

January 3, 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 030-34325/10-07(DNMS) – VA ANN ARBOR
HEALTHCARE SYSTEM, ANN ARBOR, MICHIGAN

Dear Mr. Williams:

On December 13-14, 2010, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your VA Ann Arbor Healthcare System, located in Ann Arbor, Michigan. The inspection results were discussed with Mr. Robert McDivitt, Medical Center Director and his staff at the exit meeting on December 14, 2010. 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.

This inspection also included a follow-up to a previous National Health Physics Program reactive inspection conducted on October 28, 2009, with continuing review through November 20, 2009, to review your corrective actions associated with the package containing radioactive material (Mo-99/Tc-99m generator) that was left unattended in an unrestricted area on September 21, 2009. Your corrective actions in response to the violation appeared to be appropriate and we have no further questions regarding this matter. No violations of NRC requirements were identified during this inspection.

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/

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

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 21-00159-04

Enclosure:
Inspection Report No. 030-34325/10-07(DNMS)

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/2010-07

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 Ann Arbor Healthcare System

2215 Fuller Road

Ann Arbor, Michigan 48105

Permit No. 21-00159-04

Licensee Contact: Melonie Wissing, RSO

Priority: 2 Program Code: 02110

Telephone No. 734-845-3406

Date of Last Inspection: January 20-21, 2004

Date of This Inspection: December 13-14, 2010

Type of Inspection: ☐ Initial

() Announced

(X) Routine

(X) Unannounced

() Special

Next Inspection Date: NA

(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

(X) Follow-up on previous violations

Inspector(s) Darrel Wiedeman

/RA/

(Signature)

Date 01/03/2011

Approved Patricia J. Pelke

/RA/

(Signature)

Date 01/03/2011

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA – The VA Ann Arbor Healthcare System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

The VA National Health Physics Program (NHPP) conducted a reactive inspection on October 28, 2009 with continuing review through November 20, 2009, in response to a reported event involving a package of radioactive material left in an unrestricted area of the hospital. One of the two violations identified during the reactive inspection was categorized as a Severity Level III violation (10 CFR 20.1802). On September 21, 2009, a package containing radioactive material (Mo-99/Tc99m generator) was left unattended in an unrestricted area for 68 minutes.

The permittee implemented corrective actions that included: (1) revised and clarified the healthcare system policy for receipt of a package with radioactive material that is delivered outside the normal working hours; (2) provided training to police service staff regarding the revised procedures; (3) recalled all keys to the hot lab that were in the possession of the VA police department; and (4) no longer accept after-hour delivery of radiopharmaceuticals.

The NRC inspector concluded that the permittee implemented appropriate corrective actions to preclude further violations. This issue (NMED No. 100539) is now considered closed.

One Severity Level IV violation was identified that involved an isolated failure to verify that the radioactive drug administered was in accordance with the written directive, during the last routine inspection by the NRC on January 20-21, 2004.

3. INCIDENT/EVENT HISTORY:

No additional events have been reported since the last NRC inspection on January 20-21, 2004.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

The VA Ann Arbor Healthcare System, Ann Arbor, Michigan (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 21-00159-04). The facility is a 100 bed hospital authorized for diagnostic, therapy and human research medical use. 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. Staff from the VA National Health Physics Program (NHPP) accompanied the NRC inspector. According to the licensee staff that was interviewed, there have been no fires, explosions, medical events or fatalities involving 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 five full-time nuclear medicine technologists and five authorized user (physicians) that work in the nuclear medicine department. The permit authorizes two locations of use, the main hospital in Ann Arbor, Michigan and the other location is a clinic located in Toledo, Ohio. The permittee performs primarily bone scans every Thursday at the Toledo, Ohio facility and approximately 4-6 patients are treated there each week. 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. provides this service one day per week at the main hospital. The workload from the mobile PET services and the main hospital is approximately 27,000 diagnostic procedures per year. The permittee estimated that 80% of the annual workload is diagnostic cardiac scans. The remaining workload consists of bone, liver and iodine-131 thyroid scans. During 2009-2010, the permittee performed 20 whole body scans with iodine-131, 15 hyperthyroid treatments and 30 thyroid cancer treatments. All use of iodine-131 is in capsule form.

The inspector reviewed 28 random samples of written directives for the period of 2009-2010. The inspector concluded that the written directives met the requirements in 10 CFR 35.40. The highest whole body exposure for the period calendar year 2009-2010 was less than 100 mrem and the highest extremity exposure was 1,080 mrem. No new medical events or overexposures to radiation were identified.

The NRC inspector interviewed 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 individuals had a good understanding of the definition of a medical event and who to report a medical event to. According to the RSO, she provided the most recent training to the nuclear medicine physicians and technologists regarding the definition of a medical event on May 14 and 15, 2010.

Research Activities

The permittee previously authorized four researchers to perform biomedical research activities with microcurie quantities of sulphur-35, iodine-125 and hydrogen-3 in approximately five research laboratories. Only three of the four researchers were currently active. The NRC inspector conducted independent radiation surveys in all research laboratories and did not identify any contamination or unusual/unexpected radiation levels. The RSO performs periodic wipe tests of the research labs for removable contamination. No significant contamination has been identified during the period of 2009-2010.

2. SCOPE OF INSPECTION:

Record review: The inspector reviewed a random sample of nuclear medicine written directives, radiation survey records, dose calibrator records, radiation safety committee minutes, training records, leak test records, waste disposal records and dosimetry records.

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

Focus Areas Evaluated: MC 2800, Chapter 05.01 b. 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 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 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 licensee'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). The inspector also conducted independent radiation surveys of a representative sample of active research laboratories and waste holding areas. The NRC inspector did not identify any unusual or unexpected radiation levels in or around the research laboratories or waste holding rooms.

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.

5. PERSONNEL CONTACTED:

#Ginny Creasman, Pharm.D, Assistant Director
*#Milton Gross, MD., Authorized User (Physician)
* Robert McDivitt, FACHE, Medical Center Director
* Randall Ritter, Associate Director
*#Melonie Wissing, M.S., Radiation Safety Officer
*Eric Young, M.D., Chief of Staff
*#Paul Yurko, Program Manager, National Health Physics Program

Use the following identification symbols:

Individual(s) present at entrance meeting

* Individual(s) present at exit meeting