May 6, 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 030-34325/11-30(DNMS) ─ VA NEBRASKA WESTERN IOWA HEALTH CARE SYSTEM, OMAHA, NEBRASKA

Dear Mr. Williams:

On March 1 through April 8, 2011, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your VA Nebraska Western Iowa Health Care System, (VANWIHCS), located in Omaha, Nebraska. The inspection results were discussed with Ms. Nancy Gregory, Acting Director and selected members of her staff at the telephonic exit meeting on April 8, 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.

However, the NRC inspector identified two concerns during the inspection which will require a response. In your response, you will need to address each concern described below by describing what action(s) the National Health Physics Program (NHPP) will take to evaluate the concerns and how it will assure the NRC that the issues will be addressed and corrected by the VANWIHCS.

Concern 1: The inspector observed a nuclear medicine stress test study that was being performed in the Cardiology Department and noted that a technician and a physician in the treatment room who were participating in the procedure were not wearing personal dosimetry. After the study was completed the inspector asked the radiation safety officer (RSO) if the individuals were trained radiation workers. The RSO confirmed that the individuals were trained radiation workers, and that they were required by a procedure tied down in the permit to wear their assigned personal dosimeters while working with patients being treated with radioactive materials. Subsequent to the inspection, a representative of the NHPP and NRC staff members performed independent calculations of the expected radiation dose to each individual and noted that they were well below Title 10 of the Code of Federal Regulations (CFR) 20.1502 (a)(1) requirements for monitoring the occupational dose to individuals. Nevertheless, the NRC is concerned that the permittee was not complying with a procedure that was tied down in the permit which required these individuals to wear dosimetry.

Concern 2: The inspector toured several research laboratories, observed work practices in the laboratories, and interviewed available laboratory staff. Based on the inspector's observations, the NRC has an overall concern about the apparent lack of control of radioactive material being used and stored in laboratories and noted inconsistencies in radioactive material inventory control practices between laboratories and researchers. For example, some researchers updated their inventory after each use of permitted material, while others updated their inventories on a less frequent basis. In addition, some researchers were unaware that radioactive material had been added to their storage area from laboratories that were no longer active. The inspector discussed the concerns with the RSO who initiated an investigation in order to verify that all permitted material could be accounted for and that nothing was misplaced or lost. On March 24, 2011, the RSO confirmed that he had accounted for all permitted radioactive material that had been assigned to the research laboratories.

Concern 3: Based on the inspector's observations, the NRC is also concerned about the permittee's apparent failure to implement procedures which require that periodic area wipe tests for removable contamination be conducted in research laboratories. During an interview with a researcher, the inspector determined that the researcher was unaware of the requirement to perform wipe tests for removable contamination in his laboratory. The RSO performed wipe tests for removable contamination and on March 21, 2011, confirmed that the results were negative for removable contamination.

Please submit your response to the concerns described above within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response 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. 26-00138-10

Enclosure:
Inspection Record

Concern 2: The inspector toured several research laboratories, observed work practices in the laboratories, and interviewed available laboratory staff. Based on the inspector's observations, the NRC has an overall concern about the apparent lack of control of radioactive material being used and stored in laboratories and noted inconsistencies in radioactive material inventory control practices between laboratories and researchers. For example, some researchers updated their inventory after each use of permitted material, while others updated their inventories on a less frequent basis. In addition, some researchers were unaware that radioactive material had been added to their storage area from laboratories that were no longer active. The inspector discussed the concerns with the RSO who initiated an investigation in order to verify that all permitted material could be accounted for and that nothing was misplaced or lost. On March 24, 2011, the RSO confirmed that he had accounted for all permitted radioactive material that had been assigned to the research laboratories.

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Enclosure:
Inspection Record

See Distribution List

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Letter to Gary Williams from Patricia J. Pelke dated May 5, 2011

SUBJECT: NRC INSPECTION REPORT 030-34325/11-30(DNMS) – VA NEBRASKA WESTERN IOWA HEALTH CARE SYSTEM, OMAHA, NEBRASKA

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INSPECTION RECORD

Region III Inspection Report No. 030-34325/11-30(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 Nebraska Western Iowa Health Care System – Omaha Division
4101 Woolworth Avenue
Omaha, NE 68105

Permit No. 26-00138-10

Permittee Contact: Michael Christensen, RSO Telephone No. (402) 995-3440
Priority: 2 Program Code: 2110/3610/3510

Date of Last Inspection: August 19 - 20, 2008 Date of This Inspection: March 1 - April 8, 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
( ) Follow-up on previous violations

Inspector: ***/RA/*** by Kevin G. Null for Date: May 5, 2011
Jason M. Razo, Health Physicist, Region IV

Approved: ***/RA/*** Date: May 6, 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:

NA - The VA Nebraska Western Iowa Health Care System is a permittee of the Department of Veterans Affairs (DVA) Master Materials License (MML).

