

March 24, 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 030-34325/11-16(DNMS) AND NOTICE OF VIOLATION – VA SIERRA NEVADA HEALTH CARE SYSTEM, RENO, NEVADA

Dear Mr. Williams:

On March 10, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your VA Sierra Nevada Health Care System (VASNHCS) facility located in Reno, Nevada. The inspection results were discussed with Steven Brilliant, M.D., Chief of Staff and selected members of the medical center staff at the exit meeting on March 10, 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, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation involved the failure to monitor incoming packages for radioactive contamination as required by Title 10 of the Code of Federal Regulations (CFR) 20.1906(b) (1), which is described in detail in the enclosed inspection report. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is being cited because it was identified by the NRC. The corrective actions to address the above violation were discussed with the Radiation Safety Officer and the Chief of Staff at the exit meeting on March 10, 2010.

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 the following concerns during this inspection that you need to address in your response: 1) the NRC inspector confirmed that the prostate brachytherapy program at the VASNHCS has been inactive for approximately three years, yet the current permit (Amendment No. 46 dated August 23, 2010) authorizes the use of iodine-125 and palladium-103 for any manual brachytherapy procedure permitted by 10 CFR 35.400. It is our understanding that the VASNHCS would be required to comply with the "Criteria to Start or Restart Prostate Brachytherapy Programs" dated February 2, 2011; however, there is currently no limitation on the permit (e.g., possession for storage only) that precludes the use of 10 CFR 35.400 material. Please provide the provisions the National Health Physics Program (NHPP) has established to ensure that the VASNHCS cannot order, receive, and use 35.400 materials while the material remains on their permit; 2) the NRC inspector noted that VASNHCS has approximately 250 brachytherapy sources (35.400 material) in storage, with no projected plans for disposal. Please submit the provisions the NHPP has established with the VASNHCS for the disposal of these sources; and 3) the NRC inspector noted during his interviews with the nuclear medicine staff, that it was apparent they had not received any recent training or instruction regarding the requirements for identification and reporting of medical events. Furthermore, the individuals interviewed stated that since they only perform diagnostic studies that do not require a written directive, they did not feel that a medical event could occur. Please describe the actions the NHPP will take to address this concern with the VASNHCS.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response 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>. 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.

As immediate corrective actions to the violation, the NRC inspector confirmed with the Radiation Safety Officer that all incoming packages of radiopharmaceuticals will be monitored for removable contamination. The NRC inspector determined that training was the root cause of the violation because permittee staff were unaware of the requirements in 10 CFR 20.1906(b) (1). In addition, this issue was not identified during previous audits by the Radiation Safety Officer.

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
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 27-15192-01

Enclosure:

1. Notice of Violation
2. Inspection Record

G. Williams

-3-

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Enclosure 1

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 March 10, 2011, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 CFR 20.1906(b) (1) requires each licensee to monitor the external surfaces or 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, the permittee failed to monitor the external surfaces of packages labeled with a White I label for radioactive contamination and the packages were not exempt from the monitoring requirements. Specifically, the permittee did not monitor packages containing millicurie quantities of technetium-99m in liquid form for at least four years up to and including March 10, 2011, the date of this inspection.

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 23rd day of March 2011.

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

1. AMENDMENTS AND PROGRAM CHANGES:

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

2. INSPECTION AND ENFORCEMENT HISTORY:

During a previous National Health Physics Program (NHPP) inspection on May 11-12, 2010, with continuing review through September 20, 2010, no violations of NRC requirements were identified.

During the previous NRC reactive inspection (Extent of Condition) conducted from October 8, 2008 to April 24, 2009, two violations and one Open Item was identified. The violations include: (1) failure to perform post-treatment plans to verify that the administered dose was in accordance with the written directive as required in 10 CFR 35.41(b)(2); and (2) failure to record the total dose after implantation on four written directives as required by 10 CFR 35.40(b)(6)(ii). During the inspection, the inspector identified one Open Item involving eight patient prostate implant brachytherapy cases where the D-90s (dose to 90 percent of the prostate) exceeded 20 percent of the prescribed dosage. See NRC Inspection Report No. 030-34325/2008-030(DNMS) (ML101440380) for specific details regarding the violations identified and Open Item.

During this inspection, the prostate brachytherapy program was inactive; however, the inspector confirmed that the permittee implemented appropriate corrective actions in response to the previous NRC inspection findings. These corrective actions included: (1) the permittee staff was made aware of the importance of timely post-treatment plans and the requirement to document the total dose after implantation on the written directive, and (2) the permittee revised their written procedures for the prostate seed implant program to implement the Veterans Health Administration (VHA) standard procedures when the brachytherapy program is reactivated. The NRC inspector verified the implementation of the permittee's corrective actions. This issue is now considered closed.

3. INCIDENT/EVENT HISTORY:

No events have been reported since the last NRC inspection conducted from October 8, 2008 to 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:

Kurt Schlegelmilch, M.D., Medical Center Director
Steven Brilliant, M.D., Chief of Staff
Richard Breslow, Ph.D., Radiation Safety Officer (RSO)
Lenore Amante, M.D., Radiologist, Chair RSC
Ian Love, M.D., Authorized User Physician

The VA Sierra Nevada Health Care System, Reno, Nevada (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a limited scope medical permit (Permit No. 27-15192-01). The facility is a 100 bed hospital authorized for diagnostic and therapy medical use authorized in 10 CFR 35.100, 35.200, and 35.400. The permittee is also authorized for in vitro studies permitted under 10 CFR 31.11. A member of the VA NHPP staff accompanied the NRC inspector during this inspection. According to the permittee staff interviewed, there have been no fires, explosions, medical events or fatalities involving radioactive materials, lost/stolen radioactive materials or overexposures to radiation since the last NRC inspection. The inspector did not identify anything contrary to the above statements made by the permittee staff.

Nuclear Medicine Program

At the time of this inspection, the permittee had two full-time nuclear medicine technologists and two authorized user physicians that work in the department. The permittee conducts approximately 2,400 diagnostic procedures per year. Approximately 50 to 60 percent of the annual workload is diagnostic cardiac scans. The remaining workload consists of bone, liver and iodine-123 thyroid uptake studies and scans. Currently, the permittee does not participate in positron emission tomography (PET) diagnostic procedures. No medical events were identified. During the inspection of the nuclear medicine hot lab, the inspector asked the technologist to perform a constancy test on the dose calibrator with the same sealed sources (cesium-137 and barium-133) 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. This permittee is not authorized for radiopharmaceutical therapy. The inspector verified that the permittee has not received any radiopharmaceuticals that require a written directive. This permittee does not use molybdenum-99/technetium-99m generators. All doses are unit doses procured from a licensed nuclear pharmacy.

The inspector interviewed an authorized user physician, two 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. All individuals had somewhat of an understanding of the definition of a medical event and the reporting requirements. The nuclear medicine staff indicated that they did not feel that a medical event could occur at their facility because they do not use therapeutic radiopharmaceuticals that require a written directive. The inspector stated to the RSO that during the next training session, the permittee staff should review the medical event definitions and reporting requirements in 10 CFR 35.3045, specifically, the dose limit threshold of 50 rem to skin or organs. According to records provided by the RSO, the nuclear medicine staff received radiation safety training (refresher training) on December 2, 2010, but the training did not include a discussion regarding medical events or reporting requirements. The NRC has identified this as a concern.

During this inspection, it was observed that the permittee routinely uses syringe shields and the technologists were assigned whole body and extremity dosimetry. During the inspection of the nuclear medicine program, the inspector reviewed a representative sample of records for the period of 2007-2010 and discussed the following areas with the nuclear medicine technologist: package surveys, daily/weekly radiation surveys, disposal of radioactive materials, and dose calibrator verification tests.

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 routinely received packages labeled with a Radioactive White I label, the package was not exempt from the monitoring requirement for radioactive contamination, and the permittee did not perform the required monitoring. Specifically, packages received by the permittee contained millicurie quantities of technetium-99m in liquid form and the permittee did not monitor the packages for removable radioactive contamination on the day of the inspection, March 10, 2011, and for at least the past four years. The permittee's failure to monitor packages for removable contamination is an apparent violation of 10 CFR 20.1906(b) (1).

