VETERANS AFFAIRS

Dear Dr. Petzel:

On December 8-12, 2008, the U.S. Nuclear Regulatory Commission (NRC) inspectors conducted an announced reactive inspection at the Department of Veterans Affairs (DVA) National Health Physics Program (NHPP) office in North Little Rock, Arkansas. The purpose of the inspection was to review the NHPP inspection activities and event response to the multiple medical events involving prostate brachytherapy at the Philadelphia Veterans Affairs Medical Center (PVAMC). The inspection included a review of the NHPP's inspection and enforcement process, the status of the commitments in the Confirmatory Action Letter (CAL 3-08-004) dated October 14, 2008, and an assessment of the National Radiation Safety Committee's (NRSC's) oversight of the NHPP's response to the multiple medical events at the PVAMC.

The inspection activities were expanded to include an extent of condition assessment to determine whether or not the problems identified at the PVAMC existed at all of the other DVA facilities with active prostate brachytherapy programs. These inspections were conducted between October 8, 2008, and April 24, 2009, at the following permitted DVA facilities: (1) G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; (2) VA Medical Center, Cincinnati, Ohio; (3) VA Medical Center, Minneapolis, Minnesota; (4) VA Puget Sound Healthcare System, Seattle, Washington; (5) VA Sierra Nevada Healthcare System, Reno, Nevada; (6) Samuel S. Stratton VA Medical Center, Albany, New York; (7) VA New York Harbor Healthcare System, Brooklyn, New York; (8) VA Boston Healthcare System, Boston, Massachusetts; (9) VA Medical Center, Washington, District of Columbia; (10) VA Greater Los Angeles Healthcare System, Los Angeles, California; (11) VA Medical Center, San Francisco, California; (12) VA Medical Center, Durham, North Carolina; and (13) Hunter Holmes McGuire VA Medical Center, Richmond, Virginia. Our inspection included in-office review through April 22, 2010. The continued NRC in-office review included an assessment of your 15-day written reports for medical events reported at the VA Jackson, the VA Cincinnati, the VA Brooklyn, the VA Los Angeles, and the VA Durham facilities. Our in-office review also included a review of patient dose data for medical events reported at the VA Brooklyn, the VA Los Angeles and the VA Durham facilities, training records for numerous facilities, and patient treatment records for several facilities. The enclosed report presents the results of the inspection activities of the NHPP and the DVA facilities with active prostate brachytherapy programs.

Based on the results of these inspections, three apparent violations were identified which involved eleven DVA facilities that are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site athttp://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involved the failure to: (1) develop, implement, and maintain adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive as required in Title 10 Code of Federal Regulation (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); and (3) notify the NRC by telephone by the next calendar day after discovery of a medical event as required in 10 CFR 35.3045(c). The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the preliminary inspection exit meetings at each respective facility. A final exit meeting informing your staff of the apparent violations was conducted via telephone on April 22, 2010.

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 the apparent violations has been scheduled for June 30, 2010, at 1:00 pm (CDT) at the NRC Region III office in Lisle, Illinois. This conference will be open to public observation in accordance with Section V of the NRC Enforcement Policy.

In view of the Notice of Violation and Proposed Imposition of Civil Penalty - $227,500 issued to the DVA on March 17, 2010, and the apparent violations identified during our extent of condition inspection, you should be prepared to present at the predecisional enforcement conference, not only the specific corrective actions taken for each apparent violation, but also the broad corrective actions taken or that will be taken by the NHPP to provide the NRC reasonable assurance that the NHPP's current operations (including all NRC licensed activities under its jurisdiction) can be conducted under the Master Materials License (MML) in compliance with the Commission's requirements and that the health and safety of the public will be protected.

In addition to the apparent violations, the NRC identified a number of concerns that impact the effectiveness of the DVA's MML program. The concerns involve the NRSC's oversight of the MML; the NHPP inspection, enforcement, and technical assistance processes; and the status of the CAL commitments. Furthermore, the NHPP performed routine inspections at the PVAMC, and reactive inspections focused on the prostate brachytherapy programs at the PVAMC and the other 12 DVA facilities with active prostate brachytherapy programs, and failed to identify significant violations. 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 and discussed in detail in Part I, Section 8 of the enclosed report during the predecisional enforcement conference. The NRC does not expect the DVA to discuss in detail, the corrective actions previously provided or taken as part of the CAL, or in response to the PVAMC actions.

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 conference will provide an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html.

In addition, three potential violations were identified during the inspection at three DVA facilities, which are not being considered for escalated enforcement action. The potential violations involve the failure to conduct a physical inventory as required by 10 CFR 35.67(g), the failure to complete written directives (specifically to record the total dose upon completion of an implant) as required by 10 CFR 35.40(6)(ii), and the failure to provide complete information in a 15-day written report (for a medical event) to the NRC as required by 10 CFR 35.3045(d).

As discussed with members of your staff during the telephonic exit meeting on April 22, 2010, we are continuing to evaluate one open item identified during the inspection. The open item involved the inspectors' identification of brachytherapy post-treatment plans where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. The results of our evaluation will be provided to you by separate correspondence.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent and potential 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 enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

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

Sincerely,

/RA by Patrick L. Louden acting for/

Steven A. Reynolds, Director
Division of Nuclear Material Safety

Docket No.: 030-34325
License No.: 03-23853-01VA

Enclosure:
Inspection Report No. 030-34325/2008-030(DNMS)

cc w/encl: Charles Anderson, M.D., Ph.D.,
Chair, NRSC
Gary Williams, M.S., Director, NHPP

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Chair, NRSC
Gary Williams, M.S., Director, NHPP

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Letter to G. Williams from Steven A. Reynolds dated May 24, 2010

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 030-34325/2008-030(DNMS) - DEPARTMENT OF VETERANS AFFAIRS

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REGION III

Docket No.:	030-34325
License No.:	03-23853-01VA
Report No.:	030-34325/2008-030(DNMS)
EA No.:	EA-10-081
CAL No.:	3-08-004
Licensee:	Department of Veterans Affairs National Health Physics Program
Locations Inspected:	National Health Physics Program North Little Rock, Arkansas
	G.V. (Sonny) Montgomery VA Medical Center Jackson, Mississippi
	VA Medical Center Cincinnati Cincinnati, Ohio
	VA Medical Center Minneapolis, Minnesota
	VA Puget Sound Health Care System Seattle, Washington
	VA Sierra Nevada Health Care System Reno, Nevada
	Samuel S. Stratton VA Medical Center Albany, New York
	VA New York Harbor Healthcare System Brooklyn, New York
	VA Boston Healthcare System Boston, Massachusetts
	VA Medical Center Washington, District of Columbia
	VA Greater Los Angeles Healthcare System Los Angeles, California

Enclosure

	VA Medical Center San Francisco, California
	VA Medical Center Durham, North Carolina
	Hunter Holmes McGuire VA Medical Center Richmond, Virginia
Dates of Inspection:	October 8, 2008 through April 24, 2009, with continued in-office review through April 22, 2010
Preliminary Exit Meeting	December 12, 2008 (at NHPP headquarters)
Final Exit Meeting	April 22, 2010 (by telephone)
Inspectors:	Cassandra F. Frazier, Senior Health Physicist Kenneth J. Lambert, Senior Health Physicist Deborah A. Piskura, Health Physicist Darrel G. Wiedeman, Senior Health Physicist
Approved by:	Patricia J. Pelke, Chief Materials Licensing Branch Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Department of Veterans Affairs
Master Materials License
NRC Inspection Report No. 030-34325/2008-030

This announced U. S. Nuclear Regulatory Commission (NRC) reactive inspection was conducted to evaluate the Department of Veterans Affairs (DVA) inspection and enforcement activities in response to the multiple medical events involving prostate brachytherapy treatments reported by the Philadelphia Veterans Affairs Medical Center (PVAMC). This inspection included an assessment of the DVA's National Radiation Safety Committee's (NRSC) oversight of the National Health Physics Program's (NHPP) response to the multiple medical events at the PVAMC. Based on the increasing numbers of medical events reported by the PVAMC, as well as, medical events reported at other DVA medical facilities that performed prostate brachytherapy treatments, the NRC issued a Confirmatory Action Letter (CAL) (CAL 3-08-004) on October 14, 2008.

The program areas assessed during the inspection of the DVA's NHPP are summarized as follows: (1) the NHPP's response to the medical events at the PVAMC; (2) the NRSC's oversight and involvement in the NHPP's event follow-up activities at the PVAMC, including inspections and the assessment of patient doses; (3) the NHPP's response to requests for technical assistance from the PVAMC; (4) the NHPP's enforcement process for the PVAMC; (5) the NHPP's involvement in computer connectivity issues and network access issues at permittees that performed prostate brachytherapy treatments; and (6) the status of the CAL.

Part I of this inspection report addresses the findings of the NRC inspection of the DVA's NHPP. The NRC conducted a reactive inspection on December 8-12, 2008, at the DVA's NHPP. The NRC identified a number of concerns that impact the effectiveness of the DVA's Master Materials License (MML) program. The concerns involve the NRSC's oversight of the MML; the NHPP inspection, enforcement, and technical assistance processes; and the status of the CAL commitments. The NRC's concerns are based on the fact that the NHPP performed routine inspections at the PVAMC, and reactive inspections focused on the prostate brachytherapy programs, at the PVAMC and at the other 12 DVA facilities with active prostate brachytherapy programs, and failed to identify significant violations. Additionally, the NRSC did not provide effective oversight of the DVA's MML. Specifically, the inspectors identified the following concerns: (1) the NRSC's lack of oversight and direct involvement with the NHPP in the evaluation of medical events at the PVAMC and enforcement activities; (2) the failure of the NHPP to identify medical events and connectivity issues during previous routine inspections at the PVAMC; (3) the NHPP's enforcement process mischaracterized the violations identified at the PVAMC; (4) the NHPP's process for handling technical assistance requests from the PVAMC led to delays in assessing the patient doses; (5) the NHPP was not actively involved in resolving connectivity issues or network access in order to ensure that post-treatment plans were generated to verify the dose to the treatment site; and (6) the NHPP did not fully implement a commitment in the CAL concerning the completion of reactive inspections of the active prostate brachytherapy programs. The inspection report for the prostate brachytherapy program at the G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi has not been completed to date.

The NHPP conducted reactive inspections at the active prostate brachytherapy programs (12 total) as stated in a commitment in the CAL. The NHPP did not inspect the VA Sierra Nevada Health Care System, Reno, Nevada because that program was inactive as of

March 2008 and the NHPP considered it an inactive program. The NHPP identified violations at four facilities, the VA Cincinnati, the VA Washington, DC, the VA Los Angeles, and the VA Richmond. The NHPP also required all of the permittees authorized to perform prostate implants to provide a sample of patient cases to the VA Puget Sound Healthcare System, Seattle, Washington, for independent review by a nationally recognized expert in August 2008.

As a result of the numerous medical events at the PVAMC in 2008, Region III conducted an extent of condition inspection at 13 DVA hospitals authorized to perform prostate brachytherapy treatments. Twelve of these programs were identified by the DVA as active and one of these programs, the VA Sierra Nevada Health Care System, Reno, was identified as inactive as of March 2008, but was included in the NRC extent of condition inspection because of its recentness of activity relative to the medical events at the PVAMC. The on-site inspections were performed between October 8, 2008, and April 24, 2009, at the following DVA facilities: (1) G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; (2) VA Medical Center, Cincinnati, Cincinnati, Ohio; (3) VA Medical Center, Minneapolis, Minnesota; (4) VA Puget Sound Health Care System, Seattle, Washington; (5) VA Sierra Nevada Health Care System, Reno, Nevada; (6) Samuel S. Stratton VA Medical Center, Albany, New York; (7) VA New York Harbor Healthcare System, Brooklyn, New York; (8) VA Boston Healthcare System, Boston, Massachusetts; (9) VA Medical Center, Washington, District of Columbia; (10) VA Greater Los Angeles Healthcare System, Los Angeles, California; (11) VA Medical Center, San Francisco, California; (12) VA Medical Center, Durham, North Carolina; (13) Hunter Holmes McGuire VA Medical Center, Richmond, Virginia. The inspections included reviews of medical events reported at the VA Jackson (10 medical events reported); the VA Cincinnati (seven medical events reported); the VA Brooklyn (one medical event reported); the VA Washington D.C. (three medical events reported and all were subsequently retracted); the VA Los Angeles (three medical events reported); and the VA Durham (one medical event reported). Dates of the implants which were reported as medical events occurred between 2005 and 2009. The basis for reporting the medical events also varied for each hospital.

Part II of this inspection report addresses the findings of the NRC inspections conducted at the 13 DVA facilities authorized to perform prostate brachytherapy. In addition to the PVAMC, four other DVA medical centers, located in Cincinnati, Ohio; Jackson, Mississippi; Los Angeles, California; and Washington, D.C., suspended their prostate brachytherapy programs as medical events were identified and reported. These programs were suspended prior to the NRC inspections. One medical center, the VA Cincinnati, has restarted its prostate brachytherapy program on February 16, 2010.

