March 10, 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 030-34325/11-10(DNMS) ─ VA NEW YORK HARBOR HEALTHCARE SYSTEM, BROOKLYN, NEW YORK

Dear Mr. Williams:

On February 22-24, 2011, U. S. Nuclear Regulatory Commission (NRC) inspectors conducted a routine inspection at your VA New York Harbor Healthcare System, located in Brooklyn, New York. The inspection results were discussed with Mrs. Martina Parauda, Medical Center Director and selected members of her staff at the exit meeting on February 24, 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 our previous reactive inspection conducted between October 8, 2008 through April 24, 2009, to review your corrective actions associated with three apparent violations identified during that inspection. The apparent violations involved the failure to: (1) implement written prostate brachytherapy procedures that provide high confidence that the administered dose is in accordance with the written directive as required by Title 10 of the Code of Federal Regulations (CFR) 35.41(a)(2); (2) develop, implement, and maintain written procedures to verify that the administration is in accordance with the treatment plan and written directive as required by 10 CFR 35.41(b)(2); and (3) notify the NRC of a medical event by the next calendar day after discovery of a medical event as required by 10 CFR 35.3045(c). Your corrective actions in response to the violations 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 10 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 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. 31-02892-03

Enclosure:
Inspection Report No. 030-34325/11-10(DNMS)

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/11-10(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 New York Harbor Healthcare System
800 Poly Place
Brooklyn, New York, 11209

Permit No. 31-02892-03

Licensee Contact: Esfandiar Sarfaraz, Ph.D, Radiation Safety Officer
Telephone No. 718-836-6600 x6285

Priority: 2 Program Code: 02120/3620 secondary 02230

Date of Last Inspection**:** February 26-27, 2009 Date of this Inspection**:** February 22-24, 2011

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

Next Inspection Date: NA

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

Inspectors: */RA/* Date: 03/07/2011
Darrel Wiedeman, Senior Health Physicist

/RA/ Date: 03/09/2011
Frank Tran, Licensing Reviewer

Approved: */RA/* Date: 03/10/2011
Patricia J. Pelke, Chief, Materials Licensing Branch

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA-The VA New York Harbor Healthcare System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

During a previous reactive inspection by the National Health Physics Program (NHPP) on November 20 and December 8-9, 2008, with continuing review through December 17, 2008, no violations of U.S. Nuclear Regulatory Commission (NRC) requirements were identified. The inspection focused on a medical event and the permanent implant brachytherapy program and included all elements of a routine inspection.

The NHPP conducted an inspection of the permanent implant brachytherapy program on December 15-16, 2009; no violations of NRC requirements were identified.

The NHPP conducted a routine inspection on December 14-15, 2010 (including the permanent prostate implant brachytherapy program); no violations of NRC requirements were identified.

The NRC conducted an inspection (Extent of Condition) between October 8, 2008 through April 24, 2009, and two apparent violations were identified for the VA New York Harbor Healthcare System. These apparent violations include the failure to: (1) notify the NRC of a medical event by the next calendar day after discovery of a medical event as required by 10 CFR 35.3045(c); and (2) submit a written report within 15 days after discovery of a medical event that includes all of the information required by 10 CFR 35.3035(d).

The last routine inspection by the NRC was on February 14, 2005; no violations of NRC requirements were identified.

The permittee implemented appropriate corrective actions in response to the violations identified between the periods of October 8, 2008 through April 24, 2009, by the NRC. The licensee described their corrective actions in a letter to the NRC dated July 15, 2010. These corrective actions include: (1) the permittee revised their written procedures for the prostate seed implant program to implement the Veterans Health Administration (VHA) standard procedures; and (2) conducted training with the staff to discuss the new VHA standard procedures and medical event reporting requirements. The NRC inspectors verified the implementation of the permittee's corrective actions. This issue is now considered closed.

3. INCIDENT/EVENT HISTORY:

No events have been reported since the last NRC inspection conducted between October 8, 2008 through April 24, 2009. No open Nuclear Materials Event Database (NMED) items are pending for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Martina Parauda, Medical Center Director
Michael Simberkoff, M.D., Chief of Staff
Howard Banner, M.D., Chief of Nuclear Medicine Service
Esfandiar Sarfaraz, Ph.D., Radiation Safety Officer
Alka Mokadam, M.S., Chief, Therapeutic Medical Physicist

The VA New York Harbor Healthcare System, Brooklyn, New York, (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a limited medical permit (Permit No. 31-02892-03). The facility is a 119 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 permittee staff 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 permittee staff.

