

October 6, 2010

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

SUBJECT: NRC INSPECTION REPORT 030-34325/10-05(DNMS) PHILADELPHIA  
VETERANS AFFAIRS MEDICAL CENTER (PVAMC), PHILADELPHIA,  
PENNSYLVANIA

Dear Mr. Williams:

On September 8-9, 2010, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your Philadelphia Veterans Affairs Medical Center facility located in Philadelphia, Pennsylvania. The inspection results were discussed with Margaret O'Shea-Caplin, Interim Director and Mr. Paul Yurko, of your staff at the exit meeting on September 9, 2010. The enclosed report presents the results of this inspection.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of this inspection no violations of NRC requirements were identified.

In accordance with Title 10 Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

G. Williams

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Should you have any questions concerning this inspection, please contact Darrel Wiedeman of my staff at (630) 829-9808.

Sincerely,

*/RA/*

Patricia J. Pelke, Chief  
Materials Licensing Branch

Docket No. 030-34325  
License No. 03-23853-01VA  
Permit No. 37-000062-07

Enclosure:  
Inspection Report No. 030-34325/10-05(DNMS)

cc w/encl: Margaret O'Shea-Caplin, Interim Director, PVAMC

G. Williams

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Enclosure:  
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cc w/encl: Margaret O'Shea-Caplin, Interim Director, PVAMC

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P. Pelke, RIII

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## **PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY**

### **1. AMENDMENTS AND PROGRAM CHANGES:**

NA-The PVAMC, Philadelphia, Pennsylvania is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

### **2. INSPECTION AND ENFORCEMENT HISTORY:**

On June 22-26, August 27-28, and October 14-16, 2009, the U. S. Nuclear Regulatory Commission (NRC) conducted an announced reactive inspection of the PVAMC. During these inspections, one apparent violation was identified involving the licensee's failure to notify the NRC the next calendar day after discovery of a medical event as required by Title 10 Code of Federal Regulation (CFR) 35.3045(c). The results of the reactive inspection are documented in NRC Inspection Report No. 030-34325/2009-001(DNMS). The NRC previously identified six apparent violations during a special inspection conducted on July 23-25, and September 9-12, 2008. The NRC re-characterized one of these apparent violations into two separate violations related to the licensee's failure to develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive. The results of the special inspection are documented in NRC Inspection Report No. 030-34325/2008-029(DNMS). The apparent violations included the licensee's failure to: (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2); (2) develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive as required in 10 CFR 35.41(b)(2); (3) develop procedures that address verifying that the administration is in accordance with the written directive as required in 10 CFR 35.41(b)(2); (4) train supervised individuals regarding identification and reporting requirements for medical events as required in 10 CFR 35.27(a)(1); (5) instruct a non-supervised individual regarding identification and reporting of medical events as required in 10 CFR 19.12(a)(4); (6) report by telephone to the NRC the next calendar day numerous medical events as required by 10 CFR 35.3045(c); (7) record total dose on a written directive as required by 10 CFR 35.40(b); and (8) provide complete and accurate information in accordance with 10 CFR 30.9 in several 15-day written reports to the NRC as required in 10 CFR 35.3045(d).

The licensee's corrective actions were previously identified in NRC Inspection Report No. 030-34325/2008-029(DNMS). The licensee suspended its prostate brachytherapy program on June 11, 2008, and it remains suspended. The licensee's corrective actions included: (1) revising its procedures for the prostate brachytherapy treatments to include an evaluation and verification that the administered dose was in accordance with the written directive; (2) directions that require the radiation oncology staff to stop the procedure if there is any uncertainty associated with the treatment; (3) amending the PVAMC Sealed Source Radiotherapy policy to include: a) a comparison and evaluation of both treatment plans and associated calculations with the written directive; b) direction to allow prostate brachytherapy treatments to proceed only when the treatment planning computer is able to produce pre and post-treatment plans; and c) immediately reporting all deviations that exceed ten percent of the prescribed dose or dose fraction to the RSO and quality management staff; (4) instituting a medical center peer-review system for radiation oncology services and post-treatment evaluations; (5) providing radiation safety

training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events; (6) revising the contract for radiation oncology services to realign these services under the RSO; (7) instituting an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns; (8) suspending prostate brachytherapy treatments until all the corrective actions have been completed and they have been approved to re-start by the NHPP; and (9) conducting an external review of the prostate implant program, by physicians and medical physics consultants who were experts in performing prostate brachytherapy treatments, to evaluate the former prostate implant program and current program, and incorporating their recommendations into hospital policies and procedures. During the previous inspection, the following additional corrective actions were identified and documented in NRC Inspection Report No. 030-34325/2009-001(DNMS): (10) performing verification CTs on all patients who received prostate implants between February 25, 2002, and May 12, 2008, and re-evaluating the dose delivered to the prostate and the periprostatic tissue and/or the rectum; (11) referring eight patients to the VA Puget Sound Health Care System, Seattle for re-implantation procedures; and (12) removing one individual from performing brachytherapy treatments at VA facilities.

A Confirmatory Action Letter (CAL)(3-08-004) was issued to the NHPP on October 14, 2008. The CAL included several commitments to address the problems that led to the reported medical events involving prostate brachytherapy. Prior to issuance of the CAL, the medical center executive management suspended their prostate brachytherapy program on June 11, 2008. As of the date of this inspection, the permittee does not plan to re-start the brachytherapy program.

### **3. INCIDENT/EVENT HISTORY:**

The NHPP reported a total of 97 medical events at the PVAMC. As of the date of this inspection, no new medical events have been identified.

