

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 030-34325/11-03(DNMS) – VA MEDICAL
CENTER, DURHAM, NORTH CAROLINA

Dear Mr. Williams:

On January 10-11, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your VA Medical Center, located in Durham, North Carolina. The inspection results were discussed with you and Mr. Ralph Gigliotti, Medical Center Director and selected members of his staff at the exit meeting on January 11, 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

-2-

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

Sincerely,

***/RA by KevinG. 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. 32-01134-01

Enclosure:
Inspection Report No. 030-34325/11-03(DNMS)

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/11-03(DNMS)

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

Licensee (Name and Address):
National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

Location (Authorized Site) Being Inspected;
VA Medical Center
508 Fulton Street
Durham, North Carolina 27705

Permit No. 32-01134-01

Licensee Contact: William (Buddy) Furr, III, RSO Telephone No. 919-416-5851
Priority: 2 Program Code: 02110/3610 (secondary 2230)

Date of Last Inspection: April 20-22, 2009 Date of This Inspection: January 10-11, 2011

Type of Inspection: () Initial () Announced (X) Unannounced
(X) Routine () Special

Next Inspection Date: N/A (X) Normal () Reduced
Justification for reducing the routine inspection interval:

- Summary of Findings and Actions:
- (X) No violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
 - () Non-cited violations (NCVs)
 - () Violation(s), Form 591 issued
 - () Violation(s), regional letter issued
 - () Followup on previous violations

Inspector(s): Darrel G. Wiedeman

 /RA/ 01/28/2011
Date

Approved: Patricia J. Pelke

 /RA/KEVIN G. NULL for/ 01/28/2011
Date

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA - The VA Medical Center, Durham, North Carolina is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

The previous U.S. Nuclear Regulatory Commission (NRC) inspection on April 20-22, 2009, was prompted by a reported medical event. The medical event involved administration of 81 iodine-125 seed for a prostate brachytherapy implant. Following the implant procedure, radiographs of the patient's pelvis confirmed the correct position of the seeds within the patient. The following day, computerized tomography (CT) images of the patient revealed that eight seeds had apparently migrated. Subsequent CTs showed an additional four seeds had migrated. The final D-90 (dose to 90% of the prostate) was determined to be 56 percent below the prescribed dose of 145 Gray (Gy). It was on this basis that the licensee reported the migrating seeds as a medical event.

Prior to the April 20-22, 2009, inspection, the NRC conducted a routine inspection on September 15, 2008, and no violations were identified.

In early 2009 the permittee decided to discontinue performing prostate brachytherapy procedures. To date the permittee is no longer performing prostate brachytherapy procedures.

This issue is now considered closed.

3. INCIDENT/EVENT HISTORY:

No additional events have been reported since the last NRC inspection on April 20-22, 2009.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Ralph Gigliotti, Medical Center Director
Rudy Klopfer, Assistant Medical Center Director
Walter (Buddy) Furr, Radiation Safety Officer
Gary Williams, Director, National Health Physics Program

The Veterans Affairs Medical Center, Durham, North Carolina (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 32-01134-01). The facility is a 235 bed hospital authorized for medical diagnosis, therapy and research in humans. The permittee is also authorized for research and development as defined in Title 10 of the Code of Federal Regulations (CFR) 30.4, including animal studies, instrument calibration, student instruction, and *in vitro* studies. The permittee is also authorized for

a self-contained, self-shielded blood irradiator. Staff from the VA National Health Physics Program (NHPP) accompanied the NRC inspector. According to the licensee 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 inspector did not identify anything contrary to the above statements made by licensee staff.

Nuclear Medicine Program

At the time of this inspection, the permittee had five full-time nuclear medicine technologists and five authorized user physicians that work in the nuclear medicine department. The permittee conducts approximately 2,500 diagnostic procedures per year. The permittee estimated that 50% of the annual workload is diagnostic cardiac scans. The remaining workload consists of bone, liver and I-131 thyroid scans. During 2008-2010, the permittee performed 35 to 45 wholebody scans with iodine-131, approximately 15 hyperthyroid treatments per year and approximately ten thyroid cancer treatments per year. All use of iodine-131 is in capsule form.

The inspector reviewed approximately 90 random samples of radiopharmaceutical written directives for the period 2008-2010. The inspector concluded that the written directives met the requirements in 10 CFR 35.40. The highest whole body exposure for calendar year (CY) 2007 was 621 mrem, 2008 was 470 mrem and 2009 was 660 mrem. The highest extremity exposure for CY 2007 was 1,290 mrem, 2008 was 1,020 mrem and 2009 was 1,330 mrem. No new medical events or over exposures to radiation were identified.

The NRC inspector interviewed an authorized user physician, a nuclear medicine technologist and the Radiation Safety Officer (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 physician and nuclear medicine technologist had a good understanding of the definition of a medical event and reporting requirements.

Brachytherapy Program

In December 2008, the permittee permanently terminated its prostate brachytherapy program and does not plan to re-activate the program. The last prostate brachytherapy implant was performed on December 18, 2008. The inspector reviewed a representative sample of twelve patient treatment records for calendar year 2008. The inspector identified two prostate brachytherapy implants in which the D-90s (dose to 90% of the prostate) exceeded 20% of the prescribed dose. Both implants were performed on November 20, 2008, and showed that the administered dose exceeded the prescribed dose by 121.4% and 126%, respectively. This is considered an open item. No new medical events were identified.

Research Activities

The permittee previously authorized three researchers to perform research activities with microcurie quantities of carbon-14, iodine-125 and hydrogen-3. Currently, all three of

the researchers are active. The NRC inspector conducted independent radiation surveys in and around selected research facilities/laboratories and did not identify any contamination or unusual/unexpected radiation levels. The radiation safety staff performs quarterly wipe tests of the research labs for removable contamination. No significant contamination has been identified during the period 2007-2010.

2. **SCOPE OF INSPECTION:**

Record review: The inspector reviewed a representative sample of nuclear medicine written directives, incoming package survey records, daily/weekly radiation surveys and dose calibrator records. The inspector also verified that the data in the National Source Tracking System (NSTS) was accurate.

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

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

During the inspection of the nuclear medicine program, the inspector reviewed a representative sample of radiation survey records for the period 2008-2010 and discussed the following areas with the nuclear medicine technologists: package surveys, daily/weekly radiation surveys, disposal of radioactive materials and dose calibrator verifications. During the inspection, the inspector asked the nuclear medicine 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 permittee's records for the test performed earlier that same morning.

3. **INDEPENDENT AND CONFIRMATORY MEASUREMENTS:**

The inspector conducted independent radiation surveys with a Ludlum Model 2402, Serial No. 157587, calibrated on May 20, 2010. Surveys in and around the hot lab were consistent with the permittee's survey results. Surveys in unrestricted areas were at background (.02-.05 mR/hour). No unusual or unexpected radiation levels were identified.

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

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

No violations of NRC requirements were identified. One Open Item was identified.

4. PERSONNEL CONTACTED:

- # Dale Kuerbitz, Administrative Officer-Radiology
- # Rudy Klopfer, Assistant Medical Center Director
- * Ralph Gigliotti, Medical Center Director
- * John Shelburne, M.D. Chief of Staff
- * Walter (Buddy) Furr, Radiation Safety Officer
- * Gary Williams, Director, National Health Physics Program

Use the following identification symbols:

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