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

February 25, 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 03034325/2015003(DNMS) AND NOTICE OF VIOLATION – ROBLEY REX VA MEDICAL CENTER, LOUISVILLE, KENTUCKY

Dear Mr. Adams:

On November 18, 2015, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the Robley Rex VA Medical Center, Louisville, Kentucky with continued in-office review through February 4, 2016. The inspection was limited to a review of activities authorized under Permit Number 16-03121-02. The purpose of the in-office review was to conduct further evaluation of the details surrounding two apparent violations. The inspector conducted an exit meeting on February 9, 2016, with the management and staff at the facility.

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 the possession of a sealed cesium-137 source by the permittee that was not authorized on the permit issued to the medical center under the Master Materials License (MML). 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 inadvertent removal of the authorization for the source from the permit by the National Health Physics Program in 2009, when the permit was amended from a broad scope to a limited scope medical permit. The permittee continued to possess the source until 2012. During the exit meeting, permittee staff stated that authorizations and conditions on the permit have been reviewed with staff members, and that any future changes to the permit would be closely reviewed with training provided, as needed. Also, your staff worked with permittee staff and verified that the permittee did not possess additional radioactive material which was not authorized on the permit. In addition, your staff developed an internal

procedure to be implemented by your program managers to confirm the inventory with a permittee before amending future permits from a broad scope to a limited scope permit.

During the exit meeting, the NRC discussed the decommissioning of areas previously used for research and waste storage with permittee staff members. The permittee indicated that they would communicate with your staff about its decommissioning activities, and that your staff would follow-up with Mr. Kevin Null on the status of those activities and compliance with related NRC regulatory requirements.

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 of the *Code of Federal Regulations* (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. 16-03121-02

Enclosure:
1. Notice of Violation
2. IR 03034325/2015003(DNMS)

procedure to be implemented by your program managers to confirm the inventory with a permittee before amending future permits from a broad scope to a limited scope permit.

During the exit meeting, the NRC discussed the decommissioning of areas previously used for research and waste storage with permittee staff members. The permittee indicated that they would communicate with your staff about its decommissioning activities, and that your staff would follow-up with Mr. Kevin Null on the status of those activities and compliance with related NRC regulatory requirements.

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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. 16-03121-02

Enclosure:
1. Notice of Violation
2. IR 03034325/2015003(DNMS)

DISTRIBUTION w/encls:
See next page

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OFFICE	RIII-DNMS		RIII-DNMS		RIII		RIII	
NAME	KNull:ps		PJPelke					
DATE	2/23/2016		2/25/2016					

OFFICIAL RECORD COPY

Letter to Craig Adams from Patricia Pelke dated February 25, 2016.

SUBJECT: NRC INSPECTION REPORT 03034325/2015003(DNMS) AND NOTICE OF VIOLATION – ROBLEY REX VA MEDICAL CENTER, LOUISVILLE, KENTUCKY

DISTRIBUTION w/encls:
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 November 18, 2015, through February 4, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 10 of Master Materials License (MML) No. 03-23853-01VA requires, in part, that licensed materials may be used at Department of Veteran's Affairs facilities by Department of Veterans Affairs personnel as authorized by permits issued by the National Radiation Safety Committee (NRSC).

Permit No.16-03121-02, issued to the Robley Rex VA Medical Center, a permittee under the MML, authorized the permittee to possess, store, and use radioactive materials as authorized by the permit issued by the NRSC. Item No. 6 of the permit authorized byproduct material described in 10 CFR Part 35.100, 200, and 300, and hydrogen-3, carbon-14, phosphorus-32, phosphorus-33, sulfur-35, iron-59, and iodine-125.

Contrary to the above, from December 16, 2009 to April 30, 2012, the permittee possessed, stored, and used a sealed cesium-137 source which was not authorized on the permit.

This is a Severity Level IV violation (Section 6.3)

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 030-34325/2015003(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'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 25th day of February, 2016.

ENCLOSURE 6 – INSPECTION RECORD

Region III Inspection Report No. 2015003 **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: Robley Rex VA Medical Center
800 Zorn Avenue
Louisville, KY 40206-1499
Permit No. 16-03121-02

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

Priority: 3 **Program Codes**: 02120, 3620

Date of Last Inspection: May 15, 2013 by the NHPP (1999 by NRC)

Date of This Inspection: November 18, 2015, through February 4, 2016; exit February 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
(X) Follow-up on previous violation by NHPP

Inspector: ***/RA Patricia J. Pelke for/*** Date February 25, 2016
Penny A. Lanzisera, Senior Health Physicist
Region 1

Approved: ***/RA/*** Date February 25, 2016
Patricia J. Pelke, Chief, MLB

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

1. AMENDMENTS AND PROGRAM CHANGES:

NA - The Robley Rex VA Medical Center (permittee) in Louisville, Kentucky, 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 May 15, 2013, one non-cited violation was identified against 10 CFR 35.60(b) and 35.63 for not performing dose calibrator linearity in accordance with the manufacturer's instructions up to the highest dosage administered for iodine-131 therapies. During this inspection, the range of iodine-131 therapy dosages was reviewed and it was noted that since May 2013, the dose calibrator linearity tests were conducted up to the highest dosages administered during each quarter.