The inspector reviewed dosimetry records for calendar years (CY) 2007 through 2010. The highest whole body exposures for CY 2007 through 2010 were as follows:

CY 2007	CY 2008	CY 2009	CY 2010
901 mrem	1,100 mrem	294 mrem	390 mrem

The highest extremity exposures for CY 2007 through 2010 were as follows:

CY 2007	CY 2008	CY 2009	CY 2010
8,200 mrem	9,400 mrem	3,800 mrem	700 mrem

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.

Prostate Brachytherapy Program

A total of seventy-three patients received permanent prostate brachytherapy implants during the period September 8, 2005 through March 4, 2008. All implants were performed with Bard Model STM 1251, iodine-125 seeds. Each patient was prescribed 145 gray (Gy). During the previous NRC inspection it was learned that post-treatment plans had not been generated for many of the seventy-three patients. When this was brought to the attention of the permittee, post-treatment plans were generated by the end of 2009 for all patients that had a computerized tomograph (CT). Currently, the prostate implant brachytherapy program is inactive. The permittee has not performed any permanent prostate implants since March 2008. The NRC is concerned that the last prostate implant was completed over three years ago, the permittee does not have an active authorized user physician for 10 CFR 35.400 materials, and the current permit (Amendment No. 46 dated August 23, 2010) still authorizes the facility to perform any manual brachytherapy procedure with iodine-125 and palladium-103 permitted by 10 CFR 35.400. In addition, the inspector identified that the permittee has approximately 250 brachytherapy sources (35.400 material) in storage, with no projected plans for disposal. The NRC has identified these issues as concerns.

During the previous inspection conducted from October 8, 2008 to April 24, 2009, the inspector reviewed 97 percent of the pre and post treatment plans and identified eight prostate brachytherapy implants in which the D-90s (dose to 90 percent of the prostate) exceeded 20 percent of the prescribed dose. This is considered an Open Item. During this inspection, the inspector reviewed five additional patient treatment charts that were not available during the previous inspection. Each reviewed case showed that pre and post-plans were generated for each patient and the administered dose was within 20 percent of the prescribed dose. No new medical events were identified.

2. **SCOPE OF INSPECTION:**

Record Review: During the inspection, the inspector reviewed a representative sample of Radiation Safety Committee minutes for 2010, incidents reports, annual audits of the radiation safety program, package receipt records, training records, survey records, leak test records, waste disposal records, and dosimetry records for CY 2007 through 2010.

Inspection Procedure(s) Used: 87130, 87132

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

The purpose of this inspection was to conduct a routine inspection of the permittee's use of licensed material.

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 nuclear medicine hot lab. 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:**

One apparent violation of 10 CFR 20.1906(b) (1) was identified. Three concerns were identified associated with: (1) training of the nuclear medicine staff on identification and reporting requirements for medical events; (2) the last prostate implant was completed over three years ago, the permittee does not have an active authorized user physician for 10 CFR 35.400 materials, and the current permit (Amendment No. 46 dated August 23, 2010) still authorizes the facility to perform any manual brachytherapy procedures with iodine-125 and palladium-103 permitted by 10 CFR 35.400; and (3) the inspector identified that the permittee has approximately 250 brachytherapy sources (35.400 material) in storage, with no projected plans for disposal. The previous NRC inspection identified one Open Item (which remains open); eight prostate brachytherapy implants were identified in which the D-90s (dose to 90 percent of the prostate) exceeded 20 percent of the prescribed dose.

5. **PERSONNEL CONTACTED:**

#*Steven Brilliant, M.D., Chief of Staff

* Richard Breslow, Ph.D., Radiation Safety Officer

* Lenore Amante, M.D., Radiologist, Authorized User Physician

* Ian Love, M.D., Chief of Radiology, Authorized User Physician

#*Edward Leidholdt, Ph.D., Program Manager, National Health Physics Program

Use the following identification symbols:

#Individual(s) present at entrance meeting on 3/10/2011

*Individual(s) present at exit meeting on 3/10/2011

-END-