

January 28, 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 030-34325/11-05(DNMS) – HUNTER HOLMES  
McGUIRE VA MEDICAL CENTER, RICHMOND, VIRGINIA

Dear Mr. Williams:

On January 12-13, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your Hunter Holmes McGuire VA Medical Center facility located in Richmond, Virginia. The inspection results were discussed with Mr. Charles Sepich, Medical Center Director at the exit meeting on January 13, 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.

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 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 by Kevin G. Null  
for/***

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

Docket No. 030-34325  
License No. 03-23853-01VA  
Permit No. 45-09413-06

Enclosure:  
Inspection Report No. 030-34325/11-05(DNMS)

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

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

NA-The Hunter Holmes McGuire VA Medical Center 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 December 18-19, 2008, two violations of the U.S. Nuclear Regulatory Commission (NRC) requirements were identified. The violations include: (1) failure to retain records of surveys to account for all sources that have not been implanted, and (2) failure to perform surveys of patients with a survey meter that is adequate to detect the type and energy of the radiation released. During the previous NRC inspection on April 22-24, 2009, no violations of NRC requirements were identified, however, two open items were identified involving: (1) the D-90s exceeded 20% of the prescribed dosage for five patient brachytherapy treatments, and (2) the permittee's policy and procedures conflict with Title 10 of the Code of Federal Regulations (CFR) 35.3045(a)(1)(i). See NRC Inspection Report No. 030-34325/08-030(DNMS) (ML101440380) for specific details of the open items.

The permittee implemented appropriate corrective actions in response to the NHPP inspection findings. These corrective actions include: (1) inventory records are now being maintained for all unused brachytherapy sources returned from surgery, and (2) the permittee purchased a Victoreen Model 451 ion chamber calibrated for iodine-125, for use of patient radiation surveys.

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

No events have been reported since the last NRC inspection on April 22-24, 2009.

## **PART II - INSPECTION DOCUMENTATION**

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

Charles Sepich, Medical Center Director  
John Wilson, Ph.D, Assistant Radiation Safety Officer  
Habeeb Saleh, Ph.D, Chief Therapeutic Medical Physicist

The Hunter Holmes McGuire VA Medical Center, Richmond, Virginia, (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a limited medical permit (Permit No. 45-09413-06). The facility is a 465 bed hospital authorized for diagnostic and therapy medical use authorized in 10 CFR 35.100, 35.200, 35.300, 35.400, 35.500, and 35.600. The permittee is also authorized for research and development as defined in 10 CFR 30.4. According to the licensee staff that was 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 licensee 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 department. The permittee conducts approximately 2,300 diagnostic procedures per year. Approximately 70% of the annual work load is cardiac scans. The remaining workload consists of bone, liver and iodine-123 thyroid scans. Prior to January 2010, the permittee contracted with a company, Alliance Healthcare Services, Inc., NRC License No. 47-25570-01, to provide mobile Positron Emission Tomography (PET) diagnostic scanning services. Alliance Healthcare Services, Inc. provided this service one day per week at the main hospital. In January 2010, the contract was cancelled and now the permittee performs its own diagnostic PET imaging. The workload from the mobile PET services and the main hospital is approximately 2,300 diagnostic procedures per year. During 2009-2010, the permittee performed eleven whole body scans with iodine-123, fifteen hyperthyroid treatments and ten thyroid cancer treatments with iodine-131. The inspector reviewed forty-six representative samples of written directives for iodine-131 for the period of 2008-2010. No medical events involving the administration of iodine-131 were identified. During the inspection of the hot laboratory, 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 inspector interviewed an authorized user (physician), two nuclear medicine technologists and the Assistant Radiation Safety Officer 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 except two nuclear medicine technologists had a good understanding of the definition of a medical event and the reporting requirements. Two of the nuclear medicine technologists were confused regarding the exact definition of a radiopharmaceutical medical event (more conservative) because of guidance provided to them by the previous Radiation Safety Officer. According to records provided by the Assistant Radiation Safety Officer, the nuclear medicine staff was provided radiation safety training (refresher training) on October 14, 2010, and includes a discussion regarding medical events.

