

March 31, 2011

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 030-34325/11-18(DNMS) – VA PUGET SOUND  
HEALTH CARE SYSTEM, SEATTLE, WASHINGTON AND NOTICE OF  
VIOLATION

Dear Mr. Williams:

On February 28 through March 2, 2011, the U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your VA Puget Sound Health Care System (VAPSHCS), located in Seattle, Washington. The inspection results were discussed with Mr. David Elizalde, Medical Center Director and selected members of his staff at the exit meeting on March 2, 2011. 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.

Based on the results of this inspection, one Severity Level (SL) IV violation of NRC requirements was identified. The SL IV violation involved the failure to monitor the external surfaces of a labeled package for radioactive contamination as required by Title 10 Code of Federal Regulations (CFR) 20.1906(b)(1). The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited because it was identified by the NRC. The corrective actions to address the above violation were discussed with the Medical Center Director and the Radiation Safety Officer (RSO) at the exit meeting on March 2, 2011. As immediate corrective action to the violation, the NRC inspectors confirmed with the RSO and nuclear medicine staff that all labeled incoming packages of radiopharmaceuticals would be monitored for removable contamination. In addition, the inspectors observed a nuclear medicine staff member monitor a labeled package for removable contamination to confirm their understanding of the requirement. The inspectors determined that training was the root cause of the violation because members of the nuclear medicine staff were not aware of, or familiar with, the package monitoring procedures and the radiation safety manual. In addition, the nuclear medicine staff could not readily locate the procedures within the nuclear medicine department, and the procedures, once located, were outdated.

The violation is cited in the enclosed Notice of Violation (Notice). You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In addition to the violation, the NRC also identified three concerns during the inspection. In your response, you will need to address each of the concerns described below by describing what action(s) the National Health Physics Program will take to evaluate the concerns and how it will assure the NRC that the issues will be addressed and corrected by the VAPSHCS.

Concern 1: The inspectors noted that the nuclear medicine staff was unfamiliar with the radiation safety manual and procedures for monitoring labeled packages that contain radioactive material. Initially, the staff could not locate the radiation safety manual and procedures. Eventually the radiation safety manual was located; however, the most current version of the document was approved in 1999. Additionally, after the inspectors and nuclear medicine staff reviewed the radiation safety manual, it appeared that the nuclear medicine staff were not implementing the procedure for monitoring packages received for external radioactive contamination. The lack of awareness and familiarity by the nuclear medicine staff with the radiation safety manual and package monitoring procedures, along with the fact that the radiation safety manual had not been reviewed and revised for approximately 12 years, directly contributed to the violation.

Concern 2: The inspectors reviewed several research laboratories, observed work practices in the laboratories, and interviewed available staff. The inspectors noted inconsistencies in the way staff handle and process permitted material. Specifically, there was an apparent lack of knowledge by the research staff regarding the location of appropriate survey instruments to conduct area surveys; the lack of or inconsistent use of personal protective equipment (gloves, lab coats, etc); and poor recordkeeping related to the use and disposal of permitted material.

Concern 3: Based on the size and scope of the radiation safety program at the VAPSHCS, the radiation safety office appears to be understaffed when compared to other VA facilities of comparable size and scope. This concern is based on the findings identified above, as well as observations made during the inspection regarding the workloads in nuclear medicine, prostate brachytherapy, and research programs; and that the VAPSHCS possesses a medical broad scope permit, which also authorizes two additional locations of use in Spokane and Tacoma. At the time of the inspection, the radiation safety staff was comprised of the RSO and one helper (light duty housekeeper assigned on a temporary basis to the RSO). By comparison, we identified other permittees under the VA Master Materials License that have similar programs in size and scope, e.g., VA Medical Centers in Los Angeles and San Francisco, that have a radiation safety staff that includes an RSO and three health physicists/technicians. Based on observations made during this inspection, the NRC is concerned that the radiation safety program at the VAPSHCS may not have sufficient resources to effectively manage and implement the radiation safety program.