Based on the extent of condition inspections, three apparent violations were identified. The first apparent violation involved the licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2). Eleven examples of this apparent violation were identified at the following medical centers: the VA Jackson; the VA Minneapolis; the VA Seattle; the VA Reno; the VA Albany; the VA Brooklyn; the VA Boston; the VA Washington DC; the VA Los Angeles; the VA San Francisco; and the VA Durham. The second apparent violation involved the licensee's failure to verify that the administration is in accordance with the treatment plan, if applicable, and the written directive as required by 10 CFR 35.41(b)(2). Four examples of this apparent violation were identified at the following medical centers: the VA Jackson; the VA Reno; the VA Brooklyn; and the VA Boston. The third apparent violation involved the licensee's failure to notify the NRC, by the next calendar day after discovery of a medical event, as required by 10 CFR 35.3045(c), which occurred at the VA Brooklyn.

The NRC attributed the root cause of the inadequate procedures to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the prostate brachytherapy procedure. For example, the procedures did not specify the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The NHPP's failure to identify these inadequate procedures during its routine inspections contributed to the continued use of these inadequate policies and procedures. The DVA's corrective actions for the apparent violation of 35.41(a)(2) included developing standardized written procedures for prostate implants. The new procedures included criteria for evaluating the dose to the treatment site, methods to verify the dose to the treatment site through post-treatment planning and imaging, and medical event reporting criteria. For the VA Boston, while the permittee developed procedures to provide high confidence that each administration was in accordance with the written directive, they failed to implement them.

The NRC attributed various root causes which led to the failure to verify that the administration was in accordance with the treatment plan and the written directive. For the VA Jackson, the hospital experienced difficulties granting access to its network for a newly-hired dosimetrist. The staff also experienced difficulties transferring computerized tomography (CT) images to the treatment planning computer due to incompatible CT file format. At the VA Reno, the staff did not place emphasis or believe it was important or required to generate a post-treatment plan. At Brooklyn, the permittee experienced difficulty transferring CT images to the treatment planning computer due to incompatible CT file format. The permittee resolved the connectivity issues by upgrading its CT software and eventually installing a new CT unit. At the VA Boston, CT images were taken on some patients, however, post-treatment plans were not performed until five years after the implant. It is unknown why post-treatment plans were not performed because the authorized users who administered these treatments in 2005 were no longer associated with that facility. For the VA Boston, the permittee instituted a computerized patient record system with prompts to remind the staff of any open appointments. The radiation oncology department acquired its own CT unit enabling the department more flexibility in scheduling post-treatment CT imaging for its patients.

The NRC attributed the root cause of the licensee's failure to timely notify the NRC of a medical event at the VA Brooklyn to the staff's misunderstanding of the requirement. The medical event had been identified by the VA Brooklyn staff; however, they failed to use the information from the post-treatment plan and act accordingly. This medical event was an isolated occurrence. The permittee staff had sufficient information, from the original post-treatment plan, generated on October 10, 2008, indicating that the administered dose to the treatment site differed by more than 20 percent of the prescribed dose. However, they failed to use the information from the post-treatment plan and act accordingly by notifying the NHPP, as well as NRC, by the next calendar day. The permittee's corrective actions for the failure to report a medical event at the VA Brooklyn included providing training on NRC reporting requirements to the radiation oncology staff.

During the extent of condition inspection activities, the inspectors did not identify any issues similar to those identified at the PVAMC concerning erratic seed placement, uncertainty on how to identify medical events, inadequate training, inadequate oversight of contractors, inadequate management oversight of the prostate brachytherapy program by the Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO).

The inspectors identified brachytherapy post-treatment plans where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. The inspectors identified this issue at the VA Reno; the VA Albany; the VA Boston; and at the VA Richmond. Do to questions regarding the methodology for assigning the dose to the treatment site, this issue has been identified as an open item.

Report Details

I. The National Health Physics Program Inspection and Enforcement Activities of the Multiple Medical Events at the Philadelphia Veteran Affairs Medical Center

1 Program Overview

The Department of Veterans Affairs (DVA) is authorized under the U. S. Nuclear Regulatory Commission (NRC) Master Materials License (MML) Number 03-23853-01VA, to issue byproduct radioactive material permits and inspect DVA medical facilities throughout the United States. The DVA oversees approximately 117 permittees. At the time the Philadelphia Veterans Affairs Medical Center (PVAMC, permittee) initially reported a medical event that involved prostate brachytherapy; the DVA had a total of 13 active prostate brachytherapy programs.

The DVA MML has centralized control over its radiation control program through the National Radiation Safety Committee (NRSC) that has the responsibility for providing oversight of the implementation of the MML and associated permittee activities. The Committee has delegated the authority to manage the DVA radiation control program and DVA day-to-day operations to its National Health Physics Program (NHPP), which includes a Program Director and five Program Managers (PM) (one of which is currently vacant). The previous Program Director retired on September 3, 2009, and a PM was appointed as the interim Program Director. The interim Program Director was selected for the position on March 28, 2010. The NHPP is responsible for issuing permits, conducting inspections, responding to events, and investigating incidents and allegations.

The NRC last inspected the activities under the MML on April 16-20, 2007. No violations of NRC requirements were identified during the last inspection. The NRC previously inspected the MML on March 14-17, 2005 with one violation identified for the failure to immediately report to the NRC, two Severity Level III violations issued to its permittees. The DVA has been subject to escalated enforcement in the last two years. Specifically violations were identified at the VA Iowa City, which resulted in escalated enforcement with a $6,500 civil penalty issued April 10, 2009. The NRC determined that a substantial programmatic breakdown occurred in the PVAMC prostate brachytherapy program. *S*everal violations were identified that resulted in escalated enforcement with a $227,500 civil penalty issued on March 17, 2010.

2 NHPP's Response to the Medical Events at the PVAMC

2.1 Inspection Scope

The NRC inspectors reviewed the NHPP Inspection Report (642-08-I02), dated October 16, 2008, associated with the reported medical events at the PVAMC, the permittee's initial response to the Notice of Violation (NOV) dated November 21, 2008, and the permittee's second response dated December 29, 2008. The inspectors interviewed selected NHPP staff and reviewed licensee procedures associated with event response.

2.2 Observations and Findings

On May 28 and 29, 2008, the NHPP conducted a reactive inspection at the PVAMC in response to a reported medical event involving a prostate implant administered on May 5, 2008. The event involved the administration of brachytherapy sources that were the wrong activity and resulted in a dose to the prostate that was less than 80 percent of the prescribed dose. As part of their event response, the NHPP requested that the PVAMC perform a review of approximately 20 additional prostate brachytherapy patient cases. Based on the PVAMC's expanded review, additional medical events were identified. The scope of the reviewed cases was further expanded to include all 116 prostate brachytherapy treatments performed on 114 patients (two patients received two implants) from the start of program in 2002-2008. On June 11, 2008, the PVAMC prostate brachytherapy program was suspended and it remains suspended to date with no projected plans to restart.

On June 24 and 25, 2008, NHPP conducted a follow-up on-site inspection to evaluate the additional medical events. The DVA eventually reported a total of 97 medical events involving prostate brachytherapy treatments administered between February 2002 and June 2008. On October 16, 2008, the NHPP issued its inspection report for its reactive inspection at the PVAMC and identified four violations, which were characterized as a Severity Level III problem. Based on the inspection, the NHPP determined that the permittee failed to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the written directive and "clinical staff (e.g., physician authorized users and medical physicists) for brachytherapy procedures did not receive training about regulatory requirements to identify and report medical events;" (2) have adequate written procedures to address verification that the administration was in accordance with the treatment plan and the written directive, and included checks of the computer-generated dose calculations; (3) document the required information on a written directive for a prostate brachytherapy treatment; and (4) notify the NRC no later than the next calendar day after discovery of medical events.

The NHPP conducted routine inspections at the PVAMC on January 29-30, 2004, January 26, 2006, and January 23-24, 2008. The NHPP failed to identify the medical events during any of these previous routine inspections. Additionally, the NHPP failed to identify several program weaknesses at the PVAMC which resulted in a substantial programmatic breakdown in the prostate brachytherapy program. These weaknesses include: (1) inadequate management oversight of the prostate brachytherapy program by the RSO and the RSC; (2) inadequate quarterly audits of the brachytherapy program by the radiation safety staff; (3) failure of the RSC to take action regarding computer interface problems; and (4) the annual audits of the radiation safety program conducted by the RSO for 2006 and 2007 were not finalized and provided to the RSC for review.

The NHPP conducted follow up inspections at the PVAMC on January 20-21, 2009, June 22-26, 2009, August 26-27, 2009 and October 13-16, 2009. The October inspection was a routine inspection of the PVAMC. A portion of that inspection involved a review of the corrective actions related to the violations cited in the NHPP's inspection report issued on October 16, 2008. The inspections conducted in January, June and August 2009, were focused on the root cause(s) and corrective actions of the reported medical events and review of patient dose data. The NHPP's inspection report was issued on April 21, 2010; no additional violations were identified.

2.3 Conclusions

The NHPP conducted several routine inspections of the PVAMC program, prior to the May 2008 medical event follow-up inspection, and failed to identify the medical events and the weaknesses in the prostate brachytherapy program which resulted in a substantial programmatic breakdown of the program. However, the NHPP did an adequate follow-up inspection at the PVAMC to ensure that appropriate corrective actions were taken for the cited violations addressed in NHPP's October 2008 inspection report and Notice of Violation. The NRC concluded that the NHPP missed numerous opportunities to identify the medical events and program weaknesses at the PVAMC.

3 NRSC Oversight and Involvement in the NHPP's Event Follow-Up Activities Including Patient Dose Assessment at the PVAMC

3.1 Inspection Scope

The NRC inspectors reviewed selected NRSC meeting minutes. The inspectors also observed the quarterly NRSC meetings in 2008, 2009, and 2010. The inspectors interviewed selected NHPP staff and members of the NRSC and reviewed licensee procedures associated with event response.

3.2 Observations and Findings

The NRSC did not get involved in the patient dose evaluation process. The NRSC did not direct the process or provide oversight to ensure that patient dose assessments were completed in a consistent, methodical, and expeditious manner. For example, the PVAMC acted independently to establish an informal process to assess patient doses on a part-time basis. The process they established lacked oversight by the NRSC and the NHPP which resulted in further delays. The NRC concluded that the NRSC did not provide oversight and had no direct involvement in the PVAMC medical event evaluations.

The NRSC provided no apparent direct involvement in the identification process of medical events or the evaluation of doses to the treatment site and other organs. The NRSC provided no direction in any of the decision-making activities concerning the medical events at the PVAMC. The NRSC provided no guidance on the resources required to complete the patient dose assessments and failed to establish milestones to track the progress of the assessment. The PVAMC's decision to retain a part-time medical physicist to review the patient cases and generate post-treatment plans did not demonstrate a commitment to performance improvements. The patient dose assessments took the PVAMC and the NHPP over a year to complete.

The NRC inspectors identified that the NRSC provided minimal oversight of the "two-phase" approach used by the PVAMC to evaluate the patient dose data which proved to be ineffective and inconsistent. Previous interviews with PVAMC staff determined that the staff misunderstood its "two-phase" criteria. A significant amount of time and resources were directed at generating data for the patients that was ultimately not used in the final dose assessments. This extra data was also inconsistent with the NRC medical event reporting requirements.

Additionally, the NRC inspectors identified that the NRSC was not engaged in the decision-making activities which pertained to the medical events at the PVAMC during the quarterly committee meetings. The NRSC meetings focus on "one-way" communication from the NHPP to the NRSC. The NRSC meetings consisted of the NHPP providing information to the committee members, with little communication or discussion from the committee members on safety issues and concerns presented by the NHPP. The NRC is concerned of the NRSC's limited involvement and program oversight of the DVA's MML.

3.3 Conclusions

The NRC concluded that the NRSC provided limited oversight and direct involvement in the patient dose assessments and enforcement activities at the PVAMC in response to the multiple medical events reported. The NRC identified that the NRSC, as the principle organizational element for implementing the DVA's MML, failed to provide sufficient guidance and oversight to prevent the issues associated with the multiple medical events that occurred at the PVAMC. The NRC observed weaknesses in the NRSC's oversight and direction for event response and has not executed their authority in the enforcement process under the MML.

4 NHPP's Response to Requests for Technical Assistance from the PVAMC

4.1 Inspection Scope

The inspectors reviewed the procedures and process NHPP PMs used for reviewing and responding to information requests from the PVAMC. In addition, the inspectors interviewed the NHPP Director and NHPP PMs regarding the process and procedures.

4.2 Observations and Findings

The Veterans Health Administration (VHA), National Health Physics Program (NHPP), Internal Procedure No. 13, "VHA Consultative Support" describes the procedural guidelines for VHA consultative support by the NHPP staff. The procedure provides the guidelines for regulatory compliance assistance. The NHPP PMs are directed by the procedure to identify programmatic issues to support the implementation of the MML. The programmatic issues include responding to telephone inquiries regarding regulatory compliance information or assistance. The procedures identify a process for referring consultative support requests not within the scope of the programmatic issues to the NHPP Director or other VHA resources.