2. INSPECTION AND ENFORCEMENT HISTORY:

During the previous National Health Physics Program (NHPP) inspection on February 18, 2009, no violations were identified.

The last NRC inspection was conducted August 19 - 20, 2008. No violations of NRC requirements were identified at the Omaha location.

3. INCIDENT/EVENT HISTORY:

No events for this permittee were reported since the last NRC inspection on August 19 - 20, 2008. No open Nuclear Materials Event Database (NMED) items are pending for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Nancy Gregory, Acting Director
Donald Orton, M.D., Medical Director
Tom LaFontaine, Administrative Officer to Chief of Staff
William Boyd, Director of Radiology
Michael Christensen, Radiation Safety Officer (RSO)

The VA Nebraska Western Iowa Health Care System – Omaha Division (permittee) was authorized by the VA Master Material License No. 03-23853-01VA (licensee) to possess a broad scope medical permit (Permit No. 26-00138-10). The permittee is authorized to use material for medical diagnosis, therapy and research in humans, and for research and development as defined in 10 CFR 30.4. Mr. Gary Williams, Director of the NHPP, accompanied the NRC inspector during this inspection.

Nuclear medicine activities were primarily performed in the reconfigured nuclear medicine suite. The reconfiguration included space for a new Positron Emission Tomography (PET) handling and treatment area; however, PET flourine-18 radioisotopes had not yet been used at the time of the inspection. Three nuclear medicine technologists (NMTs) shared daily responsibilities. The permittee only used unit doses received from the local Cardinal Health radiopharmacy. A typical weekly workload includes 10-15 heart scans and 15-20 total scans of all other types including, but not limited to, thyroid, renal, and lung scans.

Medical and non-medical research is conducted in a dedicated section of the hospital complex where material that is commonly used included iodine-125, hydrogen-3, carbon-14, and sulphur-35. The permittee possesses a nominal

600 millicurie cesium-137 sealed source that is used by the RSO to perform instrument calibrations. The RSO also supervises the long-lived radioactive waste storage program.

2. SCOPE OF INSPECTION:

Inspection Procedures Used: 87126, 87131 and 87134

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

Nuclear Medicine Program

The inspector toured the remodeled nuclear imaging suite. Radioactive materials were stored in a dedicated hot lab. The door to the hot lab automatically locked whenever the door closed. The NMTs identification badges were programmed to authorize access to the hot lab. Closed circuit cameras were installed so that physicians or NMTs in the reading room could monitor patients in the waiting area. The main doors to the nuclear medicine suite were programmed to unlock at 0630 with routine delivery from the radiopharmacy at 0645. The NMTs are available at that time to accept delivery of the packages.

The NMTs rotated daily start times and shared QA/QC responsibilities. An NMT demonstrated package receipt procedures and daily constancy tests for the Capintec CRC-15R dose calibrator. Nuclear medicine staff stated that Cardinal Health performs quarterly audits of the nuclear medicine department and equipment. The Cardinal Health auditor reviewed records and ensured that the dose calibrator received its linearity and accuracy tests when required. The inspector reviewed Cardinal Health's reports and discussed them with the nuclear medicine staff and RSO.

The inspector reviewed waste disposal records with the chief NMT. They developed a system to track "open," "closed," or "standby" waste. Radioactive waste that is held for decay is stored in the hot lab. The inspector also reviewed records of disposal of radioactive waste that is held for decay, as well as results of surveys that were conducted to demonstrate that the waste was at background radiation levels before disposal. The surveys were conducted using a calibrated radiation survey instrument prior to disposal with normal trash.