G. Williams

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

Should you have any questions concerning this inspection, please contact Kevin Null of my staff at (630) 829-9854.

Sincerely,

*/RA/*

Patricia J. Pelke, Chief  
Materials Licensing Branch  
Division of Nuclear Materials Safety

Docket No. 030-34325  
License No. 03-23853-01VA  
Permit No. 46-00990-01

Enclosures:

1. Notice of Violation
2. Inspection Record

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## NOTICE OF VIOLATION

Department of Veterans Affairs  
North Little Rock, Arkansas

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

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 28 through March 2, 2011, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 Code of Federal Regulations (CFR) 20.1906(b) (1) requires each licensee to monitor the external surface of packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Contrary to the above, from December 15, 2010, through February 28, 2011, the permittee failed to monitor the external surface of 17 packages labeled with a Radioactive White I label for radioactive contamination and the packages were not exempt from the monitoring requirement for radioactive contamination. Specifically, 17 packages that were received by the permittee from December 15, 2010, through February 28, 2011, contained millicurie quantities of technetium-99m in liquid form and the permittee failed to monitor each package for radioactive contamination.

This is a Severity Level IV violation (Section 6.3.d.3).

Pursuant to the provisions of 10 CFR 2.201, the Department of Veterans Affairs is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Because your response will be made 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>. To the extent possible, your response

should not include any personal privacy, proprietary or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 31<sup>st</sup> day of March 2011.



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

### 1. AMENDMENTS AND PROGRAM CHANGES:

NA - The VA Puget Sound Health Care System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

### 2. INSPECTION AND ENFORCEMENT HISTORY:

During the previous National Health Physics Program (NHPP) inspection on January 11-12, 2011, no violations were identified. The inspection focused on the permanent implant brachytherapy program.

On September 25-26, 2008, and November 17-18, 2009, the NHPP inspected the permittee with focus on the permanent implant brachytherapy program. No violations were identified.

The U.S. Nuclear Regulatory Commission (NRC) conducted an inspection (Extent of Condition) between October 8, 2008 through April 24, 2009, focused on the prostate brachytherapy program (onsite at the VA Puget Sound Health Care System on November 19, 2008). No violations of NRC requirements were identified at the VA Puget Sound Health Care System.

The last NRC routine inspection was conducted on February 10-11, 2004. No violations of NRC requirements were identified.

### 3. INCIDENT/EVENT HISTORY:

No licensee events for this permittee have been reported since the last NRC inspection between October 8, 2008 through April 24, 2009. No open Nuclear Materials Event Database (NMED) items are pending for this permittee.

## **PART II - INSPECTION DOCUMENTATION**

### 1. ORGANIZATION AND SCOPE OF PROGRAM:

David Elizalde, Medical Center Director  
DeAnn Lestenkof, Deputy Director  
Joseph Rajandran, M.D., Chair, Radiation Safety Committee  
David Dunn, M.S., Radiation Safety Officer (RSO)

The Veterans Affairs Health Care System, Seattle, Washington (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 46-00990-01). The facility is a 300 bed hospital authorized for medical diagnosis, therapy and research in humans. The permittee is also authorized for research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and in vitro studies. A member of the NHPP staff accompanied the NRC inspectors during this inspection. According to the permittee staff that were interviewed, since the last NRC inspection there have been no fires, explosions, medical events or fatalities involving radioactive



materials, lost/stolen radioactive materials or over exposures to radiation. The inspectors did not identify anything contrary to the above statements made by permittee staff.

### **Nuclear Medicine Program**

At the time of this inspection, the permittee had four full-time nuclear medicine technologists and five authorized user physicians that work in the nuclear medicine department. The permittee conducts approximately ten to twelve diagnostic procedures per day. The permittee estimated that 50 percent of the annual workload is diagnostic cardiac scans. The inspectors reviewed a representative sample of written directives that were prepared for radiopharmaceutical studies from 2008 to 2010.

