UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 30, 2016

Mr. Craig L. Adams, MPH, 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 03034325/2016005(DNMS) AND NOTICE OF VIOLATION – VA EASTERN COLORADO HEALTH CARE SYSTEM, DENVER, COLORADO

Dear Mr. Adams:

On May 19, 2016, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the VA Eastern Colorado Health Care System, Denver, Colorado, with continued in-office review through June 9, 2016. The inspection was limited to a review of activities authorized under Permit Number 05-01401-02. The purpose of the in-office review was to conduct further evaluation of the details surrounding one apparent violation. The inspector conducted a final exit meeting with Ron Moubry, M.D., Deputy Director of Imaging, and Peter Vernig, Radiation Safety Officer (RSO) of the facility on June 10, 2016.

The inspection was an examination of activities conducted under the permit as they relate to radiation safety and to compliance with the Commission's rules and regulations. 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.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation involved a failure to maintain a record of an evaluation that was conducted by the RSO in determining that extremity monitoring was not required for nuclear medicine technologists. Extremity monitoring was discontinued on July 2, 2015. The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation because an NRC inspector identified the violation.

The root cause of the violation was the RSO's lack of knowledge of the record-keeping requirements in Title 10 of the *Code of Federal Regulations* (CFR) Part 20, and failure on the part of the RSO to consult with the permittee's management and Radiation Safety Committee (RSC). During the final exit meeting, a representative of permittee management and the RSO stated that corrective action had been taken to create a record of the evaluation that was

conducted by the RSO to include the basis for the decision that extremity monitoring was not required for nuclear medicine technologists.

Permittee management made a commitment that the issue would be discussed at the next RSC meeting, and that the record of evaluation would be amended accordingly to reflect the committee's input and decision. The inspector communicated to senior management during the preliminary exit meeting that neglecting to consult with the RSC about the RSO's evaluation and decision to stop extremity monitoring for nuclear medicine technologists may be a violation against the permit issued to the permittee by the NHPP, and that this concern would be forwarded to the NHPP for its review during a future NHPP inspection.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with Title 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures, and your response, if you choose to provide one, will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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. 05-01401-02

Enclosures:
1. Notice of Violation
2. IR 03034325/2016005(DNMS)

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Docket No. 030-34325
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DISTRIBUTION w/encl:
See next page

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OFFICE	RIII-DNMS		RIII-DNMS		RIII		RIII	
NAME	KNull:ps		PJPelke					
DATE	6/29/2016		6/30/2016					

OFFICIAL RECORD COPY

Letter to Craig Adams from Patricia Pelke dated June 30, 2016.

SUBJECT: NRC INSPECTION REPORT 03034325/2016005(DNMS) AND NOTICE OF VIOLATION – VA EASTERN COLORADO HEALTH CARE SYSTEM, DENVER, COLORADO

DISTRIBUTION w/encl:
Darrell Roberts
John Giessner
Christine Lipa
Richard Skokowski
Carole Ariano
Paul Pelke
Carmen Olteanu

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 May 19, 2016, through June 9, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1501(a) requires, in part, that each licensee make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels. *Survey*, means an evaluation of the radiological conditions and potential hazards incident to the presence of radioactive material.

Title 10 CFR Part 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and requires the use of individual monitoring devices by adults likely to receive, in one year, from radiation sources external to the body, a shallow dose in excess of 10 percent of 50 rem to the skin of any extremity.

Title 10 CFR Part 20.2103 requires, in part, that each licensee maintain records showing the results of surveys required by Section 20.1501.

Contrary to the above, the VA Eastern Colorado Health Care System, a permittee of the Department of Veterans Affairs Master Materials License, failed to maintain a record of an evaluation that was conducted by the RSO to determine that nuclear medicine technologists shallow dose to the skin of any extremity were not in excess of 10 percent of 50 rem and therefore, extremity monitoring was not required. As of July 2, 2015, extremity monitors were not required for nuclear medicine technologists.

This is a Severity Level IV violation (Section 6.7).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation 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 030-34325/2016005(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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website 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.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 30th day of June, 2016.