During this inspection, it was 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 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. The highest whole body exposures for the calendar years (CY) 2007 through 2010 were as follows:

CY 2007	CY 2008	CY 2009	CY 2010
1,202 mrem	964 mrem	343 mrem	260 mrem

The highest extremity exposures for calendar years (CY) 2007 through 2010 were as follows:

CY 2007	CY 2008	CY 2009	CY 2010
9,320 mrem	9,560 mrem	5,050 mrem	1,270 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.

### **High Dose-Rate Remote Afterloader Brachytherapy**

To date the permittee has not used the high dose-rate (HDR) remote afterloader brachytherapy unit for patient treatments. The permit was amended to add the HDR device and approved in May 2007 by the NHPP; however, subsequent to the approval, the permittee decided to install the device into a separate room rather than place the HDR in a shared accelerator therapy treatment room. A 10 curie iridium-192 sealed source was installed into the unit on August 2010, to allow the permittee to do certain quality control checks, interlock tests and a radiation survey of surrounding areas inside and outside the new HDR treatment room. At the time of this inspection, the results of the survey have not been submitted to NHPP for their review and approval.

### **Prostate Brachytherapy Program**

The permittee performs approximately 60 prostate implant brachytherapy implants per year. The permittee has three authorized-user physicians that oversee the brachytherapy program. The permittee contracts with the Virginia Commonwealth University for medical physics support. The inspector reviewed a representative sample of patient treatment records for CY 2009 (23 cases) and 2010 (52 cases). The inspector 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 inspector identified five prostate brachytherapy implants in which the D-90s (dose to 90% of the prostate) exceeded 20% of the prescribed dose. The implants were performed on November 17, 2009, April 27, 2010, May 11, 2010, May 25, 2010 and August 17, 2010. This is considered an open item. No new medical events were identified.

### **Research Activities**

The permittee authorized two researchers to perform research activities with microcurie quantities of carbon-14 and hydrogen-3. Both of the researchers are currently active and perform research in five separate laboratories. 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 bi-monthly audits that included a review of wipe test records of the research labs. According to the assistant radiation safety officer, no significant contamination events were identified during the period of 2007-2010.

2. **SCOPE OF INSPECTION:**

**Record review:** During the inspection, the inspector reviewed a representative sample of patient treatment records and written directives for the administration of iodine-131 for CY 2008 to 2010 (46 cases) and 75 written directives and treatment plans for prostate implant brachytherapy performed during CY 2009-2010. The inspector reviewed a representative sample of Radiation Safety Committee minutes, incidents reports, and annual audits of the radiation safety program, package receipt records, training records, survey records, leak test records, waste disposal records, and CY 2007 through 2010 dosimetry records.

**Inspection Procedure(s) Used:** 87131, 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, HDR treatment room 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. The inspector identified five Open Items associated with D-90s that exceed 20% of the prescribed dose.

5. **PERSONNEL CONTACTED:**

- \*Charles Sepich, Medical Center Director
- \* Habeeb Saleh, Ph.D, Radiation Oncology, Medical Physicist
- \* Timothy Burke, M.D., Nuclear Medicine, Authorized User Physician
- \* Michael Chang, M.D., Radiation Oncology, Authorized User Physician
- \* Wilhelmina Estrada, M.D., Nuclear Medicine, Authorized User Physician
- \* John Hunter, M.D., Radiation Oncology
- # Kathy Lange, Directors Secretary
- \*#John Wilson, Ph.D, Assistant Radiation Safety Officer
- \* Paul Yurko, Program Manager, NHPP via phone on 1/13/2011

Use the following identification symbols:

#Individual(s) present at entrance meeting on 1/12/2011

\*Individual(s) present at exit meeting on 1/13/2011