The NRC inspectors reviewed the process for telephone inquires (requests) received by the NHPP PM from the permittees. The NHPP indicated that telephone inquiries are processed based on the significance of the issues. If the request is straightforward in nature, it is typically answered by the NHPP PM at the time of the telephone call or within a short period of time (1 or 2 days). These straightforward telephone calls are not usually documented. However, if documentation is required it will be by electronic mail (e-mail). Telephone requests with significant issues are documented by e-mail and are tracked by the NHPP PM who received the telephone call. The PM prepares a draft response and provides the permittee request and draft response to each NHPP PM for review and comment. The final written response is provided to the permittee in an e-mail entitled, "record of contact." The NHPP PM generally has 30 days to respond to a

telephone request, but typically respond within a couple of days. For requests that require a more detailed assessment and involve an extensive response, the final resolution is provided in a memorandum from the NHPP Director to the permittee.

The inspectors evaluated the NHPP's response for technical assistance during the multiple medical events reported by the PVAMC. During the June 22-26, 2008, reactive inspection at the PVAMC, the NRC inspectors reviewed the process for evaluating and determining the medical events at the PVAMC. Staff at the PVAMC stated to the inspectors that between May 2008 and July 2008, several telephone requests were made to the NHPP for technical assistance in developing a methodology to calculate doses to the skin or an organ or tissue other than the treatment site as required by 10 CFR 30.3045(a)(3). However, the PVAMC staff informed the NRC inspectors that they had not received a response for technical assistance from the NHPP. The PVAMC staff explained to the inspectors that they were having difficulty in determining the most appropriate approach for calculating doses to other organs and tissues. They further stated that NHPP provided no definitive response to their request for assistance in calculating doses to other organs and tissues.

The NHPP informed the PVAMC that any request for technical assistance should be made in writing. The NRC inspectors noted that the PVAMC appeared to be confused and not aware that technical assistance requests must be in writing. Subsequently, the PVAMC provided a written request to the NHPP for assistance in developing a methodology for calculating the dose to other organs and tissues other than the treatment site. The NRC observed that the PVAMC's misunderstanding of the process to obtain technical assistance from the NHPP delayed the PVAMC's ability to assess the patient dose data and determine whether medical events occurred.

4.3 Conclusions

The inspectors noted that although the NHPP had an informal process for receiving and responding to technical assistance requests, the process for requesting technical assistance was not formalized (no written procedures) and led to a lack of understanding by the PVAMC on the proper method for submitting the request. The NRC concluded that the delayed response by the NHPP hindered the PVAMC's ability to assess the patient dose data, evaluate the safety significance and the magnitude of the medical events, and report the medical events in a timely manner.

5 NHPP's Enforcement Process for the PVAMC

5.1 Inspection Scope

The inspectors reviewed the NHPP procedures and processes for issuing violations and determining the appropriate severity level, reports and violations issued to permittees, and permittee responses to violations. The inspectors also interviewed selected NHPP staff.

5.2 Observations and Findings

The Veterans Health Administration (VHA), National Radiation Safety Committee Standard Operation Procedure 03, "National Radiation Safety Committee Enforcement Procedures," documents the policy and process used by the NHPP to assess the safety

significance of violations and determine the appropriate response by NHPP. The procedure provides guidance on dispositioning a violation, determining the severity level of the violation, and ensuring the permittee's response and corrective actions were appropriate and in accordance with the NRC Enforcement Policy.

On October 16, 2008, the DVA issued an inspection report regarding the NHPP inspection activities at the PVAMC and cited four violations. The violations included the PVAMC's failure to: (1) have adequate written procedures to provide high confidence that each administration was in accordance with the written directive and "clinical staff (e.g., physician authorized users and medical physicists) for brachytherapy procedures did not receive training about regulatory requirements to identify and report medical events;" (2) have adequate written procedures to address verification that the administration was in accordance with the treatment plan and the written directive, and included checks of the computer-generated dose calculations; (3) document the required information on a written directive for a prostate brachytherapy treatment; and (4) notify the NRC no later than the next calendar day after discovery of medical events. The NHPP characterized these violations as a Severity Level III Problem.

The NRC Enforcement Policy describes an example of a Severity Level II Violation in Supplement VI, Example B.3, "a substantial programmatic failure to implement written directive or procedures for administrations requiring a written directive, such as a failure of the license's procedures to address one or more of the elements in 10 CFR 35.40 or 35.41, or the failure to train personnel in those procedures, that results in a medical event." The circumstances surrounding the multiple medical events which occurred at the PVAMC met the criteria outlined in the above example as a Severity Level II Violation. According to the NHPP Program Director, it was their position that the severity level of the violations was irrelevant for their enforcement purposes and they were more concerned about the permittee's corrective actions rather than the severity level of the violations. The NRC concluded that the NHPP mischaracterized the violations at the PVAMC as a Severity Level III problem which did not represent the safety significance and the egregiousness of the violations identified at the PVAMC.

On November 21, 2008, the PVAMC provided its response to the NHPP inspection report and NOV. The PVAMC disagreed with the violation regarding reporting requirements for a medical event, and provided incorrect information regarding the applicability of the training requirements for physicians and medical physicists. The NHPP determined that the PVAMC's response was adequate and closed the NOV in a letter to PVAMC dated December 5, 2008. The NRC identified that the NHPP accepted the response to the NOV, even though the PVAMC response denied a violation and included inaccurate information regarding training requirements for physicians and medical physicists.

During the inspection of the NHPP, the inspectors questioned the NHPP staff regarding their acceptance of the PVAMC's response which denied a violation. The inspectors also questioned the NHPP staff regarding their acceptance of the incorrect training information the PVAMC provided in its response. Based on the NRC's questions during the inspection, the NHPP contacted the PVAMC Director and instructed him to rescind the November 21, 2008, response and resubmit a response to the NOV which accepted all of the violations and provided correct training information. On December 29, 2008, PVAMC senior management rescinded its November 21, 2008, letter responding to the violations and provided a revised response to the NOV accepting all of the violations.

On December 29, 2008, PVAMC provided a revised response to the NOV accepting all the violations. In a memorandum from the NHPP to the PVAMC dated January 27, 2009, the NHPP subsequently accepted the PVAMC's revised response to the NOV.

The inspectors identified that the NHPP's enforcement procedure is not clear on whether the NRSC should be notified of the Severity Level I, II, or III violation, provide its review and concurrence prior to the NOV being issued. In order to provide appropriate oversight and to ensure that the Severity Level of the violation is appropriately characterized, it would be appropriate for the NRSC to provide its review and concurrence prior to the violation being issued to the permittee.

The inspectors identified that the violations for the medical events at the PVAMC were issued without prior review and approval by the NRSC. This is an example where the NRSC should have been consulted in order to determine the appropriate severity level of the violations. The NRC is concerned that the NHPP issues Severity Level I, II, or III violations without prior NRSC review and concurrence. This process prevents the NRSC from providing the oversight required to ensure that the severity level of the violation(s) is characterized appropriately and is in accordance with the NRC Enforcement Policy. Additionally, the NHPP does not have a formal process for evaluating contested or disputed violations.

5.3 Conclusions

The NHPP accepted the PVAMC's response which disagreed with the violation regarding reporting requirements for a medical event, and provided incorrect information regarding the applicability of the training requirements for physicians and medical physicists. The NHPP re-evaluated the PVAMC's response only when prompted by the NRC. The NHPP's acceptance of a denial to an NOV without further assessment and response to the permittee is not consistent with NRC policy and procedures. In addition, the NHPP's characterization of the violations identified during its inspection at the PVAMC was not consistent with the NRC Enforcement Policy. The NRC observed that the NHPP issues Severity Level I, II, or III violations without prior NRSC review and concurrence, which precludes the NRSC from providing the oversight required to ensure that the violation severity level characterization is appropriate and in accordance with the NRC Enforcement Policy. These issues have been identified as concerns by the NRC staff.

6 NHPP Involvement in Computer Connectivity Issues and Network Access

6.1 Inspection Scope

The inspectors reviewed connectivity issues and DVA network access with the NHPP and at each of the 13 permittees with prostate brachytherapy programs included in the extent of condition inspection. The inspectors also interviewed selected NHPP and permittee staff.

6.2 Observations and Findings

The NRC became aware of the connectivity issues at the PVAMC during its special inspection. The connectivity issue involved the inability to import CT images into the

treatment planning computer because the treatment planning computer was not a DVA approved computer network system. This issue was subsequently resolved by acquiring the appropriate approval from DVA headquarters. The connectivity issues experienced at the PVAMC are addressed in NRC Inspection Report Nos. 030-34325/2008-029 (DNMS) and 030-34325/2009-001(DNMS). In light of the connectivity issues identified by the NRC at the PVAMC, the inspectors reviewed connectivity capabilities and computer network access issues at all of the 13 permittees with prostate brachytherapy programs included in the extent of condition inspection.

The NRC inspectors identified additional connectivity and network access issues, which affected the permittee's ability to generate post-treatment plans at DVA facilities located in Jackson, Reno, and Brooklyn. The time period these connectivity and network access issues occurred ranged from several months to several years. The NHPP became aware of the connectivity issues and the incompatible file format at the VA Jackson in September 2008 and at the VA Reno in October 2008, just prior to the respective NRC inspections on October 8-9, 2008 and January 19-22, 2009. Both of these prostate brachytherapy programs were inactive at the time of the NRC inspections and the connectivity issues had been resolved by the permittees. The permittee's inability to generate post-treatment plans directly impacted their capability to evaluate the administered dose to the prostate and verify that it was in accordance with the written directive.

The NRC inspector learned that the VA Brooklyn experienced connectivity issues between July 2007 and October 2007. A service representative for the CT unit attempted to retrieve the affected patient CT data; however, not all the patient data was retrievable. The department received a software upgrade in October 2007, re-established connectivity and closely monitored the ability to generate treatment plans. The medical center installed a replacement CT unit in October 2008 which resolved the connectivity issue. The connectivity issue was not identified in the NHPP's Inspection Report Number 630A4-08-I01 which documented the results of the NHPP's reactive inspection at the VA Brooklyn.

The inspectors noted that the NHPP was not involved in connectivity issues. The NHPP did not identify the connectivity issues at the PVAMC during its routine inspection in January 23-24, 2008. The connectivity issues were documented in the PVAMC's RSC meeting minutes; however, the NHPP did not review these records and appeared to be unaware of the issues. In addition, the NHPP failed to identify connectivity issues at the VA Jackson, the VA Reno, and the VA Brooklyn.

According to the NHPP, it was not responsible for resolving connectivity issues at their permittees' sites. The NHPP stated that these connectivity and computer access issues did not involve NRC regulatory requirements. The NRC concluded that the NHPP did not identify the connectivity issues during their inspections and they failed to recognize the significance of this issue. The NHPP took no active involvement or provided assistance to permittees which experienced connectivity issues or delays in being granted network access so that post-treatment plans could be generated to verify the dose to the treatment site.

6.3 Conclusions

The NHPP did not identify connectivity issues during their inspections. In addition, the NHPP was not actively involved in resolving connectivity issues or network access in order to ensure that post-treatment plans were generated to verify the dose to the treatment site. The connectivity issues, which occurred between September 2005 and October 2008 at the VA Reno, were not identified during the last NHPP routine inspection on May 22-23, 2007. Finally, the connectivity issues at the VA Brooklyn, which occurred between July and October 2007, were not identified during the NHPP's previous reactive inspection on November 20 - December 17, 2008.

7 Status of the Confirmatory Action Letter

7.1 Inspection Scope

The inspectors reviewed the status of the licensee's commitments to be taken in response to the NRC's Confirmatory Action Letter (CAL), dated October 14, 2008. The inspectors also interviewed selected NHPP PMs.

7.2 Observations and Findings

On October 14, 2008, the NRC issued a CAL (3-08-004) to the NHPP documenting the commitments made by the DVA to identify and address the problems that led to several reported medical events at DVA hospitals and to prevent their recurrence. The CAL documented commitments made by the NHPP that included: (1) conducting inspections of the active prostate brachytherapy programs at the DVA hospitals authorized to perform prostate cancer treatments; (2) developing and implementing standardized procedures for prostate cancer treatments at all DVA hospitals; (3) correcting the incompatible data transmission problems at the PVAMC and at the VA Jackson that prevented post-treatment dose analysis; (4) identifying the root causes of the medical events and implementing corrective actions; (5) suspending any prostate brachytherapy program where 20 percent or more of the treatments have been identified as medical events; (6) conducting an inspection to confirm that all necessary corrective actions have been taken prior to restarting any suspended brachytherapy treatment program, and notifying the NRC when a suspended brachytherapy program restart is planned; and (7) conducting an inspection of any new prostate brachytherapy treatment programs at other DVA facilities to confirm that the facility has implemented the enhanced DVA procedures.

The NHPP conducted reactive inspections at all the active prostate brachytherapy programs authorized to perform prostate brachytherapy treatments and with one exception, the VA Jackson, provided the results of these inspections to the NRC. The NHPP initiated its on-site inspections on August 27, 2008, at the VA Albany, and concluded their on-site inspection activities on January 22, 2009. The NHPP conducted a site visit instead of an inspection at the VA Boston. The inspectors noted that the NHPP's inspection report for the VA Jackson had not been issued to date.