ENCLOSURE 6 – INSPECTION RECORD

Region III Inspection Report No. 2016005 **License No.** 03-23853-01VA
Docket No. 030-34325

Licensee National Health Physics Program (115HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
North Little Rock, AR 72114

Location: VA Eastern Colorado Health Care System
1055 Clermont Street
Denver, CO
Permit No. 05-01401-02

Licensee Contact: Craig Adams, Director **Telephone No**. 501-257-1573

Priority: 2 **Program Codes**: 02110, 3610

Date of Last Inspection: June 17, 2014 by the NHPP

Date of This Inspection: May 19, 2016 through June 9, 2016

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
( ) Follow-up on previous violation by NHPP

Inspector: ***/RA/*** Date 6/29/2016
Kevin G. Null, Health Physicist

Approved: ***/RA/*** Date 6/30/2016
Patricia J. Pelke, Chief, MLB

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA - The VA Eastern Colorado Health Care System in Denver, Colorado 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 conducted on June 17, 2014, two severity level IV violations were identified. One violation involved Title 10 of the *Code of Federal Regulations* (CFR) Part 20.1904(a) for failing to have a clearly visible label on a vial containing radioactive material that was used to check a dose calibrator. The second violation involved 10 CFR 20.1801 for failure to secure three research rooms that were posted as containing radioactive materials.

3. INCIDENT/EVENT HISTORY:

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

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Sallie Houser-Hanfelder, Director
Ellen Mangione, M.D., Chief of Staff
Ron Moubry, M.D., Deputy Chief of Imaging
Peter Vernig, Radiation Safety Officer (RSO)
Amy Ipson, Chief Nuclear Medicine Technologist

The permittee is a DVA facility that is authorized under a Veterans Health Administration permit to use byproduct material for medical use and research studies. The DVA is authorized to issue permits to VA facilities under the NRC MML No. 03-23853-01VA.

2. SCOPE OF INSPECTION:

The VA Eastern Colorado Health Care System is a medical broad scope permittee authorized for any byproduct material with atomic numbers 1-83 in unsealed form, sealed sources with atomic numbers 3-83, molybdenum-99, technetium-99m, iodine-131, and radium-223 for medical diagnosis, therapy, and research in humans. The permittee is also authorized to conduct research and development as defined in 10 CFR 30.4, including animal studies, instrument calibration, student instruction, and in vitro studies. In addition, the permittee is authorized to conduct shielding evaluations using unsealed technetium-99m at various locations of use in listed on the permit.

This was a routine, unannounced inspection. The nuclear medicine department performed 6-8 diagnostic studies daily using primarily technetium-99m. There were two full-time certified staff nuclear medicine technologists (NMT), and one full-time Chief NMT. The nuclear medicine department included two diagnostic imaging rooms and one hot lab. Unit doses were used for imaging procedures and are received from Cardinal Health. Technetium-99m generators and PET radionuclides were not being used. The permittee performed about 20 iodine-131 therapy procedures per year using capsules.

Through the Radiation Safety Committee (RSC), the permittee had approved four authorized users for the use of iodine-131. No other radiopharmaceutical therapy procedures have been performed, including the use of radium-223. Written directives for calendar years 2015 and 2016, patient release criteria, and patient instructions were reviewed by the inspector with no concerns identified.

The permittee was authorized to conduct research studies, although the program was not very active. At the time of the inspection there was one study that had been recently approved by the RSC in April 2016 involving the use of microcurie quantities of labeled iodine-125, with a total possession limit of eight milicuries. There were no authorized users or radiation workers in the research program who were available during the inspection. The inspector followed up on a violation which the National Health Physics Program (NHPP) identified in 2014, which pertained to the security of three research laboratories. It appeared that the permittee adequately addressed the violation. The inspector did not identify any security issues in the research program.

