September 20, 2012

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 NO. 03034325/2012001(DNMS) AND NOTICE OF VIOLATION – VA MEDICAL CENTER, ST. LOUIS, MISSOURI

Dear Mr. Williams:

On October 27, 2011, through August 8, 2012, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the VA Medical Center, St. Louis, Missouri with continued in-office review through August 28, 2012. The purpose of the in-office review was to obtain and review information that was unavailable during the onsite inspection including leak test and physical inventory records at the Cheyenne, Wyoming facility. The inspection was limited to a review of activities authorized under Permit Number 24-00144-05, and included an inspection at each of the following eight facilities authorized on the Permit: St. Louis, Missouri (John Cochran and Jefferson Barracks Divisions); Marion, Illinois; Wichita, Kansas; Cheyenne, Wyoming; Fort Harrison, Montana; Kansas City, Missouri; and Poplar Bluff, Missouri. The inspector conducted an exit briefing with permittee staff at the conclusion of the onsite inspections and Tom Huston, Ph.D., of your office on August 28, 2012.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violations concerned the failure to provide training as required by Title 10 of the Code of Federal Regulations (CFR) Section 19.12(a), and the failure to leak test sealed sources as required by Title 10 CFR
Section 35.67(b)(2). The NRC is citing the violations in the Notice because an NRC inspector identified the violations.

The root cause of the first violation was the Poplar Bluff staff's failure to recognize that a new employee (cardiac nurse) had been assigned to assist with cardiac stress tests. The permittee took immediate corrective action and provided training for the individual on April 16, 2012. In addition, the permittee plans to develop a system to aid them in identifying new employees who

may require training. The root cause of the second violation was the Cheyenne staff member's lack of experience and historical knowledge of the permittee's radiation safety program. The staff member was new to the program and had minimal communication with the permittee's Radiation Safety Officer after being hired by the permittee. The permittee took immediate corrective action on August 8, 2012, and performed a leak test of the sources, and will address long term corrective actions by revising and updating its training program to include specific information on leak testing requirements. As a result of the above, you are now in compliance with NRC requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures 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 or the enclosed report, please contact Kevin Null of my staff at 630-829-9854.

Sincerely,

/RA by Tamara E. Bloomer Acting for/

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

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 24-00144-05

Enclosures:
1. Notice of Violation
2. Inspection Record

may require training. The root cause of the second violation was the Cheyenne staff member's lack of experience and historical knowledge of the permittee's radiation safety program. The staff member was new to the program and had minimal communication with the permittee's Radiation Safety Officer after being hired by the permittee. The permittee took immediate corrective action on August 8, 2012, and performed a leak test of the sources, and will address long term corrective actions by revising and updating its training program to include specific information on leak testing requirements. As a result of the above, you are now in compliance with NRC requirements.

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DISTRIBUTION:
Cynthia Pederson
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OFFICE	RIII DNMS		RIII DNMS		RIII DNMS			
NAME	KGNull: jm*KGN		RHays		PJPelke*TEB for			
DATE	9/19/12		9/17/12		9/20/12			

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Department of Veterans Affairs
Washington, D.C.

License No. 03-23853-01VA
Docket No. 030-34325

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 27, 2011, through August 8, 2012, with continued in-office review through August 28, 2012, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the Code of Federal Regulations (CFR) 19.12(a) requires, in part, that all individuals who in the course of their employment are likely to receive in a year an occupational dose in excess of 100 mrem (1mSv) shall be kept informed of the storage, transfer, and use of radiation or radioactive material; instructed in the health protection problems associated with exposure to radiation and/or radioactive material; instructed in precautions and procedures to minimize exposure to radioactive materials, and in the purpose and functions of protective devices employed; instructed of their responsibility to promptly report to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material; and instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material.

   Contrary to the above, between February 2012, and April 12, 2012, the licensee failed to inform a staff member who was assigned to work in the cardiac stress laboratory at the John J. Pershing VA Medical Center in Poplar Bluff, Missouri, of the regulations and the conditions of the license. The staff member was likely to receive in a year an occupational dose in excess of 100 mrem and had not been informed of the storage, transfer, and use of radiation or radioactive material, instructed in the health protection problems associated with exposure to radiation and/or radioactive material; instructed in precautions and procedures to minimize exposure to radioactive materials; and in the purpose and functions of protective devices employed; instructed of their responsibility to promptly report to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material; and instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material.

   This is a Severity Level IV violation (Section 6.3).