## **PART II - INSPECTION DOCUMENTATION**

### **1. ORGANIZATION AND SCOPE OF PROGRAM:**

Gary Williams- Director, National Health Physics Program  
Margaret O'Shea Caplan- Interim Medical Center Director, PVAMC facility  
John Callahan- Interim Associate Director Finance- PVAMC facility  
Mary Moore, Radiation Safety Officer, PVAMC facility

This facility is a Department of Veterans Affairs hospital located in Philadelphia, Pennsylvania. The facility is a 300 bed general hospital that treats approximately 1,600 out-patients daily. This permittee has a broad scope permit (permit No. 37-00062-07) authorized for diagnostic, therapy and research in humans as defined in 10 CFR 30.4. The permit was amended on January 27, 2009, to remove their authorization for brachytherapy procedures under 10 CFR 35.400. Staff from the VA National Health Physics Program accompanied the NRC inspector during this inspection.

## **Nuclear Medicine Program**

At the time of this inspection, the permittee had five full-time nuclear medicine technologists and four authorized users (physicians) that work in the department. The permittee conducts approximately twenty diagnostic procedures per day. The typical workload consists of bone, liver, cardiac and iodine-123 thyroid scans. During 2009, the permittee performed two whole body scans with iodine-131, seven hyperthyroid treatments and eleven thyroid cancer treatments. All use of iodine-131 is in capsule form only. The inspector reviewed eighteen random samples of written directives for 2009 through 2010. The NRC inspector concluded that all of the written directives that were reviewed met the requirements of 10 CFR 35.40. No medical events involving the administration of iodine-131 were identified. During this inspection, the inspector observed that the permittee routinely uses syringe shields and the technologists were properly wearing whole-body and extremity dosimetry. During the inspection of the nuclear medicine program, the inspector reviewed a random sample of records for the period of 2009-2010 and discussed the following areas with the nuclear medicine technologists: package surveys, daily/weekly radiation surveys; disposal of radioactive materials; and dose calibrator verifications. The inspector asked the technologist to perform a constancy test on the dose calibrator with the same sealed source (cesium-137) and in the same manner in which it was performed earlier that morning. The constancy test results matched the licensee's records for the test performed earlier that same morning.

The highest whole body exposure for the period calendar year (CY) 2009 through 2010 was 243 mrem and the highest extremity exposure was 251 mrem.

## **Research Activities**

The permittee previously authorized seven researchers to perform research activities with microcurie quantities of phosphorus-32 and/or hydrogen-3. Three of the researchers are currently active and four were inactive. The NRC inspector conducted independent radiation surveys in all research laboratories and did not identify any contamination or unusual/unexpected radiation levels. The radiation safety staff performs monthly audits that include wipe tests of the research labs for removable contamination. No significant removable contamination was identified during the period 2008-2010.

## **Prostate Brachytherapy Program**

On June 11, 2008, the permittee voluntarily suspended their prostate brachytherapy program and the NHPP terminated their authorization to perform any further brachytherapy implants on January 27, 2009. According to management at the PVAMC, the permittee does not plan to re-activate the prostate brachytherapy program.

The PVAMC previously (2008-2009) reported 97 medical events that involved brachytherapy (prostate seed) implants. No new medical events have been identified. The authorized user physicians that performed the brachytherapy implants and the medical physicists that were involved in the dose treatment planning are no longer employed at this facility.

The inspector interviewed an authorized user (physician) in the nuclear medicine

department, a researcher, nuclear medicine technologist and the RSO regarding their understanding of the definition of a medical event, who to report the medical event to and how they determine if a medical event occurred. All individuals had a good understanding of the definition of a medical event and who to report a medical event to.

The NRC inspector toured the Radiation Oncology department and confirmed that all radioactive sources have been removed from that department and no sources remained in the department.

**2. SCOPE OF INSPECTION:**

**Record review:** During the inspection, the inspector reviewed a random sample of patient treatment records and written directives for the administration of iodine-131 for CY 2009 (12 cases), and 2010 (6 cases). The inspector reviewed Radiation Safety Committee meeting minutes, incidents reports, annual audits of the radiation safety program, written directives, package receipt records, training records, survey records, leak test records, waste disposal records, and dosimetry records.

**Inspection Procedure(s) Used:** 87131, 87132, 87134

**Focus Areas Evaluated:** 03.01 through 03.07

The purpose of this inspection was to conduct a routine inspection of the permittee's use of license material and to follow-up on the suspended prostate brachytherapy program.

**3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

The inspector conducted independent radiation surveys with a Ludlum Model 2402, Serial No. 157587, calibrated on May 5, 2010. The inspector conducted surveys in and around the hot lab and the research labs. The inspector's surveys were consistent with the permittee's survey results. Surveys in unrestricted areas were at background (0.02-0.05 mR/hour). No unusual or unexpected radiation levels were identified.

The NRC inspector concluded that no worker or member of the public received a dose of radiation in excess of the limits specified in 10 CFR 20.1201 or 20.1301.

**4. VIOLATIONS, NON-CITED VIOLATIONS, AND OTHER SAFETY ISSUES:**

No violations of NRC requirements were identified.

5. **PERSONNEL CONTACTED:**

- # Margaret O'Shea Caplan, Interim Medical Center Director
- # Mary Moore, RSO
- # John Callahan, Interim Associate Director-Finance
- # Paul Yurko, M.S., Program Manager, NHPP

Use the following identification symbols:

- # Individual(s) present at entrance and exit meeting

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