Nuclear Medicine Program

At the time of this inspection, the permittee had three full-time nuclear medicine technologists and three authorized user physicians that work in the department. The permittee conducts approximately 2,400 diagnostic procedures per year. Approximately 50 percent of the annual work load is cardiac scans. The remaining workload consists of bone, liver, lung, brain scans and iodine-123 thyroid uptake studies. During 2007-2010, the permittee performed approximately six whole body scans, eight hyperthyroid treatments and three thyroid cancer treatments per year with iodine-131. The permittee uses iodine-131 in capsule form only. The inspector reviewed approximately twenty-five representative samples of written directives for iodine-131 for the period of 2007-2010. No medical events involving the administration of iodine-131 were identified. During the inspection of the nuclear medicine hot lab, 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 permittee records for the test performed earlier that same morning.

The 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. All individuals had a good understanding of the definition of a medical event and the reporting requirements. According to records provided by the RSO, the

nuclear medicine staff was provided radiation safety training (refresher training) in September 2009, and included a discussion regarding the definition of a medical event and reporting requirements.

During this inspection, the inspector observed that the technologists routinely use syringe shields and 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 technologists: 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
131 mrem	89 mrem	85 mrem	81 mrem

The highest extremity exposures for CY 2007 through 2010 were as follows:

CY 2007	CY 2008	CY 2009	CY 2010
250 mrem	<50 mrem	<50 mrem	<50 mrem

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.

High Dose-Rate Remote Afterloader Brachytherapy

The licensee provides High Dose Rate (HDR) brachytherapy treatments to cancer patients that have been referred by other medical facilities. The licensee has two full time medical physics staff, two part-time dosimetrists and three authorized user physicians. The permittee performs approximately two HDR brachytherapy treatments per month. On December 20, 2010, an 11.8 curie iridium-192 sealed source was installed in the HDR.

This inspection consisted of an in-depth review of the permittee's HDR brachytherapy program. The inspector reviewed a representative sample of recent leak test records, patient treatment records, written directives and calibration records and did not identify any deficiencies. The inspector interviewed the medical physicist and discussed the permittee's procedures for determining doses for patients undergoing HDR treatments. The inspector observed the permittee test the radiation detection alarm system, treatment room door interlocks, console emergency retraction switch and accelerator/HRD interlock switch. All safety systems functioned as designed and no deficiencies were identified. The radiation oncology staff was provided training in April 2009 and the training session included a discussion of the requirements for identifying and reporting medical events.

Prostate Brachytherapy Program

The permittee performs approximately eight to ten prostate brachytherapy implants per year. The permittee has one authorized user physician that supervises the

brachytherapy program. The inspector reviewed a representative sample of patient treatment records for CY 2007 through 2011 (21 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 permittee implemented the VHA standard operating procedures for prostate implant brachytherapy in April 2009. The permittee staff indicated that 100% of the brachytherapy cases are reviewed in-house and each year five prostate brachytherapy cases are sent out to an affiliate hospital for peer review.

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

Research Activities

Currently the permittee does not have any authorized users performing research activities.

Other Areas Inspected

The inspectors toured the package receiving area of the hospital and discussed the permittee's procedures with the staff. The inspectors observed the patient room (8-West, Room 314) that is used to house patients undergoing iodine-131 therapy and discussed safety procedures with the nursing staff. The inspectors toured the brachytherapy source storage room (G 116A) and reviewed the permittee's procedures for inventory control. The inspectors toured the waste monitoring room (G-147) and observed the permittee test the radiation monitoring system. No deficiencies or violations of NRC requirements were identified during the tours of the above referenced areas of the hospital.

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 (25 cases), written directives and treatment plans for prostate implant brachytherapy (21 cases) and HDR brachytherapy treatment plans (15 cases) for CY 2007 through 2011. The inspectors reviewed a representative sample of radiation safety committee meeting minutes, incidents reports, 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: Manual Chapter 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 inspectors conducted independent radiation surveys with a Ludlum Model 2402, Serial No. 157587, calibrated on May 5, 2010. The inspectors conducted surveys in and around the nuclear medicine hot lab, HDR treatment room and the waste storage rooms. 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 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.

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

No violations of NRC requirements were identified.

5. PERSONNEL CONTACTED:

*Martina Parauda, Medical Center Director
#Veronica Foy, Associate Director
*Michael Simberkoff, M.D., Chief of Staff
#*Esfandiar Sarfaraz, Ph.D., Radiation Safety Officer
*Alka Mokadam, M.S., Chief, Therapeutic Medical Physicist
*David Schreiber, M.D., Radiation Oncology
*Howard Banner, M.D., Chief, Nuclear Medicine Service
*Loohvy Phildor, Administrative Officer, Radiation Oncology
*Ramez Morkos, Chief, Radiation Therapist
*Christine Crockett, Health System Specialist (Executive Office)
* Patrick Malloy, M.D., Chief, Radiology Service
*Kathy Gaine, Compliance Officer
#*Paul Yurko, Program Manager, National Health Physics Program

Use the following identification symbols:
#Individuals present at entrance meeting on 2/22/2011.
*Individual(s) present at exit meeting on 2/24/2011.

-END-