The NHPP developed standardized procedures for conducting prostate brachytherapy treatments and issued these procedures on January 9, 2009, to all of the active brachytherapy programs with a target implementation date of April 24, 2009, and finalized the procedures on June 9, 2009.

The DVA corrected the incompatible data transmission problems which prevented post-treatment dose assessment at the PVAMC in January 2008 and at the VA Jackson on February 8, 2008. The DVA subsequently added the treatment planning computer systems to its network and granted network access to the appropriate DVA personnel responsible for the generation of post-treatment plans. The prostate brachytherapy programs remain inactive at these DVA medical centers.

The NHPP generated a listing of root causes and corrective actions implemented to prevent recurrence of medical events in order to satisfy commitments in Item 4 of the CAL. The root causes and corrective actions were previously documented in the NRC Inspection Reports 030-34325/2009-001(DNMS) and 030-34325-2008-029(DNMS).

Regarding Item 5 of the CAL, the DVA suspended five programs and no additional prostate brachytherapy programs have been suspended.

Regarding Item 6 of the CAL, the commitments were completed for one suspended prostate brachytherapy program at the VA Cincinnati. Prior to the restart of this suspended prostate brachytherapy program, the NHPP conducted an inspection on June 30 to July 1, 2009, with continued in-office review to October 22, 2009. The purpose of the inspection was to confirm that all the corrective actions required by the CAL had been implemented. No violations were identified during the NHPP's inspection. The NHPP discussed their restart plans with the NRC staff and provided notification to the NRC on February 16, 2010 that the VA Cincinnati planned to resume its prostate brachytherapy program. However, as an additional requirement for restart of the suspended brachytherapy program, the NHPP required the VA Cincinnati to submit its post-treatment plans and written directives for its first ten implants to a DVA expert for an independent review.

Regarding Item 7 of the CAL, the DVA has not initiated any new prostate brachytherapy programs since the CAL was issued.

The NRC will continue to evaluate the status of the CAL commitments and close the commitments under separate correspondence.

7.3 Conclusions

The NHPP completed its on-site inspections of all DVA hospitals with active prostate brachytherapy programs as specified in Item 1 of the CAL on January 21, 2009. However, an inspection report for the VA Jackson has not been issued to date. The NHPP developed standardized procedures for prostate implants on January 9, 2009, with a target implementation date of April 24, 2009, and finalized the procedures on June 9, 2009. The DVA corrected the incompatible data transmission problems at the PVAMC and at the VA Jackson that prevented post-treatment dose analysis; the prostate brachytherapy programs remain inactive at these DVA medical centers. The DVA completed its assessment of the root causes and corrective actions for the multiple medical events on January 22, 2009. Regarding Item 5 of the CAL, five prostate brachytherapy programs were suspended. No additional prostate brachytherapy programs have been suspended. Regarding Item 6 of the CAL, the NHPP completed its restart commitments for a previously suspended program at the VA Cincinnati on

February 16, 2010. Item 7 of the CAL remains open because no new prostate brachytherapy programs have been established at any other DVA facilities.

8 Areas of Concern

8.1 Inspection Scope

The inspectors identified several areas of concern regarding the licensee's event follow-up at the PVAMC and its inspections conducted at the other 12 active prostate brachytherapy programs. This section re-summarizes the concerns previously discussed in this inspection report.

8.2 Observations and Findings

The NRC is concerned that the NRSC does not provide sufficient direction and oversight to the NHPP to effectively implement the MML. Specifically, the areas where the NRC has concerns are summarized below:

A. National Radiation Safety Committee Oversight

The NRC is concerned that the NRSC lacks oversight and direct involvement with the NHPP in the PVAMC medical event evaluations and enforcement activities. Specifically:

- The NRC is concerned that the NRSC has not fulfilled their role in providing oversight and direction for event response and has not executed their authority in the enforcement process under the MML.

- The NRSC was not involved in the patient dose evaluation process. The NRSC did not direct the process or provide oversight to ensure that patient dose assessments were completed in a consistent, methodical, and expeditious manner.

- The NRSC provided no direction in any of the decision-making activities concerning the medical events at the PVAMC. The NRSC provided no guidance on the resources required to complete the patient dose assessments and failed to establish milestones to track the progress of the assessment. The patient dose assessments took the PVAMC and the NHPP over a year to complete.

- The NRC is concerned that for medical events of this scope and magnitude, the NRSC did not have greater involvement in the decision-making process.

- The NRC is concerned that the NRSC was not adequately engaged in the discussions pertaining to the medical events at PVAMC during the quarterly committee meetings. The NRSC meetings appear to focus on "one-way" communication from the NHPP to the NRSC. The NRSC meetings consist of the NHPP providing information to the committee members, with no direction from the NRSC and little communication or

discussion from the committee members on safety issues and concerns presented by the NHPP.

B. Inspection Process

The NRC identified that the NHPP missed opportunities to identify medical events and several program weaknesses during their previous routine inspections on January 29-30, 2004, January 26, 2006, and January 23-24, 2008, at the PVAMC.

The NHPP conducted reactive inspections at the active prostate brachytherapy programs (12 total) as stated in a commitment in the CAL. The NHPP identified violations at four facilities (the VA Cincinnati, the VA Washington, DC, the VA Los Angeles, and the VA Richmond). The NRC conducted reactive inspections at these same 12 facilities, in addition to the VA Reno, after the NHPP on-site inspections. The NRC inspectors identified violations at 11 facilities. The NRC is concerned that the NHPP missed opportunities and failed to discover violations at the other VA facilities during their reactive inspections.

In addition, the NRC is concerned that the NHPP issued an Inspection Report (630A4-08-I01), with no violations for a reactive inspection involving a medical event at the VA Brooklyn, while the NRC identified several apparent and potential violations. The NHPP issued an inspection report with six "recommendations." Based on the NRC's review of this inspection report, one of these "recommendations" for Brooklyn should have been characterized as a violation of 10 CFR 35.41(a)(2).

The NRC is concerned that the NHPP performed routine inspections at the PVAMC, and reactive inspections focused on the prostate brachytherapy programs, at the PVAMC and at the other 12 DVA facilities with active prostate brachytherapy programs, and failed to identify significant violations.

C. Enforcement Process

The NRC is concerned that the NHPP accepted the PVAMC's initial response to the NOV where the permittee did not concur with the violation involving the failure to report the medical events. The permittee further stated its position that training for experienced authorized user physicians and authorized medical physicists was not a regulatory requirement. The NHPP only questioned the PVAMC response when prompted by the NRC inspectors during the December 2008 inspection. Subsequently, the PVAMC rescinded its original response and submitted a revised response to the NOV accepting all the violations.

The NRC is concerned that the NHPP characterized the violations identified during its inspection at the a PVAMC as Severity Level III problem. However, the NRC Enforcement Policy clearly described a violation involving a medical event associated with the failure to train staff as a Severity Level II violation.

The NRC is concerned that issuing Severity Level I, II, or III violations prior to NRSC review and concurrence prevents the NRSC from performing their oversight responsibility to implement the MML effectively.

D. NHPP Technical Assistance Request Process

The NRC is concerned that the NHPP's process for requesting technical assistance is not formalized and could lead to a lack of understanding by the permittees on the proper procedure for submitting a request. Specifically, between May and July 2008, the PVAMC requested assistance from the NHPP in developing a methodology to calculate doses to other organs and tissues. Since the PVAMC had no clear criteria to initially evaluate the doses to other organs and tissues, this delayed the medical center's ability to assess the patient dose data.

E. Connectivity Issues

The NRC is concerned that the NHPP did not identify connectivity issues during their inspections. Additionally, the NHPP was not actively involved in resolving connectivity issues or network access at its permittees in order to ensure that post-treatment plans were generated to verify the dose to the treatment site.

F. Confirmatory Action Letter

NRC is concerned that the commitments in the CAL have not been fully implemented. The NRC is concerned that the NHPP inspection report for the VA Jackson has not been issued to date for the NHPP's reactive inspection conducted on October 8-11, 2008. Additionally, a site visit was conducted at the VA Boston while the CAL commitment stated that the NHPP would perform reactive inspections at all of the active prostate brachytherapy programs.

8.3 Conclusions

The NRC identified a number of concerns that impact the effectiveness of the DVA's MML program. The concerns involve the NRSC's oversight of the MML; the NHPP inspection, enforcement, and technical assistance processes; and the status of the CAL commitments. The NRC's concerns are based on the fact that the NHPP performed routine inspections at the PVAMC, and reactive inspections focused on the prostate brachytherapy programs, at the PVAMC and at the other 12 DVA facilities with active prostate brachytherapy programs, and failed to identify significant violations.

The inspectors identified six concerns that include: (1) the NRSC's oversight; (2) the NHPP inspection process; (3) the NHPP's enforcement process; (4) the NHPP's process for handling technical assistance requests; (5) NHPP's failure to identify and address the connectivity issues; and (6) the status of the CAL.

II. Extent of Condition Inspections at DVA Permittees Authorized for Permanent Prostate Brachytherapy

1 Program Overview

As of the dates of this inspection, twelve permittees had active permanent prostate brachytherapy programs. The permittees with active brachytherapy programs included: (1) G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi; (2) VA Medical Center, Cincinnati, Cincinnati, Ohio; (3) VA Medical Center, Minneapolis, Minnesota; (4) VA Puget Sound Health Care System, Seattle, Washington; (5) Samuel S. Stratton

VA Medical Center, Albany, New York; (6) VA New York Harbor Healthcare System, Brooklyn, New York; (7) VA Boston Healthcare System, Boston, Massachusetts; (8) VA Medical Center, Washington, District of Columbia; (9) VA Greater Los Angeles Healthcare System, Los Angeles, California; (10) VA Medical Center, San Francisco, California; (11) VA Medical Center, Durham, North Carolina; and (12) Hunter Holmes McGuire VA Medical Center, Richmond, Virginia. As of March 4, 2008, the brachytherapy program at the VA Sierra Nevada Health Care System, Reno, Nevada was inactive due to the departure of the authorized physician user. However, the NRC included the VA Reno in the extent of condition inspection because of its recentness of activity relative to the medical events reported at the PVAMC.

In 2008, the NHPP requested permittees with active brachytherapy programs to submit their ten most recent prostate implant cases to an in-house DVA expert physician at the VA Puget Sound Health Care System in Seattle, Washington, for an independent review. Two facilities (the VA Cincinnati and the VA Jackson) reported medical events based on the expert's re-contouring of the prostate. Based on the independent review, the DVA expert identified no medical events at the remaining DVA facilities.

As part of the CAL commitments, the NHPP conducted reactive inspections in 2008-2009 at all the DVA hospitals with active brachytherapy programs; the NHPP conducted a site visit at the VA Boston. The NHPP identified Severity Level IV violations at the VA Cincinnati, the VA Washington, DC, the VA Los Angeles, and the VA Richmond. The NHPP inspection report for the VA Jackson was still pending at the time this report was issued. Although the NHPP did not include the VA Reno in their inspection activities, the previous NHPP inspection on May 25, 2007 identified no violations. The VA Reno was not included in the NHPP reactive inspections because that program was determined to be "inactive" by the DVA at the time the CAL was issued. The NHPP identified no violations during its inspections at the VA Minneapolis, the VA Puget Sound, the VA Albany, the VA Brooklyn, the VA Boston, the VA San Francisco, and the VA Durham. The NHPP inspected brachytherapy programs on a two year frequency. In 2009, the NHPP changed its inspection frequency for brachytherapy programs to annually.

In light of the numerous medical events at the PVAMC, the NRC conducted an inspection at each VA facility with an active prostate brachytherapy program and included the VA Reno for a total of 13 facilities. The purpose of the extent of condition inspections was to determine if any other prostate brachytherapy programs had issues similar to those identified at the PVAMC. The inspectors did not identify any issues similar to those at the PVAMC concerning erratic seed placement, uncertainty on how to identify medical events, inadequate training, inadequate oversight of contractors, and, inadequate management oversight of the prostate brachytherapy program by the RSC and RSO during the extent of condition inspections. The focus of the inspections was to: (1) determine the adequacy of the permittee's written procedures to provide high confidence that each prostate seed implant was in accordance with the written directive; (2) determine how the permittee verified that the administered dose for a prostate implant was in accordance with the written directive; (3) evaluate the training of permittee staff involved in the prostate implants, with emphasis on identification of medical events and medical event reporting criteria; and (4) identify any additional medical events.

2 G.V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi

2.1 Inspection Scope

On October 8-9, 2008, the NRC inspector conducted an announced reactive inspection of the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi to review the facts that led to ten reported medical events. The inspector toured the facility, observed equipment used for the implant procedure, interviewed selected staff, and reviewed selected patient treatment records and procedures. The inspector subsequently reviewed training records for the medical physicists and authorized user physicians. An NHPP inspector accompanied the NRC inspector.