Radiopharmaceutical studies that required a written directive included the use of iodine-131 for hyperthyroid treatments, whole body scans, and thyroid cancer treatments. The inspectors concluded that the written directives met the requirements in 10 CFR 35.40.

During 2008 - 2010, the permittee performed approximately ten whole body scans, ten-twelve hyperthyroid treatments and four thyroid carcinoma treatments per year with iodine-131. Typical doses of iodine-131 range between 10-30 millicuries for hyperthyroid treatments and 100-150 millicuries for thyroid cancer treatments. Iodine-131 is administered in capsule form only. The RSO reviews release criteria with patients and performs calculations in accordance with NUREG-1556, Vol. 9. Patients are released to their private residences only with confirmation that they can live alone for the higher iodine-131 dosage administrations, otherwise, they are hospitalized. The permittee provides instructions to the patients when they are discharged from the hospital and patients are released under the provisions of 10 CFR 35.75.

The inspectors reviewed dosimetry records for the period 2009-2010. The highest whole body exposure for calendar year (CY) 2009 was 2187 mrem, and 2010 was 1650 mrem. The highest extremity exposure for CY 2009 was 2151 mrem, and 2010 was 5304 mrem. No over exposures to radiation were identified.

The NRC inspectors interviewed two authorized user physicians, three nuclear medicine technologists 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. The RSO, authorized user physicians and nuclear medicine technologists had a good understanding of the definition of a medical event and reporting requirements.

The inspectors observed a cardiac stress test and an iodine-131 treatment (thyroid cancer). During the cardiac stress test, the inspectors observed that the technologist used a syringe shield and was wearing whole body and extremity dosimetry, and protective clothing (gloves and lab coat). During the iodine-131 thyroid treatment, the inspectors observed the following activities: the RSO prepare the patient room to minimize the spread of any contamination; the technologist measure the iodine-131 dose; the RSO transport the dose from the hot lab to the patient room in a shielded container; and the authorized user physician provide instructions to the patient. The inspectors also observed the RSO conduct surveys of the patient and adjacent areas after the patient received the iodine-131 dose. The areas were appropriately posted with radiation warning signs and survey results were documented. The inspectors interviewed the nurses who were providing care to the patient. The nurses

demonstrated that they had been trained and had a good understanding of radiation safety precautions to follow when caring for patients that receive a therapeutic dose of iodine-131. The inspectors observed that the radiation safety staff who provided care for this patient wore appropriate dosimetry as well as other personal protective equipment including lab coats, gloves and shoes covers. The inspectors did not identify any violations of NRC requirements during these procedure.

During the inspection of the nuclear medicine program, the inspectors reviewed a representative 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 verification tests. The inspectors 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 inspectors also asked the technologist to demonstrate the package survey techniques and as a result, a violation of NRC requirements was identified. Title 10 CFR 20.1906(b)(1) requires each licensee to monitor the external surfaces of packages labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71. During the inspection it was determined that the permittee received packages labeled with a Radioactive White I label, the packages were not exempt from the monitoring requirement for radioactive contamination, and the permittee did not perform the required monitoring. Specifically, the permittee did not monitor 17 labeled radioactive material packages for removable contamination from December 15, 2010, through February 28, 2011. The permittee's failure to monitor packages for removable contamination is an apparent violation of 10 CFR 20.1906(b)(1).

Based on interviews of the nuclear medicine technologists, the inspectors determined that the nuclear medicine technologists were not familiar with package survey requirements and they could not readily locate the package survey procedures within the department. Additionally, the inspectors noted that the radiation safety manual, which included incoming package survey procedures, had not been revised since 1999.

The permittee implemented immediate corrective actions in response to the violation. The permittee required all nuclear medicine technologists to conduct radiation surveys and wipe tests of all incoming labeled radioactive material (RAM) packages. Additionally, the RSO stated to the inspectors that he was in the process of revising the radiation safety manual and procedures and provided a draft copy of portions of the manual to the inspectors.

