

March 17, 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 030-34325/11-15(DNMS) – VA GREATER LOS ANGELES HEALTHCARE SYSTEM, LOS ANGELES, CALIFORNIA

Dear Mr. Williams:

On February 14–16, 2011, the U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at the VA Greater Los Angeles Healthcare System, located in Los Angeles, California. The inspection results were discussed with Ms. Marlene Brewster, Associate Director, Patient Care Services, and selected members of her staff at the exit meeting on February 16, 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 and its enclosure 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 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. 04-00181-04

Enclosure:
Inspection Report No. 030-34325/11-15(DNMS)

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OFFICIAL RECORD

INSPECTION RECORD

Region III Inspection Report No. 030-34325/11-15(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 Greater Los Angeles Healthcare System
11301 Wilshire Boulevard
Los Angeles, California 90073
AND
16111 Plummer Street
Sepulveda, California 91393

Permit No. 04-00181-04

Licensee Contact: Mark A. Sitek, RSO
Telephone No. 310-268-3993

Priority: 2 Program Code: 2110/3610

Date of Last Inspection: October 8, 2008 through April 24, 2009 (On-site at the VA Greater Los Angeles Healthcare System from March 23-25, 2009)

Date of this Inspection: February 14-16, 2011

Type of Inspection: Initial Announced Unannounced
 Routine Special

Next Inspection Date: N/A Normal Reduced

Summary of Findings and Actions:

- 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): /RA/
 Kevin G. Null, Senior Health Physicist

Date: 03/17/2011

Approved: /RA/
 Patricia J. Pelke, Chief, Materials Licensing Branch

Date: 03/17/2011

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

N/A – The VA Greater Los Angeles Healthcare System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

From January 21, 2009, through March 26, 2009, the Department of Veterans Affairs National Health Physics Program (NHPP) conducted a reactive inspection of the permittee's prostate brachytherapy program. One Severity Level IV violation was identified for failure to develop and implement written procedures to provide high confidence that each administration was per the written directive. The permittee implemented appropriate corrective actions in response to the NHPP inspection findings.

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 Greater Los Angeles Healthcare System from March 23-25, 2009), that focused on the prostate brachytherapy program. No violations were identified. The last routine inspection by the NRC was on July 31 through August 1, 2006; no violations of NRC requirements were identified.

3. INCIDENT/EVENT HISTORY:

No events have been reported since the last NRC inspection that was conducted between October 8, 2008 through April 24, 2009.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Marlene Brewster, Associate Director, Patient Care Services
Christian S. Head, M.D., Associate Director, Chief of Staff, Patient Care Services
Mark Sitek, Radiation Safety Officer

The VA Greater Los Angeles Healthcare System (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 04-00181-04). The facility is a 250 bed hospital that is authorized by the permit 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 operates two cyclotrons for the production of positron emission tomography (PET) radionuclides and radiopharmaceuticals that are used for medical diagnosis and research studies. Products of the cyclotron are also transferred to the University of California in Los Angeles for medical and research purposes. Radionuclides are also approved for use at a second location at 16111 Plummer Street, Sepulveda, California. A staff member from the NHPP accompanied the NRC inspectors. 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 that work in the nuclear medicine department. Nuclear medicine studies are conducted at the Los Angeles location of use located at 11301 Wilshire Boulevard. The permittee conducts approximately 25 diagnostic procedures per day (10 nuclear medicine studies and 15 PET procedures). The nuclear medicine procedures are primarily cardiac studies. The permittee prepares written directives for the administration of iodine-131 for therapeutic procedures (hyperthyroid and thyroid cancer treatments). Approximately five studies are conducted per calendar quarter, with a range of 50–70 millicuries administered for hyperthyroid treatments and 150–200 millicuries for thyroid cancer treatments. Iodine-131 is administered in capsule form only. All treatments are administered by an approved authorized user, who also receives a bioassay for intake of iodine-131. The permittee periodically administers samarium-153 for palliative therapy.

The inspectors reviewed a representative sample of radiopharmaceutical written directives for the period 2009-2010. 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 110 mrem, and for CY 2010 was 1000 mrem. The highest extremity exposure for CY 2009 was 10.39 rem, and CY 2010 was 6.59 rem. The extremity exposures were from work with PET radionuclides. No medical events or over exposures to radiation were identified.

The NRC inspectors interviewed an authorized user physician, two nuclear medicine technologists, the Radiation Safety Officer (RSO), and one member of the Radiation Safety staff regarding their understanding of the definition of a medical event, who to report a medical event to, and how they determine if a medical event occurred. These individuals had a satisfactory understanding of the definition of a medical event, as well as associated reporting requirements.

Brachytherapy Program

The last sealed source brachytherapy prostate treatment was performed on February 12, 2009. At the time of this inspection, the permittee indicated that there were no plans to initiate any sealed source brachytherapy treatments. If the permittee plans to perform prostate brachytherapy procedures in the future, they need 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, the NHPP will conduct an onsite assessment to evaluate the permittees readiness to perform prostate brachytherapy procedures.

Research Activities

Research studies conducted under the permit are performed at the Los Angeles address. A limited level of research is also conducted at 16111 Plummer Street, Sepulveda, California. Radionuclides are used for in vitro research studies, and primarily included microcurie quantities of carbon-14, hydrogen-3, phosphorus-32, and iodine-125. At the time of the inspection, the permittee's Radiation Safety Committee (RSC), which meets on a quarterly frequency each calendar year, approved seventeen permits for research and development (R&D) studies and 60 principal investigators (PIs). Approximately one half of the RSC approved PI's are actively using permitted radioisotopes in approximately 23 to 25 active laboratories. According to the RSO, there are 62 staff members in the R&D program who are monitored for radiation exposure.