2.2 Observations and Findings

The G. V. (Sonny) Montgomery VA Medical Center 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 varying activity based on the written directives prepared by the specific authorized user physician. The permittee administered an average of ten prostate implants each year. The prostate brachytherapy program was implemented by two contract authorized user physicians who prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. One contract medical physicist and one dosimetrist (employed by the permittee) provided support services and generated treatment plans for the prostate cases. On September 18, 2008, the facility suspended its brachytherapy program. The permittee has no projected plans to restart the prostate brachytherapy program.

The permittee stated that CT imaging of the patients was performed one or two days after the implant and again at four weeks to verify that the administered dose was in accordance with the written directive. A member of the radiation safety staff was physically present in the operating room during each implant and performed patient surveys. The RSO audited the brachytherapy program each quarter and reviewed the written directives to determine if the administered dose was in accordance with the written directive. According to the RSO, no medical events were identified by the radiation safety staff.

In July 2008, the permittee staff, including contractors, involved with prostate implants received training on NRC medical event criteria. The RSO provided training to the radiation oncology staff annually. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed a random sample of pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the ten random samples of patient treatment records reviewed, no issues were identified. In 2008, the permittee was asked to submit ten brachytherapy cases to the VA Puget Sound Healthcare System, Seattle, Washington, for evaluation. Eight of these ten cases were determined to be medical events. The permittee submitted additional cases for review. Subsequently, the permittee was informed that a total of ten cases were determined to be medical events because the administered dose to the treatment site was less than 80 percent of the prescribed dose. It was the permittee's position that the medical

events were the result of re-contours of the prostate and represented a difference of medical opinion between two physicians and were not the result of erratic or misplaced seeds. The re-contouring resulted in a decrease of the administered dose to the treatment site to less than 80 percent of the prescribed dose. It was on this basis that the licensee reported these ten cases as medical events.

The inspector reviewed the permittee's written procedures for brachytherapy, which were in place at the time of the implants, entitled, "Written Directive Procedures Radiation Therapy," (undated) and noted that Section 5 of the procedures did not describe the process to follow for conducting post-treatment plans and did not describe when the follow up CT is performed. The permittee stated that even though the procedures were silent regarding this issue they routinely performed a CT scan within one day after treatment and at one month after treatment. Post-plans were done with the CT images to determine the administered dose to the treatment site.

Title 10 Code of Federal Regulations (CFR) 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's written procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector discovered that from May 2007 to February 2008, the permittee did not perform a post-plan evaluation of the seed implants to determine if the administered dose to the treatment site was in accordance with the written directive on approximately 37 patients that were treated prior to February 2008. The RSO indicated that prior to February 2008 the permittee was having difficulty transferring CT data to the treatment planning system because of different and incompatible file formats and failure to provide network access to a newly hired dosimetrist. In February 2008, the newly hired dosimetrist found a "work around" by manually copying the CT data onto a compressed disc (CD), converting the data to the correct format, and entering the data into the computer treatment planning system. This work around was an attempt to "catch up" on the backlog of cases where no post-plans were generated. At this same time it was also discovered that some of the CT data was missing from the permittee's computer

network. Subsequently, the missing CT data was located on a storage tape and post-treatment plans were generated from that CT data. The inspector identified that the permittee continued to treat patients with prostate implants even though there was uncertainty in the dose distribution to the patients' prostate during the period May 2007-February 2008. As of September 2008, all post-treatment plans were completed. The inspector also discovered that during the period from February 2005 to May 2007, post-treatment plans were occasionally performed on certain patients but the authorized user physicians did not review or approve the plans. It was determined that the two authorized user physicians did not agree on how to contour the prostate on pre-treatment plans, therefore, post-treatment plans were not reviewed or approved during the period of February 2005 to May 2007.

Title 10 CFR 35.41(b)(2), provides, in part, that the procedures required by 10 CFR 35.41(a)(2) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive. Between the May 2007 and February 2008, the permittee's procedure entitled, "Written Directive Procedures Radiation Therapy" (undated), did not address alternate methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. During this period, a post-treatment dose verification was not performed on 37 patients that received brachytherapy implants. This is an example of an apparent violation of 10 CFR 35.41(b)(2).

The root cause of the permittee's failure to verify that the administration was in accordance with the written directive and the treatment plan was attributed to the fact that the permittee did not place emphasis or believe it was important or required to generate a post-treatment plan.

The NHPP previously inspected the permittee on September 20, 2006, no violations were identified. The most recent inspection was conducted on October 8-11, 2008, with a focus on the brachytherapy program. The NHPP's inspection results were still pending at the time this report was issued.

2.3 Conclusions

The inspector identified examples of two apparent violations concerning the permittee's failure to: (1) have written procedures that provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a)(2), and (2) verify that the administration is in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2).

The inspector identified that the permittee continued to treat patients with prostate implants even though there was uncertainty in the dose distribution to the patients' prostate during the period from May 2007 to February 2008.

3 VA Medical Center, Cincinnati, Cincinnati, Ohio

3.1 Inspection Scope

On October 15-16, 2008, the NRC inspector conducted an announced reactive inspection of the VA Medical Center- Cincinnati in Cincinnati, Ohio to review the facts

that led to the seven reported medical events. The inspector evaluated the circumstances leading up to the reported medical events and the licensee's subsequent event investigation. The inspector toured the facility, observed equipment used for the implant procedure, interviewed selected staff, and reviewed selected patient treatment records and procedures. An NHPP inspector accompanied the NRC inspector.

3.2 Observations and Findings

The VA Medical Center-Cincinnati is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with varying activity based on the written directives prepared by the authorized user physician. The permittee administered an average of 100 prostate implants each year. The prostate brachytherapy program was implemented by one contract authorized user physician who prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. Three contract medical physicists from the University of Cincinnati provided support services and generated pre- and post-treatment plans for the prostate implant cases.

The permittee performed CT imaging of the patients either one or two days following the implant in order to evaluate the treatment. The timing of the CT imaging was dependant on the physical condition of the patient. A member of the radiation safety staff was always available to conduct radiation surveys if and when needed during and after the implant procedure.

The inspector interviewed the authorized user physician, the contract medical physicists, and the RSO regarding their understanding of medical event identification and medical event reporting criteria. During the interviews, these individuals demonstrated their knowledge of NRC regulatory requirements. The NHPP provided additional training on June 23-25, 2009, to the permittee staff, including contractors, involved in the prostate brachytherapy program.

The inspector reviewed a random sample of pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the ten random samples of patient treatment records reviewed, no issues were identified. The permittee was asked to submit ten brachytherapy cases to the VA Puget Sound Healthcare System, Seattle, Washington, for evaluation. An additional 20 cases were also submitted to the VA Puget Sound Healthcare system for review. Subsequently, the permittee was informed that 7 out of the 30 cases were determined to be medical events because the administered dose to the prostate was less than 80 percent of the prescribed dose. It was the permittee's position that the medical events were the result of re-contours of the prostate and represented a difference of medical opinion between two physicians and were not the result of erratic or misplaced seeds. The re-contouring resulted in a decrease of the administered dose to the treatment site to less than 80 percent of the prescribed dose. It was on this basis that the licensee reported these seven cases as medical events.

Title 10 CFR 35.67(g) requires the licensee in possession of sealed sources or brachytherapy sources shall conduct a semi-annual physical inventory of all such sources in its possession. The permittee's RSO stated that he does not inventory all

unused brachytherapy sources in the waste storage room. The permittee's failure to conduct a physical inventory of all unused brachytherapy sources every six months is a potential violation of 10 CFR 35.67(g). The root cause was the permittee's misunderstanding of the requirements to perform a physical inventory of all unused brachytherapy sources.

The NHPP inspected the permittee on October 16-17, 2008 and June 30 - July 1, 2009, with focus on the brachytherapy program. Two violations were identified during NHPP's inspection involving the failure to: (1) inventory sealed sources, and (2) record post-implant information on the written directive.

3.3 Conclusions

The inspector identified a potential violation of 10 CFR 35.67(g), concerning the permittee's failure to conduct a semi-annual inventory of all unused brachytherapy sources stored in the waste storage room. No additional medical events were identified.

4 VA Medical Center, Minneapolis, Minnesota

4.1 Inspection Scope

On November 17-18, 2008, the NRC inspector conducted an unannounced reactive inspection of the VA Medical Center in Minneapolis, Minnesota to review the prostate brachytherapy program. The inspector toured the facility; observed equipment used for the implant procedure, interviewed selected staff, and reviewed selected patient treatment records and procedures. At the time of the inspection, the brachytherapy program was inactive because the authorized user physician had terminated his employment with the VA Minneapolis in September 2008.

4.2 Observations and Findings

The VA Minneapolis is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 or palladium-103 (Pd-103) brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with varying activity based on the written directives prepared by the authorized user physician. The permittee administered an average of 28 cases in 2008. The prostate brachytherapy program was implemented by a single contract authorized user physician that prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. One contract medical physicist and one full-time dosimetrist (employed by the permittee) provided support services and generated treatment plans for the prostate cases.

The permittee performed CT imaging of the patients either one or two days following the implant in order to evaluate the treatment. The timing of the CT imaging was dependant on the prescribing physician's preference and physical condition of the patient. A member of the radiation safety staff was always available to conduct radiation surveys if and when needed during and after the implant procedure. The RSO audited the brachytherapy program each quarter and reviewed the written directives to determine if the administered dose was in accordance with the written directive.

During interviews, the RSO and the dosimetrist demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed the permittee's written procedures for brachytherapy and noted that the procedures did not describe the process to follow for conducting post-treatment plans and did not describe when the follow up CT is performed. The permittee stated that even though the procedures were silent regarding this issue they routinely perform a CT scan within one or two days after treatment. Post-plans are done with the CT images to determine if the dose to the treatment site is in accordance with the written directive.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's written procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector reviewed a random sample of pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the five random samples of patient treatment records reviewed no medical events were identified.

The NHPP inspected the medical center on December 8, 2008 - January 5, 2009. No violations were identified during the inspection. The NHPP made five recommendations to the facility involving: (1) developing procedures for transfer of ultrasound images to the treatment computer; (2) develop a quality control (QC) program for the transrectal ultrasound unit; (3) obtain the most current version of the treatment planning software; (4) develop procedures for leaking sealed sources; and (5) establish peer review for physician and physics staff. While the NHPP identified no violations, the NRC inspector identified one apparent violation of NRC requirements. The permittee retained another authorized physician user for prostate brachytherapy procedures and the brachytherapy program was re-activated in 2009. The NHPP inspected the permittee on January 12-13, and January 15, 2010, with focus on the brachytherapy program. One violation was identified that involved failure to review each implant record after the implant was completed to determine if a medical event occurred.

4.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive.

5 VA Puget Sound Health Care System, Seattle, Washington

5.1 Inspection Scope

On November 19, 2008, the NRC inspector conducted an unannounced reactive inspection of the VA Puget Sound Health Care System in Seattle, Washington to review the prostate brachytherapy program. The inspector toured the facility, observed a brachytherapy treatment, observed the equipment used for the implant procedure, interviewed selected staff, and reviewed selected patient treatment records and procedures.

5.2 Observations and Findings

The Puget Sound Health Care System is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125, Pd-103, and cesium-131 (Cs-131) brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with varying activity based on the written directives prepared by the authorized user physician. The permittee administered an average of 300 prostate implants each year. The prostate brachytherapy program was implemented by one authorized user physician who prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. Two medical physicists (employed by the permittee) provided support services and generated treatment plans for the prostate cases.

The permittee performed CT imaging of the patients on the day of the implant in order to evaluate the treatment. The medical physicist was physically present in the operating room during each implant and performed patient surveys, and provided instructions to the patient. The RSO audited the brachytherapy program each quarter and reviewed the written directives.

The NRC inspector reviewed a random sample of pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the 20 random samples of patient treatment records reviewed, no issues were identified.

The inspector reviewed the permittee's written procedures for brachytherapy, "Quality Management Program for Permanent Implant Brachytherapy," version 2.2, dated September 23, 2008, and noted that the procedures did not describe the process to follow for conducting post-treatment plans. The permittee stated that even though the procedures were silent regarding this issue, they routinely performed a CT scan on the day of the implant and post-plans were done with the CT images to determine if the administered dose is in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and timeframe to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

On September 25-26, 2008, and November 17-18, 2009, the NHPP inspected the permittee with focus on the brachytherapy program. No violations were identified during NHPP's inspection. The NHPP made three recommendations that included: (1) implement peer review, (2) improve record keeping, and (3) develop quality assurance (QA) on the fluoroscope. While the NHPP identified no violations, the NRC inspector identified one apparent violation of NRC requirements.

5.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive.

6 VA Sierra Nevada Health Care System, Reno, Nevada

6.1 Inspection Scope

On January 19-21, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Reno to review the prostate brachytherapy program. The inspector toured the facility; observed equipment used for the implant procedures, interviewed selected staff, and reviewed selected patient treatment records and procedures.

