UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

August 14, 2018

Edwin Leidholdt, Ph.D., Interim 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 03034325/2018002(DNMS) – MINNEAPOLIS VA HEALTH CARE SYSTEM, MINNEAPOLIS, MINNESOTA

Dear Dr. Leidholdt:

On July 18, 2018, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the Minneapolis VA Health Care System located in Minneapolis, Minnesota. The inspection results were discussed with Ms. Martina Malek, Acting Associate Director, Mr. Adam Tome, Radiation Safety Assistant, Brian Fiedler, M.D., Chair, Radiation Safety Committee, and other members of the management staff at the exit meeting on July 18, 2018. The enclosed report presents the results of this inspection.

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 control and constant surveillance of licensed material in a dose administration room on July 18, 2018. The violation is cited in the enclosed NRC Form 591M Part 1. The NRC is citing the violation because an NRC inspector identified the violation.

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 the enclosed NRC Form 591M Part 2. Therefore, you are not required to respond to this letter.

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 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 or the enclosed report, please contact Bryan Parker of my staff at 678-828-7050.

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. 22-01859-01

Enclosure:
NRC Form 591M (Parts 1, 2 and 3)

Letter to Edwin Leidholdt from Patricia Pelke, dated August 14, 2018

SUBJECT: NRC INSPECTION REPORT 03024325/2018002(DNMS) – MINNEAPOLIS VA HEALTH CARE SYSTEM, MINNEAPOLIS, MINNESOTA

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OFFICE	RIII-DNMS	C	RIII-DNMS	C				
NAME	BParker:cl	PJPelke for	PJPelke					
DATE	8/14/2018		8/14/2018					

OFFICIAL RECORD COPY

NRC FORM 591M PART 1 (07-2012) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Department of Veterans Affairs Under Secretary of Health Washington, D.C. 20420 Location: VA Health Care System, Minneapolis, MN REPORT NUMBER(S) 03034325/2018002(DNMS)	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34325	03-23853-01VA	July 18, 2018

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☐ 1. Based on the inspection findings, no violations were identified.

☐ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

☑ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations and Corrective Actions)

Contrary to Title 10, Code of Federal Regulations, 20.1802, on July 18, 2018, a nuclear medicine technologist (NMT) failed to control and maintain constant surveillance of 5.28 mCi of Tc-99m. Specifically, the NMT carried a prepared resting dose of Tc-99m sestamibi from the hot lab to a dose administration room, and left the dose unattended by licensee staff while the NMT retrieved the patient from the waiting room. In addition, interviews with permittee personnel revealed that doses were routinely left unattended in the administration room at times when the department was busy, indicating a programmatic issue. This constituted a Severity Level IV violation in accordance with Section 6.7 of the enforcement policy.

(cont'd. on Part 2)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	D. O'Dowd, E. Harvey, J. Draper	Dennis P. O'Dowd/EGH for Jason Draper	08/08/2018
BRANCH CHIEF	Patricia J. Pelke	Patricia Pelke	8/14/2018

NRC FORM 591M PART 2
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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030-34325	03-23853-01VA	July 18, 2018

(Continued)
(cont'd. from Part 1)

As a corrective action, during the exit meeting held on July 18, 2018, the permittee stated that they planned on revising the nuclear medicine department standard operating procedures (SOP) to specifically prohibit the practice of leaving doses in unsecured areas for any amount of time.

During a telephonic conversation with the permittee's Assistant RSO on August 8, 2018, the permittee confirmed that page 11-6 to the permittee's nuclear medicine policy manual under the "Control of Radioactive Material and Posting Requirements" section, was amended on July 24, 2018, to emphasize the requirement that (1) radioactive material must be secured or under constant surveillance at all times; (2) that when not in use, sealed sources must be locked in specified areas in specific rooms; and (3) that when injecting patients, nuclear medicine staff are to retrieve the dose from the hot lab only after they have brought the patient to the preparatory or stress room. The new policy statement specifically prohibits leaving radioactive material in the preparatory or stress room unattended while escorting the patient to or from the waiting area.

In addition, on the date of the inspection, all nuclear medicine staff were given instructions by the nuclear medicine supervisor to never leave radioactive material that is not in storage unattended at any time, and were instructed in follow the procedure that was adopted formally on July 24, 2018.

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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030-34325	03-23853-01VA	July 18, 2018

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87134, 87131, 87126	All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02110, 03610	2	William C. White, RSO	(612) 467-2620

☐ Main Office Inspection Next Inspection Date:

☑ Field Office Inspection Minneapolis VA Health Care System

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was an unannounced, routine inspection of a permittee under the Department of Veterans Affairs (DVA) Master Materials License. The permittee was an approximately 300-bed broad scope medical facility operating under a permit issued by the DVA's National Health Physics Program (NHPP) and authorized for medical diagnosis (including PET), therapy (both unsealed and sealed), and research in humans. The permittee is also authorized for research and development, including animal studies, instrument calibration, student instruction, and in vitro studies. The hospital had a full-time Radiation Safety Officer (RSO) and an assistant RSO, and one medical physicist. The RSO and an assistant RSO oversee day-to-day radiation safety activities, including providing radiation safety and hazmat training, instrument calibration, sealed source inventory and leak tests, surveys, and program audits. The Radiation Safety Committee (RSC), which meets quarterly, oversees the program. The nuclear medicine (NM) department was staffed with six nuclear medicine technologists (NMT) working in standard nuclear medicine and positron emission tomography (PET) areas. Each area had its own hot lab and cameras, and NMTs work in both areas as needed. The NM department operated Monday through Friday, performing a variety of procedures. Permittee staff typically performed around 15 nuclear medicine (primarily cardiac) and 8 PET diagnostic procedures daily using unit doses provided by local radiopharmacies. All doses were assayed in the dose calibrator prior to administration. In addition, NM staff performed approximately one to two therapeutic administrations of I-131 (capsule only), and Ra-223 Xofigo per month. In the radiation oncology department, one authorized user performed 15-24 permanent I-125 prostate seed implants per year. At the time of the inspection, the permitee had one active research lab that contained approximately 11 mCi of tritium. The research lab was operated by a contracted principal investigator.

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NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

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02110, 03610	2	William C. White, RSO	(612) 467-2620

☐ Main Office Inspection Next Inspection Date:

☑ Field Office Inspection Minneapolis VA Health Care System

☐ Temporary Job Site Inspection

PROGRAM SCOPE

(cont'd. from previous page)

PERFORMANCE OBSERVATIONS

The inspectors toured the facility to evaluate the permittee's measures for materials security, hazard communication and exposure control. The inspectors observed permittee staff performing several diagnostic administrations of licensed material including dose preparation and disposal. No therapeutic procedures involving sealed or unsealed material were conducted by the permittee at the time of the inspection. Permittee staff discussed and/or demonstrated various procedures, including package receipt and opening, dose calibrator QA/QC, daily and weekly contamination surveys, and waste handling. Permittee staff also demonstrated the implementation procedures for prostate seed implant program.

The inspectors performed independent and confirmatory radiation surveys which indicated results consistent with survey records, regulatory limits, and postings. The inspectors reviewed a selection of records including program reviews and audits, dosimetry, RSC meeting minutes, written directives and treatment verifications for I-131, Xofigo, and prostate seed implants, leak tests and inventories, instrument calibrations, and dosimetry. The review of dosimetry records indicated no exposures of regulatory concern.

An exit briefing was held with the Assistant RSO, the chair of the RSC, representatives of hospital management, and a representative of the DVA's NHPP (by telephone) to discuss the results of the inspection. Within the scope of the inspection, one violation was noted, as described in Part 1 of this report.