The inspector reviewed all written directives issued for iodine-131 treatments involving dosages greater than 30 microcuries and up to a maximum of 176 millicuries in 2011, and 50 percent of the same written directives issued in 2009 and 2010. Iodine-131 is administered in capsule form only. Five treatments using iodine-131 requiring a written directive were performed in 2009, 18 treatments using iodine-131 requiring a written directive were performed in 2010, and as of the date of the inspection, three treatments using iodine-131 requiring a written directive were performed in 2011. The nuclear medicine department used a patient release chart developed by Cardinal Health that was based on the NUREG-1556 Vol. 9 Appendix U criteria. The authorized user interviewed each patient that was administered an iodine-131 dosage that required a written directive and based on their living arrangements, provided patients with specific oral and written instructions to minimize exposure to members of the public. The written directives contained all of the information required by 10 CFR 35.40.

The inspector reviewed occupational radiation doses for the nuclear medicine staff. In 2009, the maximum deep dose equivalent (DDE) was 187 mrem and the maximum shallow dose equivalent (SDE) was 134 mrem. In 2010, the maximum DDE was 122 mrem and the SDE was 134 mrem.

The inspector observed an NMT prepare a unit dosage for a diagnostic patient scan that did not require a written directive. Using the dose calibrator, the NMT verified that the dose matched the prescription from the authorized user. The NMT wore all required personal protective equipment, e.g., lab coat, gloves, whole body and extremity dosimetry, etc. The inspector observed the NMT use a syringe shield and a shielded hand-held carrier to minimize exposure during transport of the dose from the hot lab to the treadmill room in the cardiology suite.

The inspector interviewed permittee staff regarding initial and refresher training for radiation workers and NMTs. An NMT verified that declared pregnant woman training topics were covered in the training. The staff was familiar with the "Scatterings" newsletter issued by NHPP, and indicated that they were comfortable in raising safety concerns to their supervisors, management, the RSO, NRC or NHPP.

Research Activities

The inspector visited multiple research laboratories and discussed radiation safety practices with various researchers and authorized users. All packages containing radioactive material for research use were received by the RSO's office. The RSO then distributed the packages to the requesting laboratory. At the time of the inspection, active research studies were being conducted using microcurie and low millicurie quantities of iodine-125, hydrogen-3, carbon-14, and sulphur-35. The inspector noted that radioactive material containers were labeled appropriately, and that refrigerators used to store radioactive material and laboratories where radioactive materials were used or stored, were also properly labeled with "Caution, Radioactive Material" signs. When laboratories were not in use, the inspector noted that the doors were locked and only accessible with a programmed personal identification card.

Liquid radioactive waste generated by the researchers was either disposed of down the sanitary sewer system if it met all the requirements of 10 CFR 20.2003, or stored in the laboratories until the RSO transferred it to the long-term storage location. The RSO provided initial radiation safety training to all new researchers. The primary investigator was responsible for providing laboratory specific radiation safety training and expectations. The inspector toured the long-term waste storage area located in the basement and observed the cesium-137 sealed calibration source in storage. The inspector reviewed selected RSO annual audits and quarterly minutes from the radiation safety committee and noted that the RSO was proactive in correcting any issues identified during the audits and meetings.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The NRC inspector conducted independent radiation surveys in the nuclear medicine department, in selected research laboratories, and in the long-term waste storage area. No unusual radiation levels were detected. The inspector also noted that where necessary, adequate shielding was in place to minimize exposures.

The inspector verified the radiation dose rates using a Thermo Electron Model RAD EYE G gamma radiation survey instrument, NRC serial number 086965, with a calibration due date of June 2, 2011.

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

No violations were identified by the NRC during the inspection. However, the NRC inspector identified the following concerns: (1) two individuals who participated in a cardiac stress study that the inspector observed were not wearing dosimetry in accordance with the permittees procedures which are tied into the permit; (2) in the research area, the inspector noted an apparent lack of control in the use and storage of permitted material as well as inconsistencies in radioactive material inventory control practices between laboratories and researchers; and (3) the inspector expressed concern over the apparent failure on the part of some research staff to implement procedures tied to the permit that require periodic laboratory surveys for removable contamination.

4. PERSONNEL CONTACTED:

#* Nancy Gregory, Acting Director
#* Tom LaFontaine, Administrative Officer to Chief of Staff
#* Michael Christensen, Radiation Safety Officer
Donald Orton, M.D., Medical Director
William Boyd, Director of Radiology
*K. Atkins, Chief Nuclear Medicine Technologist
#* Gary Williams, Director, VA National Health Physics Program

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

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