6.2 Observations and Findings

The VA Sierra Nevada Health Care System is a limited scope medical permittee authorized to use a variety of byproduct materials for therapeutic purposes under 10 CFR 35.400. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with varying activity,

based on the written directive prepared by the authorized user physician. The permittee administered an average of 15 prostate implants each year. The prostate brachytherapy program was implemented by one contractor authorized user physician who prepared the written directives. One contract medical physicist provided support services and generated treatment plans for the prostate implant cases. At the time of this inspection, the brachytherapy program was inactive because the authorized user physician left the facility on March 4, 2008. Since that time, the brachytherapy program has been inactive.

The permittee performed CT imaging on each patient, usually 30 days following the implant in order to evaluate the treatment. The RSO and/or contractor physicist were available to assist the authorized user physician and perform radiation surveys of the patient and surgical site.

The RSO and/or contractor physicist were available to assist the authorized user physician and perform radiation surveys of the patient and surgical suite.

The NRC inspector interviewed the RSO and contract medical physicist to assess their understanding of the NRC requirements for reporting medical events and the definition of a medical event. These individuals demonstrated a good understanding of their knowledge of NRC regulatory requirements.

The inspector reviewed a random sample of pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the 50 random samples of patient treatment records reviewed, the inspector identified that the permittee did not perform post-treatment plans from September 29, 2005, to October 12, 2008. The permittee stated that post-treatment plans were not routinely performed. The permittee only recently started generating post-treatment plans after the NHPP requested the submittal of post-treatment plans for independent review by a nationally recognized DVA expert. The inspector also identified eight patient brachytherapy post-treatment plans where the administered dose appeared to be 20 percent greater than the prescribed dose. This issue has been identified as an Open Item.

The inspector reviewed the permittee's written procedures for brachytherapy, "Procedure for Written Directives," (undated) and noted that the procedures did not describe the process to follow for conducting post-treatment plans and did not describe when the follow-up CT is performed. In practice, the permittee performed all these items which the inspector noted were not included in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2).

The root cause of the inadequate procedures was attributed to the NHPP's and permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with

the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector identified that the permittee performed post-treatment plans approximately one to three years following the implant. The permittee indicated that post-plans were not completed due to an inability to transfer CT images to the treatment planning computer that was maintained off-site. The permittee's procedures did not address when and how the post-plans are conducted as required in 10 CFR 35.41(b)(2).

Title 10 CFR 35.41(b)(2), provides, in part, that the procedures required by 10 CFR 35.41(a)(2) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive. Between September 29, 2005, and October 12, 2008, the permittee's procedure entitled, "Procedures For Written Directives" (undated), did not address alternate methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. During this period, a post-treatment dose verification was not performed on 50 patients that received brachytherapy implants. This is an example of an apparent violation of 10 CFR 35.41(b)(2).

The root cause of the permittee's failure to verify that the administration was in accordance with the written directive and the treatment plan was attributed to the fact that the permittee did not place emphasis or believe it was important or required to generate a post-treatment plan.

During the inspector's review of written directives, the inspector identified that on December 11, 2007, four written directives were not completed as required by 10 CFR 35.40(b)(6)(ii). Title 10 CFR 35.40(b)(6)(ii) states in part that the written directive for manual brachytherapy must specify, after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources and the total source strength and exposure time (or total dose). The permittee's failure to record the total dose after implantation but before completion of the procedure, on four written directives is an example of a potential violation of 10 CFR 35.40(b)(6)(ii).

The NHPP inspected the permittee on May 22-23, 2007, with focus on the entire diagnostic and brachytherapy program. The NHPP did not identify that brachytherapy post-treatment plans were not being conducted. No violations were identified during NHPP's inspection. While the NHPP did not identify any violations, the NRC inspector identified examples of two apparent violations and one potential violation of NRC requirements.

6.3 Conclusions

The inspector identified examples of two apparent violations concerning: (1) failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a)(2); and (2) the permittee failed to verify that the administration is in accordance with the treatment plan

and written directive as required by 10 CFR 35.41(b)(2). The inspector identified one example of a potential violation concerning the permittee's failure to record the total dose after implantation but before completion of the procedure, on four written directives as required by 10 CFR 35.40(b)(6)(ii). The inspector identified eight patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. This issue is considered an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

7 Samuel S. Stratton VA Medical Center, Albany, New York

7.1 Inspection Scope

On February 23-25, 2009, the inspector conducted an unannounced reactive inspection of the Samuel S. Stratton VA Medical Center in Albany, New York, to review the prostate brachytherapy program. The inspector toured the facility, observed equipment used for the implant procedures and treatment planning, interviewed selected staff, and reviewed selected patient treatment records.

7.2 Observations and Findings

The Samuel S. Stratton VA Medical Center is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 and Pd-103 brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with varying activity based on the written directives prepared by the authorized user physicians. The permittee administered an average of 15 prostate implants each year. The prostate brachytherapy program was implemented by two contract authorized user physicians who prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. Two contract medical physicists and one dosimetrist (employed by the permittee) provided support services and generated treatment plans for the prostate cases.

The permittee performed CT imaging of the patients either one day or three to four weeks following the implant in order to evaluate the treatment. The timing of the CT imaging was dependant on the prescribing physician's preference.

The RSO was physically present in the operating room during each implant and performed patient surveys, and provided instructions to the patient. The RSO audited the brachytherapy program each quarter and reviewed the written directives. The RSO identified no medical events during these audits.

In December 2008, the permittee staff, including contractors, involved with prostate implants received training on NRC medical event criteria. The RSO provided training to the radiation oncology staff annually. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed the permittee's written procedures entitled, "Written Directive Program for: Administration of Therapeutic Doses by Brachytherapy Sealed Source Protocol," dated December 2005. The inspector noted that the written procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method

and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The licensee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector reviewed a selected sample of 30 patient implant records including the written directive and the pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Post-treatment plans were generated with the CT images interfaced with the treatment planning computer system to determine the administered dose to the treatment site. The inspector noted that some written directives did not include a record of the total dose, after implantation but before completion of the procedure.

Title 10 CFR 35.40(b)(6)(ii) states in part that the written directive for manual brachytherapy must specify, after implantation but before completion of the procedure, the radionuclide, treatment site, number of sources and the total source strength and exposure time (or total dose). The permittee's failure to record the total dose after implantation but before completion of the procedure, on the written directive is an example of a potential violation of 10 CFR 35.40(b)(6)(ii). The permittee failed to recognize that the written directives did not include the total dose at the completion of the implant.

The inspector identified seven patient treatments, implanted in 2004, where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. The RSO presented a copy of an NRC Technical Assistance Request (TAR) addressing issues at another NRC licensee. The permittee stated their position, based on their interpretation of the TAR was that there was no upper bounding dose limit for prostate implants. This issue is considered an Open Item.

The NHPP inspected the permittee on August 27 and 28, 2008, with focus on the brachytherapy program. No violations or recommendations were identified during NHPP's inspection. While the NHPP identified no violations, the NRC inspector identified one example of an apparent violation and one potential violation of NRC requirements.

7.3 Conclusions

The inspector identified an example of an apparent violation concerning the permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a). The inspector identified an example of a potential violation of 10 CFR 35.40(b)(6)(ii) that involved the permittee's failure to record the total dose on written directives. The inspector identified seven patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. This issue is considered an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

8 VA New York Harbor Healthcare System, Brooklyn, New York

8.1 Inspection Scope

On February 26-27, 2009, the inspector conducted an unannounced reactive inspection of the VA New York Harbor Healthcare System in Brooklyn, New York. The inspection included a review of the facts that led to one reported medical event which occurred on September 18, 2008. The inspector evaluated the circumstances leading up to the medical event and the permittee's subsequent event investigation and corrective actions. The inspector toured the facility, observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

8.2 Observations and Findings

The VA New York Harbor Healthcare System, Brooklyn Campus is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The prostate brachytherapy program was implemented by three contractor authorized user physicians who prepared the written directives. Three contract medical physicists and one dosimetrist provided support services and generated treatment plans for the prostate cases. The permittee administered an average of ten prostate implants each year.

The permittee performed CT imaging of the patients 30 days following the implant in order to evaluate the treatment. In 2009, the permittee changed its process and performed CT imaging on the day of implant (day 0) as well as 30 days after the implant.

In August 2008, the permittee staff and contractors involved with prostate implants received training on NRC medical event criteria. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed the permittee's written procedures for brachytherapy, entitled "Low Dose Brachytherapy (Quality Management Program)" (undated) and noted that the procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The NRC inspection included a review of the September 18, 2008, medical event. A prostate implant was performed on September 18, 2008, with a prescribed dose of 144 Gy to the treatment site. The implant consisted of preloaded needles containing 60 I-125 seeds. As the authorized user withdrew two needles to place seeds in the anterior region of the prostate, he believed that he failed to advance the plungers prior to withdrawing these needles. As a result, three seeds were mistakenly placed in the patient's perineum and two seeds had to be removed from the patient's perineal skin. The authorized user attempted to implant additional seeds to compensate for this error. On October 10, 2008, the permittee performed a post-treatment CT and post-treatment plan with a prescribed dose to 90 percent of the prostate volume D90 calculated at 69 percent. The authorized user informed the patient of this low D90 and recommended a supplemental implant which the patient accepted. On October 30, 2008, the supplemental implant was performed with the implantation of ten additional seeds. A post treatment CT and dosimetry plan were performed the day of the second implant with the resulting combined D90 (from both implants) calculated as 90 percent of the prescribed dose. Subsequently, on March 17, 2010, the permittee provided additional information for the dose to the patient's peri-prostatic tissues. The dose to this region was reported as 152 Gy and therefore, within the dose limits specified in 10 CFR 35.3045.

Title 10 CFR 35.3045(a)(3), requires a licensee to report any event, except for an event the results in patient intervention, in which the administration of byproduct material results in a total dose delivered differs from the prescribed dose by 20 percent or more. Title 10 CFR Part 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event. The permittee was aware that the prostate did not receive a dose within 20 percent of the 144 Gy prescribed dose. As such, when the permittee performed a post-treatment plan for the procedure on October 10, 2008, the permittee had adequate information to recognize that a medical event had occurred on September 18, 2008. Although the authorized user recognized that the procedure was not performed in accordance with the written directive and treatment plan, he was not familiar with the NRC's definition of a medical event or the reporting requirements for medical events. The medical event was reported to the NRC on November 18, 2008. The permittee's failure to notify the NRC of a medical event by the next calendar day after discovery of the medical event constitutes an apparent violation of 10 CFR 35.3045(c). Further, the NHPP did not identify the permittee's failure to report the medical event as a violation during its November 2008 inspection.

The root cause of the permittee's failure to timely notify the NRC of a medical event was an isolated occurrence and attributed to the staff's misunderstanding of the requirement. The authorized user felt the patient case was not complete at the time knowing that the implant was not to his standard based on the D90. Once the physician performed a supplemental implant, he considered the case complete. The physician believed the combined D90 represented the dose delivered to the treatment site. Although the permittee staff had sufficient information based on the original post treatment plan for the first implant to indicate that the dose to the treatment site differed by 20 percent of the prescribed dose, they failed to use the information they had and act accordingly by notifying the NHPP as well as the NRC prior to November 18, 2008, that a medical event occurred. The permittee's corrective actions for the failure to report a medical event at Brooklyn included providing training on NRC's medical event reporting requirements to the radiation oncology staff.

The NHPP submitted a 15-day written report of the medical event as required by 10 CFR 35.3045(d) in a letter dated December 1, 2008, with the permittee's report dated November 22, 2008, as an attachment. The 15-day written report was deficient, in that, the permittee did not describe why the event occurred and did not describe their corrective actions to prevent recurrence.

Title 10 CFR 35.3045(d) requires, in part, that a permittee 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 inspector's review, the written report submitted December 1, 2008, failed to adequately describe: (1) why the event occurred; and (2) what actions were taken or planned to prevent recurrence. Specifically, for these two areas, the written report merely indicated that "the event occurred because three seeds were placed lower than the prostate region," and that the corrective action indicated that "extreme care is always taken in delivery of needles/ seeds. An unusual event occurred and care will be taken to assure it does not recur." This incomplete information was material to the NRC because it affected the NRC's ability to timely determine the significance of the event and the adequacy of the

permittee's corrective actions. Further, the NHPP did not provide or require additional information from the permittee regarding its 15-day written report.
On February 16, 2010, the NRC requested additional information regarding the permittee's written report on the medical event. The permittee's response repeated the deficient information with referrals to its procedures which reference physics checks that were irrelevant to the cause of the medical event and the actions required to prevent recurrence. The permittee's failure to provide complete information in its written report is a potential violation of 10 CFR 35.3045(d). The root cause of the permittee's failure to provide adequate information in its 15-day written report is due to the permittee's lack of familiarity with what information is considered necessary to include in a written report.