The NRC inspectors 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 conducts monthly audits of the R&D program. Audits included surveys for radiation levels and removable contamination in restricted and unrestricted areas. No significant contamination or unusual radiation levels have been identified since the last NRC inspection.

Cyclotron Production Program

The inspectors toured the facility that contains two cyclotron units which are used to generate accelerator-produced radionuclides for medical diagnosis and research. One unit is an older 45 MeV cyclotron that was donated to the VA facility by the University of California in Los Angeles. This device is not routinely used by the permittee and it remains in standby mode in the event its service is required. The second newer unit is a 19 MeV cyclotron which is used on a daily basis. This unit is predominantly used to produce fluorine-18 for nuclear medicine imaging studies. A small amount of carbon-11 is produced for research purposes. Liquid and gas targets are used for the production of accelerator-produced radionuclides.

The permittee employs two full-time chemists and two full-time cyclotron engineers who are responsible for implementing and maintaining the program. Accelerator-produced nuclides are transferred from the cyclotron through delivery lines to four processing hoods for chemical synthesis. Effluent from all four processing fume hoods is filtered before being released. The cyclotron staff conducts weekly radiation level surveys and wipe tests for removable contamination in the production, synthesis, and target storage areas. Used targets are stored in the cyclotron vault.

Waste Burial Site

The inspectors toured the waste burial site which is located on the VA Los Angeles property at 11301 Wilshire Boulevard. The area was used several years ago as a burial site for medical waste, including animal carcasses, radiological scintillation vials, and other miscellaneous medical waste containing radioactive material. The permittee hired a contractor to evaluate the site for the presence of buried radioactive and medical wastes from historic waste disposal practices on the property. At the time of the inspection, the final report was pending review by the Department of Veterans Affairs

(DVA). The DVA plans to submit a copy of the report to the NRC Region III office for review.

The inspectors noted that the entire area was controlled by a chain link fence and that access is controlled through a locked gate. There are no structures or buildings erected on, or within, the fenced-in site. According to the RSO, the permittee has no plans to use the site for other purposes, and does not plan to release it for unrestricted use.

2. SCOPE OF INSPECTION:

Record review: The inspectors reviewed a representative sample of nuclear medicine written directives, incoming package survey records, radiation safety committee (RSC) meeting minutes, daily/weekly radiation surveys, and dose calibrator records.

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

Focus Areas Evaluated: Inspection Manual Chapter 2800, Section 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 2009-2010 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 inspectors observed a nuclear medicine technologist perform a daily constancy check on the dose calibrator and explain the procedure that is used for receipt of packages that contain radioactive materials. The inspectors observed a second technologist draw a unit dose of fluorine-18 for a diagnostic PET imaging study and inject a patient. The inspectors noted that both technologists were wearing appropriate protective clothing, and whole body and extremity dosimetry. The inspectors concluded that the tests and work practices were performed in a manner consistent with NRC guidance and in accordance with NRC regulations.

Additionally, the inspectors reviewed the RSC meeting minutes for calendar years 2009 and 2010, and confirmed that the permittee adequately tracked its radiation safety issues/concerns and effectively responded to those issues/concerns.

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. No unusual or unexpected radiation levels were identified.

The inspectors also conducted independent radiation surveys in selected research laboratories located at the Los Angeles and Sepulveda facilities. The NRC inspectors did not identify any unusual or unexpected radiation levels in or around the research

laboratories. 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.

Independent surveys were also conducted by the inspectors in and around the cyclotron and synthesis laboratories, the cyclotron control room, as well as on the roof directly above the cyclotron and synthesis fume hoods. Radiation levels in the cyclotron and synthesis areas (both restricted areas) ranged from 0.60–0.80 mR/hour, and radiation levels in the control room were essentially at background levels (0.01–0.02 mR/hour). The roof above the cyclotron units is a restricted area and properly posted in accordance with 10 CFR Part 20. Access to the roof is limited to cyclotron staff members and the Radiation Safety Office staff.

Surveys were also conducted by the inspectors near the fenced in perimeter of the waste burial site located at 11301 Wilshire Boulevard. Radiation levels were at background levels (0.03–0.05 mR/hour).

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

No violations of NRC requirements were identified.

4. **PERSONNEL CONTACTED:**

- * Marlene Brewster, Associate Director, Patient Care Services
- #Dean C. Norman, M.D., Chief of Staff/Acting Director
- #Christian S. Head, M.D., Associate Director Chief of Staff
- *Caroline Goldweis, M.D., Acting Chief of Staff, Clinical Information
- *Joan Lopes, Chief, Quality Management
- *Michael Mohler, M.D., Chief, Organizational Improvement
- #*Sandi Riley-Graves, Health Systems Specialist
- #*Mark Sitek, Radiation Safety Officer
- #*Stuart Mirell, Ph.D., Physicist, Cyclotron Facility and Nuclear Medicine Service
- #*Lisa Carrasco, Health Physicist, Radiation Safety Office
- #*Ronald Nusbaum, Assistant Radiation Safety Officer
- #*Craig Adams, Program Manager, National Health Physics Program

Use the following identification symbols:

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