### **Brachytherapy Program**

The permittee performs approximately 300-350 prostate brachytherapy implants each year using iodine-125 and palladium-103 seeds (90 percent of the implants involve iodine-125 and 10 percent involve palladium-103). The permittee has one authorized user physician who prepared the written directives and performed the prostate

brachytherapy implants. Two authorized medical physicists provide support services (e.g., generated treatment plans; verified number of seeds before, during and after the implants; and conducted radiation surveys of the patient and the operating room). The permittee performed computed tomography (CT) imaging of the patient on the day of the implant to evaluate the treatment. The RSO reviewed 100 percent of the records of prostate brachytherapy implants. In addition, at least five patient records are sent out for an external review each year. The permittee implemented the VA standard operating procedures for prostate implant brachytherapy in April 2009.

The inspectors reviewed a representative sample of 59 patient treatment records (based on available records at the time of the inspection) for the period from November 2010 through the date of the inspection. The inspectors noted that a pre and post-treatment plan was performed on each patient to determine that each prostate brachytherapy treatment was performed in accordance with the written directive as required by 10 CFR 35.41(b)(2). The standard prescribed dose was 144 Gray (Gy) using iodine-125 seeds. The inspectors identified 31 prostate brachytherapy treatments in which the D-90s (dose to 90 percent of the prostate volume) exceeded 20 percent of the prescribed dose. From the sample of patient treatment records reviewed, the highest prostate dose administered (212.25 Gy) exceeded the prescribed dose (144 Gy) by 147.39 percent. The D-90 doses that exceeded 20 percent of the prescribed dose are considered an Open Item. No new medical events were identified.

### **Research Activities**

The permittee's Radiation Safety Committee, which meets on a quarterly basis, authorized 16 principle investigators (PI) to perform research activities. Currently, there were 12 active PIs. The NRC inspectors conducted independent radiation surveys in and around selected research laboratories and did not identify any contamination or unusual/unexpected radiation levels. The radiation safety staff conducts routine audits of restricted and unrestricted areas which includes surveys for radiation levels and removable contamination. No significant contamination or unusual radiation levels have been identified since the last NRC inspection.

Based on a tour of several research laboratories, interviews of staff, and observations of work practices in the laboratories, the inspectors noted inconsistencies in the way staff handle and process permitted material, which we have identified as concerns. Examples include an apparent lack of knowledge regarding the location of appropriate survey instruments to conduct area surveys; an apparent lack of knowledge regarding the location of the radiation safety manual and laboratory safety procedures; the lack of or inconsistent use of personal protective equipment (gloves, lab coats, etc); and poor record-keeping related to the use and disposal of permitted material.

## **2. SCOPE OF INSPECTION:**

Record Review: The inspectors reviewed a representative sample of radiation survey records for the period 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 inspectors also reviewed a representative sample of training records for the period 2008-2010 and the latest record for January 2011 training. During the inspection, the inspectors observed nuclear medicine technologists perform a constancy test on the dose calibrator, perform patient

injections, administer a therapeutic dose of iodine-131, and conduct area surveys in restricted and unrestricted areas. These activities were performed in a manner consistent with NRC guidance and in accordance with NRC regulations.

Inspection Procedure(s) Used: 87126, 87131, 87132 and 87134

Focus Areas Evaluated: Manual Chapter 2800, Section 05.01b.1.(a) through (h)

Additionally, the inspectors reviewed a representative sample of the Radiation Safety Committee meeting minutes for the year of 2009-2010 and confirmed that the permittee adequately tracked its radiation safety issues/concerns and effectively responded to those issues/concerns. The inspectors also reviewed the sealed source inventory and leak test records for the calendar year of 2009-2010. The sealed source quantities were consistent with the permittee's license conditions. No violations of NRC requirements were identified.