Discussions with permittee staff revealed that between July and October 2007, the permittee experienced connectivity issues which impacted the ability to transfer CT images into the treatment planning computer and generate post-treatment plans to assess the administered dose to the prostate. As a result, the permittee was unable to generate post-treatment plans for some patients. The permittee contacted the CT unit service representative who attempted to retrieve the patient CT data. Patient CT data was only retrieved for certain patients. The permittee attempted to contact the remaining patients and re-schedule them for a second post-treatment CT. The permittee was unable to successfully contact two patients, who were implanted on June 14 and July 5, 2007, and unable to generate post-treatment plans for these patients. The permittee resolved the connectively issue in October 2007 by upgrading its CT software. The permittee obtained a new CT unit in October 2008 enabling the department to electronically archive patient CT images. Due to the fact that the permittee was unable to perform a CT on the two above referenced patients, the permittee subsequently conducted an evaluation by reviewing post-surgery diagnostic tests and reviewed post-surgical fluoroscopic images and determined that the implants were administered in accordance with the written directives. It was the permittee's position, based on their knowledge of their implant procedures, that no medical events occurred

Title 10 CFR 35.41(b)(2), provides, in part, that the procedures required by 10 CFR 35.41(a)(2) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive. In 2007, the permittee's procedure entitled, "Low Dose Brachytherapy (Quality Management Program)," (undated), did not address alternate methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. During 2007, a post-treatment dose verification was not performed on two patients who received brachytherapy implants on June 14, 2007 and July 5, 2007. This is an example of an apparent violation of 10 CFR 35.41(b)(2).

The inspector reviewed a selected sample of 22 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. Of the 22 selected patient treatment records that were reviewed, with the exception of the September 18, 2008, medical event, no additional medical events were identified.

The NHPP conducted a reactive inspection of the permittee between November 20 and December 17, 2008, with focus on the brachytherapy program. The NHPP's inspection included a review the facts that led to the medical event which occurred on September 18, 2008, and was reported to the NRC on November 18, 2008. No violations were identified during NHPP's inspection even though the medical center

reported a medical event 39 days after the discovery of the medical event. The NHPP issued six recommendations to the medical center that included: (1) an assessment of the information storage and security provisions established in the radiation oncology department; (2) dispose of Pd-103 seeds which have been in storage; (3) revise the inventory form; (4) revise the policies and procedures to specify post-implant dosimetry and require calculation of the D90, V100 or other dose indices; (5) revise QA program for the transrectal ultrasound system; and (6) revise written policies and procedures to address leaking seeds. Based on the NRC inspector's assessment, the recommendation pertaining to the permittee's policies and procedures should have been characterized as a violation of NRC requirements. While the NHPP identified no violations, the NRC inspector identified three apparent violations of NRC requirements. In addition, the NRC inspector identified a potential violation of NRC requirements.

8.3 Conclusions

The inspector identified examples of three apparent violations involving the failure to: (1) develop, implement and maintain written procedures that provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a)(2); (2) develop, implement, and maintain written procedures to verify that the administration is in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2); and (3) notify the NRC of a medical event by the next calendar day after discovery of the medical event as required by 10 CFR 35.3045(c). One potential violation was identified concerning the permittee's failure to provide complete information in its 15-day written report of a medical event as required by 10 CFR 35.3045(d).

9 VA Boston Healthcare System, Boston, Massachusetts

9.1 Inspection Scope

On March 11-13, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Boston Healthcare System in Boston, Massachusetts. The inspector toured the facility, observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

9.2 Observations and Findings

The VA Boston Healthcare System is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes at three locations in the metropolitan Boston area. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The permittee administered prostate implants at the Jamaica Plain Campus. The prostate brachytherapy program was implemented by two authorized user physicians who prepared the written directives. One contract medical physicist and one dosimetrist (employed by the permittee) provided support services and generated treatment plans for the prostate cases. The permittee administered approximately 30-35 prostate implants each year.

Prostate doses were evaluated with the CT images interfaced with the treatment planning computer system to determine the dose to the treatment site. The permittee

performed CT imaging of the patients 30 days following the implant in order to evaluate the treatment.

On February 3, 2009, the permittee staff, including the contract medical physicist, involved with prostate implants received training on NRC medical event criteria. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements. According to the staff, NHPP also provided training on NRC medical event criteria during the September 2008 site visit.

The inspector reviewed a selected sample of 42 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. In 2005, the permittee administered 31 prostate implants, however based on the information available in the patient charts and interviews with the radiation oncology staff, no CT imaging or post-treatment dosimetry was performed for ten patients. The inspector noted that this issue was not identified during the NHPP September 2008, site visit. In February 2010, the NRC requested additional information regarding these ten patient treatments. Subsequent to this request, the permittee determined that post-plans were not generated for 11 patients implanted in 2005; and an additional case was identified by the permittee in 2010. Post-plans were generated for 7 of the 11 patients after the NRC inspection (five years after the implant). For 4 of these 11 cases, no post-plans were generated due to unavailable CT data for these patients. The hospital affirmed that some patients did not keep their scheduled CT appointment and that other patients did not make an appointment for their CT. It is the permittee's position, based on their review of the radiographs taken immediately following the implants to verify that the seeds were correctly placed, that no medical events occurred. It is unknown why post-treatment plans for these patients were not performed because the authorized users who administered these treatments in 2005 are no longer associated with the DVA facility. The permittee instituted a computerized patient record system with prompts to remind the staff of any open appointments. In addition, the radiation oncology department acquired its own CT unit in 2005, enabling the department more flexibility and control in scheduling post-treatment CT imaging for its patients.

Title 10 CFR 35.41(a)(2) requires, in part, 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. Item o. Post Implant Evaluation, of the permittee's procedure entitled, "Brachytherapy Program QMP," (undated) states that, "within one month following the seed implant, every patient will be scheduled to receive a post-operative CT scan of the prostate. The CT scan will be imported to the TPC [treatment planning computer] and a graphic dose distribution plan and a DHV [dose volume histogram] will be generated by Physics." The permittee's failure to implement its written procedures to provide high confidence that each administration is in accordance with the written directive, that required a dose distribution plan (also known as a post-treatment plan) for seven patients, implanted in 2005, who received a post-operative CT scan within one month of the seed implant, is an example of an apparent violation of 10 CFR 35.41(a)(2). The permittee generated a post-treatment plan for these seven patients, five years following their one month CT scans performed in 2005.

Title 10 CFR 35.41(b)(2), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.

In 2005, the permittee's procedures entitled, "Brachytherapy Program QMP," (undated), did not address alternate methods for verification that the treatment was in accordance with the written directive when the normal verification method was unavailable. In 2005, a post-treatment dose verification was not performed on four patients who received brachytherapy implants. This is an example of an apparent violation of 10 CFR 35.41(b)(2).

The inspector identified twelve patient treatments, implanted in 2005, where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. The permittee stated their position, based on their understanding there was no upper dose boundary limits for prostate implants. This issue is considered an Open Item.

The NHPP conducted a site visit of the permittee between September 9 and 10, 2008, with focus on the brachytherapy program. No violations were identified during NHPP's site visit. The NHPP made six recommendations to the facility which included: (1) evaluate the efficiency for its counting equipment; (2) amend its policies and procedures to address verifying the identity of the patient and confirming that the seeds brought to the operating room are for that specific patient; (3) modify the policies and procedures to specify when the post-implant portion of the written directive should be signed by the authorized physician user; (4) review procedures for providing and documenting training provided to staff involved with the brachytherapy program; (5) provide written reports for acceptance testing and commissioning (of equipment, sources, etc); and (6) locate survey reports for the LINAC vaults (not an NRC-licensed activity). While the NHPP identified no violations, the NRC inspector identified one apparent violation of NRC requirements.

9.3 Conclusions

The inspector identified examples of two apparent violations involving the failure to: (1) implement written prostate brachytherapy procedures that provide high confidence that the administered dose is in accordance with the written directive as required by 10 CFR 35.41(a)(2), and (2) develop, implement, and maintain written procedures to verify that the administration is in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2). The inspector identified twelve patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. This issue is considered an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

10 VA Medical Center, Washington, District of Columbia

10.1 Inspection Scope

On March 18-20, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Medical Center in Washington, D.C. The inspector evaluated the circumstances leading up to three reported medical events which were subsequently retracted based on additional information obtained during the permittee's subsequent investigation. The inspector toured the facility, observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

10.2 Observations and Findings

The VA Washington, D.C. is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The medical center exclusively used Pd-103 for its implants which NRC assumed regulatory responsibility and jurisdiction for at Federal facilities on November 30, 2007, based on the Energy Policy Act of 2005. The prostate brachytherapy program was implemented by two authorized user physicians who prepared the written directives. Two medical physicists (employed by the permittee) provided support services and generated treatment plans for the prostate cases. The permittee administered typically five or six prostate implants each year. The permittee performed CT imaging of the patients 30 days following the implant in order to evaluate the treatment. The permittee initiated post-treatment patient CT imaging in 2005. At the time of this inspection, the permittee's permanent prostate implant program was suspended.

On November 5, 2008, the permittee staff involved with prostate implants received training on NRC medical event criteria. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The permittee submitted four patient cases for external review. Based on the initial information in the patients' charts, for three treatments administered on December 4, 2007, March 5, 2008, and April 2, 2008, the D90 was less than 80 percent of the prescribed dose and these treatments were reported as medical events on September 26, 2008. Upon further review and additional CT imaging, the permittee generated additional post-treatment plans which revealed that the D90 values exceeded 80 percent of the prescribed dose. External review by a national DVA expert confirmed the revised D90 values. The NHPP retracted these medical events on December 2, 2008.

The inspector reviewed that permittee's written procedures for prostate brachytherapy treatments, entitled, "Quality Management Program 1998," which had been in effect for all prostate implants administered between 2007 and 2008. The inspector noted that the 1998 procedures neither referenced criteria for evaluating the implants nor described the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, as of November 30, 2007, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, permittees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive is an example of an apparent violation of 10 CFR Part 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The permittee revised its procedures for administrations requiring a written directive on February 13, 2009, as corrective action in response to the violation identified by the NHPP. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector reviewed a selected sample of 27 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. The medical center exclusively used Pd-103 for its implants which NRC assumed regulatory responsibility and jurisdiction for at Federal facilities on November 30, 2007, based on the Energy Policy Act of 2005. Between November 30, 2007, and the dates of this inspection, the medical center administered seven permanent implants. Between 2004 and November 2007, the permittee performed 19 implants. The inspector determined that for the implants administered in 2004, no CT imaging was performed and therefore no dose information was available in these patients' charts. In addition, for two patient treatments implanted in January 2007 and September 2007, the D90 values were reported as 57.8 percent and 71 percent of the prescribed dose respectively. These treatments were administered prior to November 30, 2007, the date that NRC assumed jurisdiction and regulatory responsibility at Federal facilities for accelerator-produced materials. During the NHPP inspection on September 20 through December 2, 2008, the NHPP did not identify that the implants administered in January and September 2007 that the administered dose was less than 80 percent of the prescribed dose.

The NHPP inspected the permittee between September 20 and December 2, 2008, with focus on the brachytherapy program. The NHPP's inspection included a review the facts that led to three reported medical events which were subsequently retracted. Three violations were identified for the medical center's failure to: (1) develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive and the treatment plan (10 CFR 35.41(a)); (2) instruct supervised individuals (10 CFR 35.27(a)); and (3) perform surveys of patients with a survey meter adequate to detect the type and energy of the radiation released (10 CFR 35.75). The NRC inspector also identified an example of an apparent violation of 10 CFR 35.41(a)(2).

10.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR Part 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive.

11 VA Greater Los Angeles Healthcare System, Los Angeles, California

11.1 Inspection Scope

On March 23-25, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Greater Los Angeles Healthcare System in Los Angeles, California and included a review the facts that led to three reported medical events (two cases in 2005, and one case in 2009). The inspector evaluated the events leading up to the reported medical events and the permittee's subsequent event investigation. The inspector toured the facility, observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

11.2 Observations and Findings

The VA Greater Los Angeles Healthcare System, Los Angeles Campus is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with an activity based on the written directive prepared by the authorized user physician. The prostate brachytherapy program was implemented by one authorized user physician who prepared the written directives. One contract medical physicist and one dosimetrist (employed by the permittee) provided support services and generated treatment plans for the prostate cases. The permittee administered an average of ten prostate implants each year. Unlike other DVA facilities, this medical center prescribed prostate implants using D80 parameter on the written directive. The D80 is the prescribed dose to 80 percent of the prostate volume.

The permittee performed CT imaging of the patients 30 days following the implant in order to evaluate the treatment. At the time of this inspection, the permittee's permanent prostate implant program was suspended.

On September 8 and 10, 2008, the permittee staff and contractors involved with prostate implants received training on NRC medical event criteria. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed the permittee's written procedures for prostate brachytherapy implants entitled, "Standard Operating Procedure No. 00-11-32," dated February 2005. The inspector noted that the procedures neither referenced criteria for evaluating the implants nor described the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The licensee's failure to have written policies and procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the

permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

This inspection included a review of three medical events reported in 2009. Implants performed on June 8, 2005, and November 23, 2005, were reported as medical events on January 28, 2009. The NHPP reviewed these treatments during its inspection and concluded that these cases were medical events. The basis of these reports was an unintended dose to the patients' rectum. However the treatment site received the prescribed dose as specified in the authorized user's written directive. For each implant, a number of seeds was determined to be implanted outside the prostate and contributed a dose of 145 Gy to a specified volume of the patient's rectum.