B. Title 10 CFR 35.67(b)(2) requires that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.

   Contrary to the above, as of August 6, 2012, permittee staff at the VA Medical Center located in Cheyenne, Wyoming, had failed to test three sealed sources for leakage at the required 6 month interval. Specifically, the permittee tested a 5 millicurie cobalt-57 source, a 274 microcurie barium-133 source, and a 208 microcurie cesium-137 source for leakage on January 4, 2012, and had not tested these three sources for leakage until August 8, 2012.

   This is a Severity Level IV violation. (Section 6.3)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 03034325/2012001(DNMS)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 20th day of September 2012.

INSPECTION RECORD

Region III Inspection Report No. 03034325/2012001(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
915 North Grand Boulevard
St. Louis, Missouri 63106

Permit No. 24-00144-05

Licensee Contact: Gary Williams Telephone No. 501-257-1572
Priority: 2 Program Code: 02110

Date of Last Inspection: May 3 – 4, 2006 Date of This Inspection: October 27, 2011 through August 28, 2012

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

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

Summary of Findings and Actions:

( ) 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
(X) Violation(s), regional letter issued
( ) Followup on previous violations

Inspector(s):

/RA/ ***9/4/2012***
Kevin G. Null, Senior Health Physicist Date

/RA/ ***9/17/2012***
Robert Hays, Health Physicist Date

Approved: ***/RA Tamara E. Bloomer for/*** ***9/20/2012***
Patricia J. Pelke, Chief, Materials Licensing Branch Date

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA - The VA Medical Center in St. Louis, Missouri, 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 March 16 – 18, 2011, with continued review through May 20, 2011, no violations were identified.

The last U.S. Nuclear Regulatory Commission (NRC) routine inspection was conducted on May 3 – 4, 2006. No violations of NRC requirements were identified.

3. INCIDENT/EVENT HISTORY:

No licensee events for this permittee have been reported since the last NRC inspection. No open Nuclear Materials Event Database (NMED) items are pending for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Rima Nelson, Medical Center Director
Lynn Welling, MD, Chief of Staff
Barbara Temeck, MD, Deputy Chief of Staff
Barbara Sterkel, MD, Chair, Radiation Safety Committee
Patty Hendrickson, Director, Quality Management
Larry Chandler, Radiation Safety Officer
Sheila Rosenfeld, Nuclear Medicine Network Director

The VA Medical Center in St. Louis, Missouri, is a Department of Veterans Affairs (DVA) facility that is authorized under a Veterans Health Administration permit for medical use, and research and development, using byproduct material. The DVA is authorized to issue permits to VA facilities under the Nuclear Regulatory Commission's (NRC) Master Materials License No. 03-23853-01VA. The permittee, VA Medical Center in St. Louis, is a medical broad scope permittee with eight locations of use that included the following: (1) VA Medical Center, John Cochran Division, St. Louis, Missouri; (2) VA Medical Center, Jefferson Barracks Division, St. Louis, Missouri; (3) VA Medical Center, Marion, IL; (4) VA Medical Center, Cheyenne, Wyoming; (5) VA Medical Center, Kansas City, Missouri; (6) Robert J. Dole VA Medical Center, Wichita, Kansas; (7) Montana VA Health Care System, Fort Harrison, Montana; and (8) John J. Pershing VA Medical Center, Poplar Bluff, Missouri. Each of these locations primarily used byproduct material described in Title 10 of the Code of Federal Regulations (CFR) Part 35 for diagnostic studies. Iodine-131 was used infrequently for whole body scans and thyroid therapy, and research and development studies were conducted infrequently as well. The Radiation Safety Officer (RSO) is located at the John Cochran Division of the VA Medical Center in St. Louis, and conducted audits of each satellite location two times per

year. Each satellite location has a designated nuclear medicine technologist or health physicist who reports to the RSO. The RSO reports to the St. Louis VA Medical Center's Radiation Safety Committee (RSC). The RSC meets at least quarterly each calendar year.

2. SCOPE OF INSPECTION:

The inspectors toured the Nuclear Medicine departments at each facility, and toured research laboratories and radioactive waste storage areas, as applicable. The inspectors observed that Nuclear Medicine facilities were as described in the permits, the hot labs were secured, and "Caution, Radioactive Materials" signs were posted as required. The inspectors conducted independent surveys which verified that radiation levels were within regulatory limits. Permittee staff demonstrated proper survey instrument use, proper area surveys and wipes for contamination, and proper package receipt/return procedures. The inspectors reviewed selected records including RSC meeting minutes, RSO audits, incident reports, personnel dosimetry reports, instrument calibrations, sealed source leak tests and inventories, dose calibrator quality control, written directives, survey records for inpatient iodine-131 treatments, and justifications for patient release.