The last U.S. Nuclear Regulatory Commission (NRC) routine inspection was conducted on June 28, 1999, with no violations noted.

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 were pending for this permittee.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Troy Shilling, Associate Director, Operations
Marylee Rothschild, M.D., Chief of Staff
David Berger, Radiology Manager
Mary Michele Greenwell, Radiation Safety Officer (RSO)
Kim Sison, Lead Nuclear Medicine Technologist
Joe Howard, Chief Technologist
Carter Puckett, Executive Assistant

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 permittee is authorized for material described in 10 CFR Part 35, Sections 35.100, 200, and 300, and hydrogen-3, carbon-14, phosphorous-32, phosphorous-33, sulfur-35, iron-59, and iodine-125 for research. This was a routine, unannounced inspection. The nuclear medicine department performed 10 diagnostic studies daily using primarily technetium-99m and is staffed Monday through Friday, with on-call staffing. There are four full-time technologists, three imaging cameras, and two treadmills. Seven authorized user physicians were active in the nuclear medicine program. The permittee

used unit dosages provided by Unified Healthcare in Louisville, Kentucky. Radiopharmaceutical therapy treatments included iodine-131, samarium-153 and radium-223 administrations. The inspector confirmed that the permittee determined the dose calibrator setting for the measurement of radium-223 in accordance with the manufacturer's instructions. Six patients so far have been treated with radium-223; however, as of February 5, 2016, the permittee indicated that they were no longer performing this therapy treatment. In addition, approximately one iodine-131 hyperthyroid treatment, one iodine-131 carcinoma treatment, and one samarium-153 treatment were performed each year on an out-patient basis. Written directives, patient release criteria, and patient instructions were reviewed with no concerns noted. The permittee was in the process of requesting an amendment to its permit for the use of yttrium-90 microspheres. No PET studies have been conducted at this facility.

This permittee was last inspected by the NRC in 1999, and by the NHPP in 2013. At the time of the last NRC inspection, the permittee held a broad scope medical and research license issued by the NRC. A broad scope permit was initially issued by the NHPP in 2003. The permit was amended in 2009 from a broad scope to a limited scope permit. Research use was discontinued in 2009 in both the main hospital and Building 19, and the permittee has been in contact with the NHPP for removal of research use from the permit. The historical assessment to support decommissioning was discussed with the permittee, and additional information was requested pertaining to the status of the decommissioning. Following the on-site inspection, the licensee provided additional information on the status, which included: (1) the information gathered thus far to support the historical assessment for Building 19; (2) a description of the amendment filed with the NHPP to remove the basement facilities of Building 19; and (3) initial discussions with the NHPP for removal of research areas from the main building and in total from the permit. The NHPP indicated that they would keep NRC apprised of the status of decommissioning for this permitted use.

The NHPP conducted an inspection in 2013 and identified one non-cited violation against 10 CFR 35.60(b) for failing to perform dose calibrator linearity up to the highest dosage administered (154.3 millicuries of iodine-131). During this inspection, dose administration and dose calibrator linearity records for 2014 and 2015 were reviewed and the dose calibrator was found to be calibrated to the highest dosage administered. The RSO is a full-time physicist, and performed audits of the radiation safety program which were presented to senior management and the permittee’s radiation safety committee (RSC).

The inspector observed equipment quality control, a package receipt survey, and a patient study. The inspector reviewed audits, RSC meeting minutes, equipment and source calibration records, dosimetry reports, transportation records, waste records, and sealed source inventory and leak test records. The inspector interviewed personnel and found them to be knowledgeable of regulatory requirements and radiation safety practices. The inspector performed independent measurements, which were consistent with the permittee’s surveys.

