December 3, 2010

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 030-34325/10-08(DNMS) – SAN DIEGO HEALTHCARE SYSTEM, SAN DIEGO, CALIFORNIA

Dear Mr. Williams:

On November 16-18, 2010, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your San Diego Healthcare System, located in San Diego, California. The inspection results were discussed with Ms. Cynthia Abair, Associate Medical Center Director at the exit meeting on November 18, 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. Within the scope of this inspection no violations of NRC requirements were identified.

This inspection also included a follow-up to our previous reactive inspection conducted on November 2-3, 2009, to review the circumstances surrounding a reported medical event involving a therapeutic dose of iodine-131 that was administered through a gastrostomy feeding tube. Your corrective actions in response to the violations appeared to be appropriate and we have no further questions regarding this matter.

In accordance with Title 10 of the Code of Federal Regulations (10 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.

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

Sincerely,

/RA/ By Kevin G. Null Acting
For/

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

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 04-15030-01

Enclosure:
Inspection Report No. 030-34325/10-08(DNMS)

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DATE	12/03/10		12/03/10		12/03/10			

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/2010-08

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 San Diego Healthcare System
3350 La Jolla Village Drive
San Diego, CA 92161

Permit No. 04-15030-01

Licensee Contact: Rene Michel, M.S., RSO Telephone No. 858-552-8585 X1059
Priority: 2 Program Code: 02110/3610

Date of Last Inspection: November 2-3, 2009 Date of This Inspection: 11/16-18/2010

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

Next Inspection Date: NA ( ) 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/ Kevin G. Null for D. Wiedeman Date 12/03/2010
(Signature)

Approved Patricia J. Pelke

/RA/ Kevin G. Null for P. Pelke Date 12/03/2010
(Signature)

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

AMENDMENT #	DATE	SUBJECT
NA (Master Materials License Permittee)		

2. INSPECTION AND ENFORCEMENT HISTORY:

The previous NRC reactive inspection on November 2-3, 2009, was prompted by a reported medical event. The medical event involved administration of 187 millicuries of liquid iodine-131 that was administered through a gastrostomy (g-tube) feeding tube. It was subsequently determined that the dosage of iodine-131 was administered into the wrong port of the gastrostomy tube which resulted in an underdose to the patient's thyroid gland and an unintended dose to the patient's stomach.

The NRC inspector identified three apparent violations that included: (1) failure to develop, implement and maintain written procedures for administering byproduct material through a g-tube in accordance with Title 10 of the Code of Federal Regulations (10 CFR) 35.41(a)(2); (2) failure to notify the NRC Operations Center no later than the next calendar day of a medical event; and (3) failure to instruct members of the radiology staff regarding the proper handling of the patient's contaminated g-tube (EA-10-023).

The permittee submitted a letter to the VA National Health Physics Program (NHPP) dated January 15, 2010 (tied-down as condition No. 24.C of the permit). In this letter the permittee described their corrective actions. During this inspection the NRC inspector verified that the permittee took appropriate corrective actions by: (1) developing a detailed step-by-step procedure for g-tube administrations that includes establishing trigger levels for patient surveys and actions to be taken if trigger levels are exceeded, (2) improving communications between the radiation safety office staff and the nuclear medicine department, (3) implementing a time-out process when using unfamiliar medical devices, (4) requiring a member of the radiation safety staff to be physically present during g-tube administrations, and (5) providing formal training to the nuclear medicine technologists and authorized users regarding g-tube administrations.

This issue is now considered closed.

3. INCIDENT/EVENT HISTORY:

No additional events have been reported since the last NRC inspection on November 2-3, 2009.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Gary Williams, Director, National Health Physics Program
Stan Johnson, Medical Center Director, San Diego, CA facility
Rene Michel, Radiation Safety Officer, San Diego, CA facility

The Veterans Affairs San Diego Healthcare System, San Diego, California (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 04-15030-01). The facility is a 236 bed hospital authorized for diagnostic and therapy medical use authorized in 10 CFR 35.100, 35.200, and 35.300. The permittee is also authorized for research and development as defined in 10 CFR 30.4. 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 licensee staff.

Nuclear Medicine Program

At the time of this inspection the permittee had seven full-time nuclear medicine technologists and three authorized user (physicians) that work in the nuclear medicine department. The permittee conducts approximately 8,500 diagnostic procedures per year. The permittee estimated that 80% of the annual work load is diagnostic cardiac scans. The remaining workload consists of bone, liver and iodine-123 thyroid scans. During 2009-2010, the permittee performed 22 wholebody scans with iodine-131, 12 hyperthyroid treatments and 6 thyroid cancer treatments. Typically, all use of iodine-131 is in capsule form. The inspector reviewed 32 random samples of written directives for the period 2009-2010. The highest wholebody exposure for the period CY 2009-2010 was 586 mrem and the highest extremity exposure was 2,452 mrem. No new medical events or overexposures to radiation were identified.

The NRC inspector interviewed an authorized user (physician), 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.

Research Activities

The permittee previously authorized 24 researchers to perform biomedical research activities with microcurie quantities of calcium-45, iodine-125 and hydrogen-3 in approximately 10 research laboratories. Only 5 of the researchers are currently active and the remaining 19 researchers were inactive. The NRC 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 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: 87131, 87134

Focus Areas Evaluated: 03.01 through 03.07

During the inspection of the nuclear medicine program, the inspector reviewed a random sample of radiation survey records for the period 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 random sample of active research laboratories. The NRC inspector did not identify any unusual or unexpected radiation levels in or around the research laboratories.

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:

#Robert Smith, M.D., Chief of Staff
*#Cynthia Abair, Associate Director
Stan Johnson, Medical Center Director
* Rene Michel, M.S., Radiation Safety Officer
Michael Zorn, Assistant Radiation Safety Officer
*#Paul Yurko, National Health Physics Program
* Russell Cain, CNMT, Chief Nuclear Medicine Technologist
* Ernest Belezzouli, M.D., Director Nuclear Medicine
*#Levar Cole, NRC, Inspector General's Office

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