Inspection Procedure(s) Used: 87126, 87130, 87131, and 87134

Focus Areas Evaluated: Sections 03.01 through 03.07

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspectors conducted independent radiation surveys with two Canberra Model MRAD 213 survey meters, Serial Nos.13000571 and 13000495, calibrated on October 18, 2011, and October 19, 2011, respectively, and a Ludlum Model 2403 (Serial No. 163852) coupled to a Ludlum Model 44-9 probe (Serial No. PR138549) calibrated on May 14, 2012. Surveys in and around the nuclear medicine departments and hot labs were consistent with the permittee's survey results. Surveys in unrestricted areas were at background levels, ranging from 0.02-0.05 mR/hour. Survey results in restricted areas were at levels that ranged from background to 0.10 mR/hr.

In addition, the inspectors conducted independent radiation surveys in and around radioactive materials decay-in-storage areas. The NRC inspectors did not identify any unusual or unexpected radiation levels in or around these areas. Survey results were at background level (0.02-0.05 mR/hour).

The inspectors also conducted independent radiation surveys of a representative sample of active 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.

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

Two Severity Level (SL) IV violations of NRC requirements were identified.

While conducting a tour of the cardiac stress laboratory at the Poplar Bluff location on

April 12, 2012, an NRC inspector interviewed nursing staff who were present for a stress test which involved the injection of permitted material. During the course of the interviews the inspector identified a nurse who had recently been assigned to work in the stress lab beginning in February 2012, and had not received training as required in 10 CFR Part 19, Section 19.12.

This is a violation of 10 CFR 19.12(a), which requires that individuals who are likely to receive a dose in excess of 100 mrem in a year be instructed in, among other things, topics related to radiation safety. A review of dosimetry records of nursing staff who assisted with cardiac stress tests in calendar year 2011 confirmed that the new nurse was likely to receive greater than 100 mrem in a year.

The inspector also noted from a review of the dosimetry records, that nurses who worked in the cardiac stress laboratory consistently received less than 10 percent of the occupational dose limits for adults on a yearly basis. Therefore, the inspector concluded that radiation dosimetry for the new staff member would not have been required.

As an immediate corrective action, the permittee provided the required training to the individual on April 16, 2012.

As a long term corrective action, the permittee will develop a system to aid them in identifying new employees who may become involved in conducting and/or assisting in cardiac stress tests, and determine if they are required to be trained in accordance with 10 CFR 19.12(a).

On August 6, 2012, an NRC inspector conducted an inspection at the VA Medical Center in Cheyenne, Wyoming. The nuclear medicine technologist (NMT), who had recently been hired to replace the previous NMT, had difficulty locating specific documents and records pertaining to the radiation safety program. When questioned about the last leak test that was conducted on three sealed sources that were used in the nuclear medicine department, the NMT indicated that she was not sure when they were tested, nor could she locate leak test records of the sources during the on-site portion of the inspection.

On August 7, 2012, the NMT found the leak test records and determined that the last leak test was conducted on January 4, 2012. The NMT also confirmed that she had not leak tested the sources since the last test. The permittee took immediate corrective action and performed a leak test on August 8, 2012. Results confirmed that the sources were not leaking.

Based on a review of the sealed source and device registry, the inspector confirmed that each of the sealed sources was required to be tested for leakage every six months. Failure to perform a leak test within 6 months of the last leak test that was conducted on January 4, 2012, is a violation of 10 CFR 35, Section 35.67(b)(2).

As a long term corrective action, the RSO plans to revise PowerPoint training slides that are used for training staff at each satellite location under the permit. The slides will be updated to include more detailed information on the requirements for leak testing sealed sources.

4. PERSONNEL CONTACTED:

#Rima Nelson, Medical Center Director
*Lynn Welling, MD, Chief of Staff
#*Barbara Temeck, MD, Deputy Chief of Staff
#*Barbara Sterkel, MD, Chair Radiation Safety Committee
#Patty Hendrickson, Director, Quality Management
*Larry Chandler, Radiation Safety Officer
*Sheila Rosenfeld, Nuclear Medicine Network Director
#Marc Magill, Acting Associate Director
#Keith Repko, Chief, Engineering Service
#Jamie Cooper, Executive Office, Health System Specialist
*David Nelson, Radiology Supervisor, VA Medical Center, Cheyenne, Wyoming
*Thomas Huston, NHPP Program Manager
#Paul Yurko, NHPP Program Manager

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