On February 13, 2009, the permittee reported a third medical event for an implant performed on February 12, 2009. The basis for reporting this medical event was that five seeds were mistakenly implanted into the patient's perineum, an unintended organ or tissue, approximately 1 centimeter outside of the prostate. According to data generated by the post-treatment plan, the dose to the prostate was within 80 percent of the prescribed dose of 145 Gy. Based on interviews with the radiation oncology staff, the cause of the placement of the seeds was due to the physician's technique. In addition, this was a training case for a resident, who may have implanted the needle with these seeds. The permittee submitted its 15-day written reports as required by 10 CFR 35.3045(d) in a letters dated February 10, 2009, and February 24, 2009. The permittee's 15-day reports contained all the required information.

On February 16, 2010, the NRC requested additional information on the patient dose data for the three medical events reported in 2009. The permittee reassessed the doses to the patient's rectum and periprostatic tissues and concluded that doses were less than the prescribe dose to the prostate. Therefore, the doses to these unintended organs and tissues were within the dose limits specified in 10 CFR 35.3045(a)(3).

The inspector reviewed a selected sample of 24 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. The inspector identified five patient treatments where the administered dose to the treatment site appeared to exceed the prescribed dose by more than 20 percent. The permittee stated their position, based on their understanding, that there was no upper dose boundary limits for prostate implants, provided that the dose to other critical organs and tissues such as the rectum, was not excessive. This issue is considered an Open Item.

The NHPP inspected the permittee between January 21 and March 26, 2009, with focus on the brachytherapy program. The NHPP's inspection included a review the facts that led to three reported medical events which occurred in 2005 and 2009. One violation of Title 10 CFR 35.41(a) was identified for the medical center's failure develop, implement and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The NHPP made eight recommendations to the facility: (1) modify policies and procedures to specify when CT imaging is to be performed following the implant and include calculation of the dose indices such as D90, V100 and R100 (dose to the rectum); (2) modify the written procedures to require verification of the patient's identity; (3) develop a QA program for the transrectal ultrasound system; (4) correct connectivity issues between the CT and the treatment planning computer; (5) require the urologist to review the post-treatment plan; (6) develop a written policy to address information security with requirements to maintain backup copies of the treatment plans; (7) establish a peer-review process for the brachytherapy program; and (8) revise procedures to fully describe the authorized user's authority as described in 10 CFR 35.26.

11.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR Part 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive. The inspector identified five patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. This issue is considered an Open Item. The findings associated with the NRC's review of the Open Item will be documented in separate correspondence.

12 VA Medical Center, San Francisco, California

12.1 Inspection Scope

On March 26-27, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Medical Center in San Francisco, California. The inspector toured the facility, observed equipment used for the implant procedure, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

12.2 Observations and Findings

The VA San Francisco is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The permittee administered approximately 20 to 25 prostate implants each year. The treatments involved seeds with an activity 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. The permittee performed CT imaging of the patients 30 days following the implant in order to evaluate the treatment. An outside agency provided support services and generated treatment plans for the prostate cases.

The permittee staff involved with prostate implants received training on NRC medical event criteria on June 18, 2008, November 14, 2008, and February 20, 2009. During

interviews, these individuals demonstrated their knowledge of NRC regulatory requirements. The RSO or his assistant was physically present in the operating room during each implant and performed patient surveys, and provided instructions to the patient. The RSO audited the brachytherapy program each quarter and reviewed the written directives. No medical events were identified during these audits.

The inspector reviewed the permittee's document entitled, "Veterans Affairs Medical Center San Francisco Nuclear Medicine Service Brachytherapy Quality Management Program Form for 125I Prostate Brachytherapy Procedures Using Pre-Loaded System," (undated). The inspector noted that the document neither referenced criteria for evaluating the implants nor described the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to have written policies and procedures that provide high confidence that the administered dose is in accordance with the written directive is an example of an apparent violation of 10 CFR 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed on January 9, 2009, and finalized on June 9, 2009. The permittee incorporated the DVA's standardized procedures in its procedures.

The inspector reviewed a selected sample of 29 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive; no medical events were identified.

The NHPP inspected the permittee between on October 28 and 29, 2008, with focus on the brachytherapy program. No violations were identified during NHPP's inspection. Two recommendations were made to the permittee: (1) provide additional training concerning medical events to the authorized users; and (2) develop a QA program for the transrectal ultrasound unit. While the NHPP identified no violations, the NRC inspector identified one apparent violation of NRC requirements.

12.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR Part 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive

13 VA Medical Center, Durham, North Carolina

13.1 Inspection Scope

On April 20-22, 2009, the NRC inspector conducted an unannounced reactive inspection of the VA Medical Center in Durham, North Carolina. The inspection included a review of the facts that led to a medical event reported on January 15, 2009. The inspector evaluated the events leading up to each of the medical events and the permittee's subsequent event investigations. The inspector toured the facility, observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

13.2 Observations and Findings

The VA Durham is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The prostate brachytherapy program was implemented by one authorized user physician who prepared the written directives. Two contract medical physicists provided support services and generated treatment plans for the prostate cases. The permittee performed CT imaging of the patients one day following the implant in order to evaluate the treatment. The permittee administered approximately 40 prostate implants each year. The permittee's permanent prostate implant program was inactive as of February 2009.

On September 23, 2008, the permittee staff including the contract medical physicists and authorized user physicians received training on NRC medical event criteria. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

This inspection included a review of a reported medical event. On December 18, 2008, the authorized user performed a permanent prostate implant using 81 I-125 seeds with a prescribed dose of 145 Gy to the prostate. Following the implant procedure, radiographs of the pelvis confirmed the correct position of the seeds within the patient. The following day, CT images of the patient revealed that eight seeds had apparently migrated inferiorly to the prostate. A D90 was calculated as 62.3 percent of the prescribed dose. The patient was scheduled for a second CT on December 23, 2008. Upon examination of these CT images, the authorized user identified an additional four seeds had migrated inferiorly. A third CT was performed on January 15, 2009, showing no additional seed migration. The final D90 was determined to be 82 Gy to the prostate or 56 percent of the prescribed dose of 145 Gy. In subsequent correspondence (e-mail) the NHPP indicated that the remaining dose was delivered to the patient's perineum and estimated at 178 Gy. Once the authorized user determined that the seed migration had apparently stopped, the permittee reported the event as a medical event to the NHPP and the NRC on January 15, 2009. The authorized user could not provide an explanation as to why

the seeds had migrated. He provided reference to a professional journal article which also stated that the cause for such seed migration was unknown and apparently unpreventable. According to 10 CFR 35.3045(a)(3), an event involving seed migration would not be a reportable event to the NRC.

The inspector reviewed a selected sample of 26 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. No additional medical events were identified.

The inspector reviewed the permittee's procedures, entitled, "Written Directives Procedures Durham Veterans Affairs Medical Center," dated August 19, 2008, and noted that the procedures did not describe the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. In practice, the permittee performed all the items discussed above which the inspector noted were not described in its written procedures.

Title 10 CFR 35.41(a)(2) states, in part, that, for any administration requiring a written directive, permittees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The written procedures must address the requirements described in 10 CFR 35.41(b)(2). The permittee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive is an example of an apparent violation of 10 CFR Part 35.41(a)(2). Specifically, the permittee's procedures did not specify the criteria for evaluating the dose to the treatment site or specify the method and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive.

The root cause of the inadequate procedures was attributed to the NHPP's and the permittee's failure to recognize that its procedures did not include certain aspects of the brachytherapy procedure, such as, the criteria for evaluating the dose to the treatment site, the methods to verify the dose to the treatment site and time-frame the dose to the treatment site was verified to ensure that the administered dose was in accordance with the written directive. The DVA developed standardized procedures for prostate implants which addressed criteria used to assess the dose to the treatment site, how post-treatment imaging was performed, and the methods and time-frame to evaluate the dose to the treatment site following the implant. These standardized procedures were developed in January 9, 2009, and finalized on June 9, 2009. As corrective action, the permittee augmented its policies and procedures with an attachment dated December 2009, to include a description of the post treatment planning.

The NHPP inspected the permittee between January 26, and February 19, 2009, with focus on the brachytherapy program. The NHPP's inspection included a review the facts that led to a medical event which occurred on December 18, 2008. No violations were identified. While the NHPP identified no violations, the NRC inspector identified one apparent violation of NRC requirements.

13.3 Conclusions

The inspector identified an example of an apparent violation of 10 CFR Part 35.41(a)(2), concerning the permittee's failure to develop procedures to provide high confidence that prostate seed implants are performed in accordance with the written directive.

14 Hunter Holmes McGuire VA Medical Center, Richmond, Virginia

14.1 Inspection Scope

On April 22-24, 2009, the NRC inspector conducted an unannounced inspection of the Hunter Holmes McGuire VA Medical Center in Richmond, Virginia. The inspector toured the facility; observed equipment used for the implant procedure and treatment planning, interviewed selected staff, and reviewed procedures and a selected number of patient treatment records.

14.2 Observations and Findings

The Hunter Holmes McGuire VA Medical Center is a medical broad scope permittee authorized to use a variety of byproduct materials for diagnostic and therapeutic purposes. The therapeutic treatments included I-125 brachytherapy seeds used for permanent prostate implants. The treatments involved seeds with an activity based on the written directive prepared by the authorized user physicians. The permittee administered approximately 70 to 80 prostate implants each year. The prostate brachytherapy program was implemented by two authorized user physicians who prepared the written directives with a prescribed prostate dose dependent upon the isotope and the treatment course for the patient. Four contract medical physicists provided support services and generated treatment plans for the prostate cases. Prior to 2009, the permittee performed CT imaging of the patients four to six weeks following the implant in order to evaluate the treatment with emphasis on confirmation of the placement of the seeds. The permittee also used magnetic resonance imaging with CT imaging for its evaluations of certain cases. In 2009, the permittee changed its process and performed CT imaging on the day of implant (day 0).

In January 2009, the permittee staff and contractors involved with prostate implants received training on NRC medical event criteria. Annual training was provided to the radiation oncology staff, including the contract medical physicists and authorized user physicians. During interviews, these individuals demonstrated their knowledge of NRC regulatory requirements.

The inspector reviewed a selected sample of 33 pre- and post-treatment plans to determine if the administered dose was in accordance with the written directive. During this inspection, the inspector identified five patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. The permittee stated their position, based on their understanding through information obtained in professional meetings, that there was no upper bounding dose limits for prostate implants. This issue is considered an Open Item. The inspector also noted that the permittee referenced a maximum dose of 130 percent to the prostate in its policies and procedures. The inspector pointed out that this 130 percent maximum dose conflicts with the requirements in 10 CFR 35.3045(a)(1)(i) which describes a medical

event, in part, as a total dose delivered that differs from the prescribed dose by 20 percent or more. This issue is considered an Open Item.

The NHPP inspected the permittee between December 18 and 19, 2008, with focus on the brachytherapy program. Two violations were identified for the medical center's failure to: (1) retain records of surveys to account for all sources that have not been implanted (10 CFR 35.2404) and (2) perform surveys of patients with a survey meter adequate to detect the type and energy of the radiation released (10 CFR 35.75). The NHPP made three recommendations: (1) revise the training syllabus to include topics such as written directive and medical events; (2) revise written policies and procedures to address leaking seeds; and (3) revise written policies and procedures to address lost seeds.

14.3 Conclusions

The inspector identified five patient brachytherapy post-treatment plans where the administered dose appeared to exceed the prescribed dose by more than 20 percent. The NRC is concerned that the permittee's policies and procedures specifically reference a maximum dose of 130 percent which is in conflict with the NRC's requirements in 10 CFR 30.3045(a)(1)(i). These issues are considered Open Items. The findings associated with the NRC's review of the Open Items will be documented in separate correspondence.

15 Exit Meeting

The inspectors discussed the conclusions described in this report with the NHPP during preliminary exit meetings conducted at each respective permittee's facility and a final telephone exit meeting on April 22, 2010. The licensee did not identify any information reviewed during this inspection as proprietary in nature.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

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Numerous individuals from the respective VISN offices also participated in the on-site inspections by telephone

*Contacted by telephone on April 22, 2010, for exit meeting

LIST OF ACRONYNS AND ABBREVIATIONS USED

CAL	Confirmatory Action Letter
CFR	Code of Federal Regulations
CT	Computerized Tomography
Cs-131	cesium-131
D80	the prescribed dose to 80 percent of the prostate volume
D90	the prescribed dose to 90 percent of the prostate volume
DVA	Department of Veterans Affairs
DVH	Dose Volume Histogram
Gy	Gray
I-125	iodine-125
mCi	millicurie
MML	Master Materials License
NHPP	National Health Physics Program
NRSC	National Radiation Safety Committee
NRC	U. S. Nuclear Regulatory Commission
Pd-103	palladium-103

LIST OF ACRONYNS AND ABBREVIATIONS USED (Cont)

PM	Program Manager
PVAMC	Philadelphia Veterans Affairs Medical Center
QA	Quality Assurance
QC	Quality Control
R100	Dose to the rectum
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
TPC	Treatment Planning Computer
Sv	Sievert
V100	Prostate volume covered by at least 100% of the prescribed dose
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network