April 20, 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 030-34325/11-21(DNMS) ─ VA MARYLAND HEALTH CARE SYSTEM, BALTIMORE, MARYLAND

Dear Mr. Williams:

On March 22, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the VA Maryland Health Care System, located in Baltimore, Maryland. The inspection results were discussed with Mr. Stephen Armagon, Acting Medical Center Director, and selected members of his staff at the exit meeting on March 22, 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. 19-01058-01

Enclosure:
Inspection Report No. 030-34325/11-21(DNMS)

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| DATE | 04/20/11 | | 04/20/11 | | 04/20/11 | | | |

**OFFICIAL RECORD**

**Inspection Record**

Region III
Inspection Report No. 030-34325/11-21(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 Maryland Health Care System
10 North Greene Street
Baltimore, Maryland 21201

Permit No. 19-01058-01
Licensee Contact: Oscar James, RSO
Telephone No. 410-605-7032

Priority: 3 Program Code: 2120/3610

Date of Last Inspection: September 17, 2008
Date of This Inspection: March 22, 2011

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

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

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:
(X) No violations cited, clear NRC Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
( ) Violation(s), regional letter issued
( ) Follow-up on previous violations

Inspector: ***/RA/*** by Patricia J. Pelke for/ Date: April 20, 2011
Hector Bermudez, Health Physicist, Region I

Approved: ***/RA/*** Date: April 20, 2011
Patricia J. Pelke, Chief, Materials Licensing Branch
Region III

Enclosure

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

1. AMENDMENTS AND PROGRAM CHANGES:

   The VA Maryland Health Care System, Baltimore, Maryland, is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

   The last inspection by NRC was on September 17, 2008, with no violations identified.

   The last inspection by the National Health Physics Program (NHPP) was on November 6, 2007, with no violations identified.

3. INCIDENT/EVENT HISTORY:

   On October 20, 2010, the permittee reported an incident (reference NMED Item Number 100518) that involved a contaminated package that had been received from a local radiopharmacy. Based on an investigation into the incident by the permittee, which included communication with the pharmacy to determine the cause, the permittee concluded that the package became contaminated in their hot lab after it was delivered by the pharmacy. In order to prevent recurrence, the permittee provided training to its nuclear medicine staff in the control and prevention of cross-contamination, which included proper techniques in handling permitted material in the hot lab. In addition, the permittee provided training to its staff on Department of Transportation regulations on March 11, 2011. The permittee also plans to provide additional instructions on preventing cross-contamination in the future. They are also developing a new procedure (to be issued in June) that will address proper shipping and receiving of permitted material. Permittee representatives stated that they have not detected contamination on any packages received since this event. This issue is considered closed.

## PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

   Stephen Armagon, Acting Medical Center Director
   Oscar James, Radiation Safety Officer (RSO)

   The VA Maryland Health Care System (permittee), was authorized by the VA Master Material License No. 03-25853-01VA to possess a limited scope medical permit (Permit No. 19-01058-01) to conduct Title 10 Code of Federal Regulations (CFR) Part 35, Sections 35.100, 35.200 and 35.300 activities. The permit also includes broad scope authority to approve authorized users for research and development activities as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction and in-vitro studies. Mr. Paul Yurko, a Program Manager from the NHPP accompanied the NRC inspector during this inspection.

The RSO is a full-time employee of the medical center. He performs program audits and responds to any spills and events involving permitted material. The permittee has an active Radiation Safety Committee (RSC), which meets on a quarterly basis. The RSO provides reports of licensed activities to the RSC for review. No major spills, losses of permitted material, or medical events have occurred since the last inspection. The RSO reports to the Chief of Engineering. The Chief of Engineering reports to the Director of Operations, who reports to the Director of the facility.

The nuclear medicine department performs approximately 10-15 diagnostic studies per day, including fluorine-18 positron emission tomography (PET) studies, using unit dosages supplied by Cardinal Health. Activities are conducted by four full-time nuclear medicine technologists and five authorized physician users. There are three gamma cameras, one PET camera, and one treadmill in the department. The most common radionuclide used in nuclear medicine is technetium-99m. The permittee possesses and uses a dose calibrator, and performs approximately 20 procedures that require written directives each year.

Therapeutic dosages described in 10 CFR 35, Section 35.300 were limited to iodine-131 at the time of the inspection. Doses ranged from low millicurie quantities for hyperthyroid treatments and up to and including approximately 300 millicuries for thyroid cancer treatments. The permittee also performed whole body scans using approximately three millicuries of iodine-131. No other radionuclides were used for radiopharmaceutical therapy procedures.

The use of permitted materials in research has been declining over the years. Currently, there are seven active laboratories and four principal investigators. The most common isotopes used in the research program included iodine-125, phosphorous-32, hydrogen-3, and sulfur-35 in microcurie amounts per experiment.

2. SCOPE OF INSPECTION:

Records review: The inspector reviewed records of dose calibrator quality assurance tests, training, surveys, survey instrument functionality, written directives, and performed independent radiation surveys. The inspector also reviewed the permitted activities in research, as well as the permittee's process for handling internal safety concerns raised by medical center staff.

Inspection Procedure(s) Used: 87131 and 87126

Focus Areas Evaluated: Manual chapter 2800, Sections 05.01b.1 (a) through (h).

Through a review of records and discussions with permittee representatives, the inspector determined that the permittee included the process of addressing safety concerns as part of their routine training program. The inspector also determined that the permittee's dose calibrator was calibrated in accordance with NRC regulations. Security of the nuclear medicine department and the research laboratories was found to be in compliance with Title 10 Code of Federal Regulation, Part 20 requirements. Through reviews of records and discussions with permittee representatives, the inspector determined that dosages of permitted material which required written directives were administered as intended by the authorized physician users. Written directives

were prepared for therapeutic doses of iodine-131. The permittee limits the use of iodine-131 to capsules only. The inspector reviewed all written directives that were prepared for
CY 2010 through March 2011. The inspector noted that each record was complete and accurate, and that patients were routinely released from the facility in accordance with NUREG-1556, Volume 9 criteria. The inspector also noted that occupational radiation exposures were well within regulatory limits.

The inspector interviewed the RSO in order to assess his understanding of the definition of a medical event and the reporting criteria. The inspector concluded that the RSO had a satisfactory understanding of the definition of a medical event and reporting requirements. At the time of the inspection, there was no use of permitted material in research. The inspector reviewed waste manifests and hazmat training records and did not find any discrepancies.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector conducted independent surveys with a Ludlum Model 2401-P survey meter. The inspector identified low level contamination on a surface inside the hot lab, a restricted area. The permittee stated that such localized contamination would have been detected during their routine surveys performed throughout the day and decontaminated as required in their permit. No additional contamination or unusual radiation levels were identified.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

No violations of NRC requirements were identified.

5. PERSONNEL CONTACTED:

* Stephen Armagon, Acting Medical Center Director
*# Oscar James, Radiation Safety Officer
*# Paul Yurko, Program Manager, National Health Physics Program

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

-END-