The inspectors identified the following concern, based on the size and scope of the permittee's radiation safety program, the radiation safety office appears to be understaffed when compared to other VA facilities of comparable size and scope. This concern is based on observations made during the inspection regarding the workloads in nuclear medicine, prostate brachytherapy, and research programs; and that the permittee possesses a medical broad scope permit, which also authorizes two additional locations of use in Spokane and Tacoma. At the time of the inspection, the radiation safety staff was comprised of the RSO and one helper (light duty housekeeper assigned on a temporary basis to the RSO). By comparison, the NRC inspectors identified other permittees under the VA MML that have similar programs in size and scope, e.g., VA Medical Centers in Los Angeles and San Francisco, that have a radiation safety staff that includes an RSO and three health physicists/technicians.

### 3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent radiation surveys with a Canberra Model MRAD 213, Serial No.13000313, calibrated on November 3, 2010. Surveys in and around the nuclear medicine department and hot lab were consistent with the permittee's survey results. Surveys in unrestricted areas were at background levels (0.02- 0.05 mR/hour). Survey results in restricted areas were also at background levels.

The inspectors also conducted independent radiation surveys of areas adjacent to a room where a patient that received an iodine-131 therapy dose was housed as an inpatient. Results were consistent with the RSO's surveys. No unusual or unexpected radiation levels were identified.

In addition, the inspectors conducted independent radiation surveys in and around the radioactive waste compactor area and the radioactive material decay-in-storage area. The NRC inspectors did not identify any unusual or unexpected radiation levels in or around these areas. Survey results were at background level (0.02-0.05 mR/hour).

The inspectors also conducted independent radiation surveys of a representative sample of active research laboratories. The NRC inspectors did not identify any unusual or unexpected radiation levels in or around the research laboratories. The NRC inspectors

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.

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

One apparent violation of 10 CFR 20.1906(b)(1) was identified. In addition, the NRC inspectors identified the following concerns: 1) in both the nuclear medicine and research areas, there was an apparent lack of knowledge regarding the location of the radiation safety manual and laboratory safety procedures; additionally, the radiation safety manual and associated procedures had not been reviewed or revised since 1999; 2) in the research area, there were inconsistencies in the way staff handle and process permitted material. Specifically, there was an apparent lack of knowledge by the research staff regarding the location of appropriate survey instruments to conduct area surveys; the lack of or inconsistent use of personal protective equipment (gloves, lab coats, etc); and poor recordkeeping related to the use and disposal of permitted material; and 3) based on the size and scope of the permittee's radiation safety program, the radiation safety office appears to be understaffed when compared to other VA facilities of comparable size and scope. In addition, the previous NRC inspection identified one Open Item (examples of the Open Item were also identified during this inspection and it remains open); several prostate brachytherapy implants were identified in which the D-90s (dose to 90 percent of the prostate) exceeded 20 percent of the prescribed dose.

4. **PERSONNEL CONTACTED:**

- \*David Elizalde, Medical Center Director
- #\*DeAnn Lestenkof, Deputy Director
- # Julie Nugent-Carney, Quality Consultant/Escort
- \*Sherri Bauch, Assistant Director
- \*Bill Campbell, M.D., Chief of Staff
- \*Cathy Dickson, Acting Director, Quality Improvement
- #\*David Dunn, M.S., Radiation Safety Officer
- #\*Ward Cassels, Accreditation Readiness
- \*Joseph Rajandran, M.D., Director, Diagnosis Imaging, Chair of Radiation Safety Committee
- Kent Wallner, M.D., Chief, Radiation Oncology, Authorizer User
- Andrew Shields, M.D., Authorized User
- \*Carl Bergsagel, Ph. D., Medical Physicist, Radiation Oncology
- \*Craig Adams, Program Manager, National Health Physics Program

Use the following identification symbols:  
# Individual(s) present at entrance meeting  
\* Individual(s) present at exit meeting

-END-