The inspector toured the nuclear medicine department and active research laboratory, observed NMT's perform equipment quality control, utilize radiation survey equipment, perform a package receipt survey, and observed and validated methods used to secure and control permitted material. The inspector reviewed audits, RSC meeting minutes, equipment calibration records, dosimetry reports, and waste records. The inspector interviewed the nuclear medicine staff and found them to be knowledgeable of regulatory requirements and radiation safety practices. The inspector followed-up on a violation that the NHPP issued in 2014 for an inadequate label of a vial containing a calibration source that was used in nuclear medicine. The inspector did not identify any similar issues, and concluded that the violation had been corrected.

During permittee staff interviews and tours of the nuclear medicine department, the inspector identified that the NMT's were not wearing extremity dosimetry. Additional follow-up revealed that the RSO had reviewed the exposure history of the NMTs and concluded that their extremity doses were well below the threshold for requiring the monitoring devices described in 10 CFR 20.1502(a)(1). The evaluation was conducted by the RSO in 2015, and the use of extremity monitoring devices by the NMT's was terminated as of July 2, 2015. However, the inspector noted that the RSO did not document his evaluation and basis for the decision as required in 10 CFR 20.2103, nor did he consult with the RSC or permittee management for their input.

The failure to make a record of the evaluation is a violation of 10 CFR 20.2103. Neglecting to consult with the RSC on the RSO's evaluation and decision to eliminate the use of the dosimeters may be a violation against the permit issued to the permittee by the NHPP, which will be forwarded to the NHPP for their review.

The inspector reviewed the last five years of exposure history for the NMT's and agreed that they were not likely to exceed ten percent of the regulatory limit for occupational workers as described on 10 CFR 20.1502(a)(1). The highest reading that the inspector noted was 1182 millirem in calendar year 2012. The annual limit to the skin of the extremities is 50 rem, or 50,000 millirem. Ten percent of the annual limit is 5000 millirem.

Inspection Procedure(s) Used: 87126 and 87134

Focus Areas Evaluated: All

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

A Severity Level (SL) IV violation of NRC requirements was identified:

10 CFR Part 20.1501(a) requires, in part, that each licensee make or cause to be made, surveys of areas that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels. *Survey*, means an evaluation of the radiological conditions and potential hazards incident to the presence of radioactive material.

10 CFR Part 20.1502(a)(1) requires, in part, that each licensee monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and requires the use of individual monitoring devices by adults likely to receive, in one year, from radiation sources external to the body, a shallow dose in excess of 10 percent of 50 rem to the skin of any extremity.

10 CFR Part 20.2103 requires, in part, that each licensee maintain records showing the results of surveys required by Section 20.1501.

Contrary to the above, the VA Eastern Colorado Health Care System, a permittee of the Department of Veterans Affairs Master Materials License, failed to maintain a record of an evaluation that was conducted by the RSO to determine that nuclear medicine technologists exposures to the skin of any extremity were not in excess of 10 percent of 50 rem and therefore, extremity monitoring was not required. As of July 2, 2015, extremity monitors were not required for nuclear medicine technologists.

This is a Severity Level IV violation (Section 6.7)

Corrective actions included documentation of the evaluation that was conducted by the RSO. In addition, the RSO was instructed by senior management to present his proposal and assessment at the next RSC meeting and a collective decision will be made to determine whether or not extremity monitoring is required.

4. PERSONNEL CONTACTED:

#^ Sallie Houser Hanfelder, Director
#^ Ellen Mangione, M.D., Chief of Staff
#^* Peter Vernig, Radiation Safety Officer
^* Ron Moubry, M.D., Deputy Chief, Imaging

^ Mary S. Newell, HSS, Director
^ Dominic Gacettan, Program Analyst
^ Josh Pridgen, Acting Assistant Director
^ Steven Catbagan, Radiology
^ Keith Harmon, Chief, Organizational Improvement
^ Joseph Marin, Administrative Fellow
^ J.T. Tomas, Radiology
^ Susan Kelly, VA Congressional Relations
^ Craig Adams, Director, National Health Physics Program

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting conducted via telephone on June 10, 2016
^ Individual(s) present at the on-site preliminary exit briefing on May 19, 2016