Following the on-site inspection the inspector requested additional information from the permittee in order to complete the inspection. The permittee submitted the additional information through the NHPP in a letter dated December 23, 2015 (ML15364A502). The response described survey instrument calibrations, permittee-identified concerns with the transfer of a sealed cesium-137 source, the rationale for why the source was

inadvertently removed from the permit, dose calibrator procedures and testing, and the status of decommissioning Building 19 used for waste storage and research areas located in the main hospital. A review of the information noted that the sealed cesium-137 source had inadvertently been removed from the permit in 2009 when the permit was amended from a broad scope medical to a limited scope medical program. Neither the permittee nor the NHPP identified that the source was removed from the permit even though still in the permittee's possession when the amendment was issued. The permittee continued to possess the source until 2012 when it was transferred for disposal by permittee staff. However, at the time it was transferred for disposal, the permittee did not identify that the source was not authorized on the permit. The permittee was able to track the disposal of the source following the on-site inspection and received confirmation that the source was disposed of at the WCS Compact waste disposal facility in Andrews, Texas.

With regards to the dose calibrator daily constancy tests, the permittee provided information demonstrating that the dose calibrator was checked daily using diagnostic radionuclide settings in addition to the standard settings for cobalt-57 and cesium-137; but was not checked specifically for any therapeutic radionuclide settings, including iodine-131 and samarium-153 received in vials. However, the permittee also provided documentation to support that dial value settings are printed and checked daily, which included iodine-131. The Biodex Atomlab 200 Dose Calibrator instructions provided by the manufacturer were reviewed and indicated that a monthly check of dial values and new dial value settings when using other types of containers should be performed. However, discussions between the inspector and the dose calibrator manufacturer in February 2016 indicated that dial value settings for most commonly used isotopes for their dose calibrators are similar when in syringes, vials, and thin-walled glass ampoules.

The manufacturer indicated that care should be taken to confirm dial value settings when either low energy gammas or high energy betas are used. This information was relayed to the permittee. Following the on-site inspection, the permittee made the following revisions to their dose calibrator procedures: (1) due to the infrequent use of samarium-153, the radiopharmacy determined measurements will be used; (2) the use of radium-223 has been discontinued and if resumed, the dose calibrator setting will be re-evaluated; and (3) I-131 therapy settings on the dose calibrator will be checked daily prior to use.

Inspection Procedure(s) Used: 87126 and 87131

Focus Areas Evaluated: All

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

Independent surveys conducted by the inspector using a Ludlum Model 2401P S/N 285227, last calibrated on December 4, 2014, verified that radiation levels were within regulatory limits.

Surveys in and around the nuclear medicine department and hot lab were consistent with the permittee's survey results. Surveys in unrestricted areas were at background levels, ranging from 0.02-0.05 mR/hour.

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

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

License Condition 10 of License No. 03-23853-01VA requires, in part, that licensed materials may be used at Department of Veterans Affairs facilities by Department of Veterans Affairs personnel as authorized by permits issued by the National Radiation Safety Committee (NRSC).

Permit No.16-03121-02, issued to the Robley Rex VA Medical Center, a permittee under the MML, authorized the permittee to possess, store, and use radioactive materials as authorized by the permit issued by the NRSC. Item No. 6 of the permit authorized byproduct material described in 10 CFR Part 35.100, 200, and 300, and hydrogen-3, carbon-14, phosphorus-32, phosphorus-33, sulfur-35, iron-59, and iodine-125.

Contrary to the above, from December 16, 2009, to April 30, 2012, the permittee possessed, stored, and used a sealed cesium-137 source that was not authorized on the permit. The source continued to be secured, inventoried, and leak tested during the time of continued possession.

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

Corrective actions included retraining permittee staff on the authorizations and requirements in the permit, committing to review all future permit amendments to ensure retraining on any changes that occur, and the NHPP verifying that the permittee did not possess any other unauthorized material. In addition, in order to prevent recurrence of the violation, the NHPP drafted a procedure to be used by NHPP program managers to confirm a permittee's inventory when processing amendment requests that involve a downgrade from a broad scope to a limited scope permit.

5. PERSONNEL CONTACTED:

^Troy Shilling, Associate Director, Operations
^Marylee Rothschild, M.D., Chief of Staff
#^David Berger, Radiology Manager
#^*Mary Michele Greenwell, Radiation Safety Officer
^*Kim Sison, Lead Nuclear Medicine Technologist
^*Joe Howard, Chief Technologist
^*Carter Puckett, AO to the Chief of Staff
*John Stagner, Program Manager
*Leslie Gray, Lead Technologist, Cath Lab
*Phillip McClain, Accreditation Readiness
*Randy Johnson, QMP
*Martin Traxler, Director
*Andrea Yancey, Acting Chief of Staff

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting conducted via telephone on February 9, 2015
^ Individual(s) present at the on-site preliminary exit briefing on November 18, 2015.