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 030-34325/11-17(DNMS) ─ VA MEDICAL CENTER, SAN FRANCISCO, CALIFORNIA

Dear Mr. Williams:

On February 17, 2011, the U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at the VA Medical Center located in San Francisco, California. The inspection results were discussed with Mr. Lawrence Carroll, Director, and selected members of his staff at the exit meeting on February 17, 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.

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. 04-00421-05

Enclosure:
Inspection Report No. 030-34325/11-17(DNMS)

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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. 04-00412-05

Enclosure:
Inspection Report No. 030-34325/11-17(DNMS)

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/11-17(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
4150 Clement Street
San Francisco, CA 94121

Permit No. 04-00421-05

Licensee Contact: Arnulfo A. Germes, RSO
Telephone No. 415-221-4810

Priority: 2 Program Code: 2110/3610

Date of Last Inspection: October 8, 2008 through April 24, 2009 (On-site at the San Francisco VA Medical Center from March 26-27, 2009)

Date of This Inspection: February 17, 2011

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

Next Inspection Date: N/A (X) Normal ( ) Reduced

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 ***/RA/*** Date: 03/17/2011
Kevin Null, Senior Health Physicist

Approved: ***/RA/*** Date: 03/17/2011
Patricia J. Pelke, Chief, Materials Licensing Branch

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

N/A – The VA Medical Center is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

The Department of Veterans Affairs National Health Physics Program (NHPP) conducted a routine inspection on August 12-13, 2009, and a special inspection of the permittee's prostate brachytherapy program from September 8–9, 2010. 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 San Francisco VA Medical Center from March 26-27, 2009), focused on the prostate brachytherapy program. No violations were identified. The last NRC routine inspection was conducted on June 16, 2008; 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:

Lawrence Carroll, Director
Jeffrey A. Joseph, Acting Associate Director
Diana Nicoll, M.D., Ph.D., Chief of Staff
Arnulfo A. Germes, Radiation Safety Officer (RSO)

The VA Medical Center, San Francisco, California (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 04-00421-05). The facility is a 124 bed acute care facility 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. 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 three full-time nuclear medicine

technologists, including one supervisor, that worked in the nuclear medicine department. The permittee conducts approximately 10–15 diagnostic procedures per day (six nuclear medicine studies and nine positron emission tomography (PET) procedures). The nuclear medicine procedures are primarily cardiac studies. The procedures are performed in three imaging rooms with unit doses that are received from a commercial nuclear pharmacy. The permittee prepares written directives for the administration of iodine-131 for therapeutic procedures (hyperthyroid and thyroid cancer treatments). In 2009, the permittee performed nine iodine-131 treatments that required a written directive, and in 2010 five treatments were administered. Thyroid cancer is treated with 100–150 millicuries of iodine-131, and 8–10 millicuries of iodine-131 is administered for hyperthyroid treatments. The RSO conducts an evaluation of each patient which includes calculations in accordance with NUREG-1556, Volume 9, prior to their treatment with iodine-131 for thyroid cancer, to determine whether or not the patient can be released in accordance with 10 CFR 35.75, and provides the patients with written instructions. Approximately two patients are treated with iodine-131 that require admission to the medical center as an in-patient each year. Iodine-131 is administered in capsule form only. Samarium-153 is used very infrequently for palliative therapy. All radiopharmaceutical therapy treatments are administered by an approved authorized user physician.

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 300 mrem, and for CY 2010 was 680 mrem. The highest extremity exposure for CY 2009 was 2880 mrem, and CY 2010 was 9420 mrem. No medical events or over exposures to radiation were identified.

The NRC inspectors interviewed an authorized user physician, one nuclear medicine technologist, the Assistant Radiation Safety Officer, and the Physical Science Technologist 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.

Prostate Brachytherapy Program

The permittee performs an average of 20-25 permanent prostate implants each year. Two radiation safety committee (RSC) approved authorized user physicians supervise the permittee's prostate brachytherapy program. Both authorized users are contract radiation oncologists and are responsible for issuing a written directive for each treatment. Dosimetry and medical physics services are performed under contract with Pro-Qura, a Seattle-based firm that provides pre and post treatment plans. Prostate volume studies and contour images of the prostate are performed by a urologist on staff at the VA Medical Center. This information is forwarded to Pro-Qura and a treatment plan is developed by the contract dosimetrist.

Written directives for iodine-125 prostate implants are for 145 (gray) Gy, and 125 Gy for palladium-103 implants. Implants are performed on Friday mornings under general anesthesia and fluoroscopy. Post treatment CT images of the prostate are taken one

month after the implant and are digitally transmitted to Pro-Qura for post implant evaluation. Each post plan is reviewed by a physician at Pro-Qura who is experienced in prostate brachytherapy. The physician also performs an evaluation of the implant quality and documents the results of this evaluation on the post plan. Pre and post plans and post implant dosimetry prepared by Pro-Qura are reviewed by an authorized user physician, an urologist, and the RSO at the VA Medical Center.

The inspectors reviewed a representative sample of written directives for 2009 and 2010 for prostate brachytherapy implants. The inspectors concluded that the permittee administered the doses in accordance with the written directives. No medical events were identified.

The inspectors did not identify any prostate brachytherapy implants in which the D 90s (dose to 90 percent of the prostate) exceeded 20 percent of the prescribed dose. No new medical events were identified.

Research Activities

Radionuclides are used for in vitro research studies, and primarily included microcurie quantities of carbon-14, hydrogen-3, phosphorus-32, sulfur-35, calcium-45, chromium-51, and iodine-125. At the time of the inspection, the permittee had 14 laboratories that were approved by the RSC for research studies involving permitted radionuclides. The RSC meets on a quarterly basis each calendar year. Twelve of the 14 laboratories were active at the time of the inspection.

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 research 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.

2. SCOPE OF INSPECTION:

Record review: The inspectors reviewed a representative sample of nuclear medicine written directives, incoming package survey records, 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, explain the procedure that is used for receipt of packages that contain radioactive materials, and

describe how radiation surveys are conducted in the nuclear medicine hot lab and imaging rooms. The inspectors noted that the nuclear medicine technologists were wearing appropriate protective clothing when they handled permitted material, as well as 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. 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 permittees radioactive waste (decay-in-storage and long term storage) and sealed source storage areas. Radiation levels in the restricted storage areas ranged from 0.03–0.08 mR/hour, and radiation levels in unrestricted areas adjacent to the storage areas 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:

#* Lawrence Carroll, Director
#* Jeffrey Joseph, Acting Associate Director
*Diana Nicoll, M.D., Ph.D., Chief of Staff
Carina Mari Aparici, M.D., Chief of Nuclear Medicine
#* Robert Woodson, Assistant Radiation Safety Officer/ Health Physicist
*Gary Cecchini, Ph.D., Chair, Radiation Safety Committee
*Roy Herren, Physical Science Technologist

Marilyn Morrissey, Chief Nuclear Medicine Technologist
#*Craig Adams, Program Manager, National Health Physics Program
*Ed Leidholdt, Ph.D., Program Manager, National Health Physics Program

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting