

August 5, 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 030-34325/11-19(DNMS) – VA MEDICAL
CENTER, WASHINGTON, DISTRICT OF COLUMBIA

Dear Mr. Williams:

On May 26, 2011, U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your VA Medical Center, located in Washington, District of Columbia, with continued in-office review through July 20, 2011. The purpose of the in-office review was to evaluate the permittee's reconciliation of discrepancies discovered in inventory records, and assess a concern identified by the NRC inspectors related to the conduct of surveys for removable contamination in a research laboratory. The preliminary inspection results were discussed with Raya Kheirbek, M.D., Deputy Chief of Staff, and selected members of her staff on May 26, 2011. A final exit meeting was held with Ross D Fletcher, M.D., Chief of Staff, and other staff members of the Medical Center via telephone conference on July 20, 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. Within the scope of this inspection, no violations of NRC requirements were identified.

However, the NRC identified a concern pertaining to radiation safety procedures that were being implemented in a research laboratory (Room 1F-150). The inspectors noted that a research laboratory technician performed smears for removable contamination using a method that was not consistent with current regulatory guidance. A detailed description of the concern can be found in Part II of the enclosed Inspection Record.

Please submit a response to this concern by describing what action(s) the National Health Physics Program will take to evaluate the concern, and how it will assure the NRC that the issues will be addressed and corrected by the permittee.

In accordance with Title 10 of the Code of Federal Regulations (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide

G. Williams

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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. 08-00942-05

Enclosure:
Inspection Report No. 030-34325/11-19(DNMS)

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA - The VA Medical Center in Washington, District of Columbia, 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 October 21, 2009, 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 (on-site at the VA Medical Center in Washington, D.C., on March 18-20, 2009), that focused on the prostate brachytherapy program. No violations were identified at the site.

The last NRC routine inspection at the site was on February 5-6, 2003. One Severity Level IV violation was cited for failure to perform surveys in unrestricted areas in order to demonstrate compliance with Title 10 of the Code of Federal Regulations (CFR) 20.1302.

3. INCIDENT/EVENT HISTORY:

No events have been reported since the last NRC inspection on March 18-20, 2009. No open Nuclear Materials Event Database (NMED) items were pending for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Michael H. Dunfee, Acting Medical Center Director
Ross D. Fletcher, M.D., Chief of Staff
Natalie Merckens, Administrator for Clinical Operations
Michael Funkhouser, Radiation Safety Officer (RSO)
Gary Williams, Director, National Health Physics Program (NHPP)

The Washington D.C., VA Medical Center (permittee) was authorized by the VA Master Material License (MML) No. 03-23853-01VA (licensee) to possess a limited scope medical permit (permit No. 08-00942-05). The facility is a 174-bed hospital authorized for diagnostic and therapeutic medical use, and research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and in vitro studies. Mr. Paul Yurko, Program Manager from the VA NHPP, accompanied the NRC inspectors during this inspection. According to permittee staff that were interviewed, there have been no fires, explosions, medical events or fatalities involving radioactive materials, lost/stolen radioactive materials or over exposures to radiation since the last NRC inspection. The inspectors 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 six full-time nuclear medicine technologists (NMT) that worked in the nuclear medicine department including a Chief NMT. Within the nuclear medicine department, there were four standard gamma camera rooms, and one PET imaging room. The permittee conducts approximately 25-30 diagnostic procedures per day (19-20 nuclear medicine studies and 6-8 PET procedures) using unit doses only. According to the permittee, approximately one-third of all nuclear medicine procedures are cardiac studies. The permittee prepares written directives for the administration of iodine-131 for therapeutic procedures (hyperthyroid and thyroid cancer treatments). The permittee conducts approximately 20 iodine-131 studies annually. Typical doses of iodine-131 ranged between 10-30 millicuries for hyperthyroid treatments, and 100-150 millicuries for thyroid cancer treatments. Iodine-131 is administered in capsule form only. For calendar year (CY) 2011 to date, the permittee performed 12 iodine-131 therapy procedures. All iodine-131 therapy treatments are administered by an approved authorized user.

The inspectors reviewed a representative sample of radiopharmaceutical written directives for using iodine-131 for the period 2010-2011. The inspectors concluded that the written directives met the requirements in 10 CFR 35.40. In addition, the inspectors reviewed dosimetry records for the period 2009-2010. The highest whole body exposure for calendar year (CY) 2009 was 1,746 milli-rem (mrem), and for CY 2010 was 1,930 mrem. The highest extremity exposure for CY 2009 was 1,996 mrem, and CY 2010 was 2,261 mrem. No medical events or personnel overexposures to radiation were identified.

The inspectors interviewed the RSO, three NMTs, and the Chief NMT regarding their understanding of the definition of a medical event, who to report a medical event to, and how to determine if a medical event occurred. The RSO and nuclear medicine staff had a satisfactory understanding of the definition of a medical event and associated reporting requirements.

Brachytherapy Program

The permittee is authorized to perform sealed source brachytherapy authorized under 10 CFR 35.400 for palladium-103 seeds only. The last prostate brachytherapy treatment was performed in August 2008. At the time of this inspection, the permittee indicated that there were no plans to initiate any sealed source brachytherapy treatments based on the low number of treatments that the permittee had performed (~7 per year). If the permittee plans to perform prostate brachytherapy procedures in the future, they are required by VA policy to notify the NHPP in writing and satisfy the VA's "Criteria to Start or Restart Prostate Brachytherapy Programs" dated February 2, 2011. In addition, NHPP staff will conduct an onsite assessment to evaluate the permittee's readiness to perform prostate brachytherapy procedures prior to the restart.

Research Activities

The permittee's radiation safety committee (RSC) authorized four researchers to perform research studies as defined in 10 CFR 30.4. Currently only one researcher is active. Radionuclides are used for in vitro research studies, and primarily included microcurie quantities of hydrogen-3 and carbon-14. There are eight to nine labs authorized for the

use of permitted materials; however, only one lab was active at the time of the inspection. The NRC inspectors conducted independent radiation surveys in and around selected research laboratories and did not identify any contamination or unexpected radiation levels. The radiation safety staff performs monthly and quarterly wipe tests of the research labs for removable contamination.

The inspectors identified a concern pertaining to the implementation of radiation safety procedures in a research laboratory (Room 1F-150). Specifically, the inspectors noted that a research laboratory technician performed smears for removable contamination in a laboratory where microcurie quantities of hydrogen-3 and carbon-14 were handled, using methods that did not appear to be consistent with regulatory guidance (e.g., NUREG-1556 series) or accepted industry standards. A recognized acceptable method for performing surveys removable contamination includes swiping an area of about 100 cm² (ref. NUREG-1556, volume 11, page S-6).

At the request of the inspectors, the research laboratory technician demonstrated the technique that was used for taking smears for removable contamination in the laboratory where the radionuclides were used. Based upon the inspector's observations, it was estimated that the area that was smeared was significantly less than 100 cm², which dramatically reduced the probability of detecting the presence of removable contamination. The inspectors also determined through further interviews that this was the method that the technician had learned from a former technician.

The NRC inspectors also discovered that the Beckman LSA6500 liquid scintillation counter had been inoperable from August 2010 through April 2011, further impacting the permittee's ability to identify the presence of contamination in a timely manner. Subsequent analysis of smears that had been taken in the laboratory during this time frame were analyzed at the VA Medical Center in Baltimore, Maryland. Results of those smears appeared to be within acceptable surface contamination levels as described in NUREG-1556, Volume 11, Table S.5.

2. SCOPE OF INSPECTION:

Record review: The inspectors reviewed a representative sample of nuclear medicine written directives, incoming package surveys, daily/weekly radiation surveys, and dose calibrator records. The inspectors also reviewed a representative sample of training records for the period from CY 2009 through April 2011. During the inspection, the inspectors observed nuclear medicine technologists perform constancy tests on the dose calibrators, draw a dose for a stress test, perform patient injections, and conduct area surveys in restricted areas. The inspectors observed a technologist draw a fluorine-18 dose, measure the dose in a dose calibrator, and then inject it into a patient for a bone imaging study. The technologist wore adequate protective clothing (gloves, lab coat, whole body and ring badges) during the procedure. These activities were conducted in a manner consistent with NRC guidance and in accordance with NRC regulations. During the injection of the fluorine-18 dose, the inspectors monitored the radiation levels in unrestricted areas directly adjacent to the injection room. The inspectors did not identify any unexpected radiation levels. The inspectors also verified the accuracy of the data in the National Source Tracking System (NSTS) documentation.

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

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

During the inspection of the nuclear medicine program, the inspectors reviewed a representative sample of radiation survey records for the period CY 2009 through April 2011, 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 observed a nuclear medicine technologist perform a constancy test on the dose calibrator with the same sealed sources (cesium-137 and cobalt-60) and in the same manner in which the test was performed earlier that morning. The constancy test results were within the acceptance criteria in comparison with the permittee's records. The inspector also interviewed nurses who provided care to patients that were treated with iodine-131 regarding the training that they received in radiation safety. The nurses appeared to have an acceptable level of knowledge of the permittee's radiation safety practices and policies.

Additionally, the inspectors reviewed a representative sample of the Radiation Safety Committee (RSC) meeting minutes for the period from CY 2009 through April 2011 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 CY's 2009 through 2010, and the first quarter of 2011. The sealed source quantities were consistent with the permittee's license conditions. The leak test results were below the reporting requirement of 0.005 microcurie for removable contamination.

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 an active research laboratory. The NRC inspectors did not identify any unusual or unexpected radiation levels in or around the research laboratory. 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.

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

No violations of NRC requirements were identified.

One concern was identified that pertained to the implementation of radiation procedures in conducting smears for removable contamination in a research laboratory.

5. PERSONNEL CONTACTED:

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting

#*Ruth Anne Burris, Director, Quality Management

Richard Pasquale, Acting Associate Director

#* Raya Kheirbek, M.D., Deputy Chief of Staff

*Natalie Merckens, Assistant Officer for Clinical Operations

*Martin Wiseman, Director, Business Office

*Marc Blackman, Associate Chief of Staff for Research

*Raj Lakshman, Ph.D., Director of Research Laboratories

#* Michael Funkhouser, Radiation Safety Officer

#*Paul Yurko, Program Manager, National Health Physics Program