



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

September 22, 2016

Mr. Craig Adams, 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 03034325/2016013(DNMS) – VA NORTH TEXAS
HEALTH CARE SYSTEM, DALLAS, TEXAS

Dear Mr. Adams:

On August 31, 2016 through September 1, 2016, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the VA North Texas Health Care System, Dallas, Texas. The inspection was limited to a review of activities authorized under Permit Number 42-00220-06. The inspector conducted an exit meeting with the management and staff at the facility at the completion of the 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. Within the scope of the inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

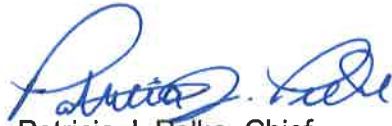
In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

C. Adams

-2-

Should you have any questions concerning this inspection or the enclosed report, please contact Kevin Null of my staff at 630-829-9854.

Sincerely,



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

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 42-00220-06

Enclosure:
IR 03034325/2016013(DNMS)

C. Adams

-2-

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/

Patricia J. Pelke, Chief
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Enclosure:
IR 03034325/2016013(DNMS)

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NAME	KNull:ps <small>(via-e-mail)</small>		JDyker PJPelke for		PJPelke			
DATE	9/22/2016		9/22/2016		9/22/2016			

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SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Under Secretary for Health Washington, D.C. Location: VA North Texas Health Care System Dallas, Texas REPORT NUMBER(S) 2016013	2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. DOCKET NUMBER(S) 030-34325	4. LICENSE NUMBER(S) 03-23853-01VA	5. DATE(S) OF INSPECTION August 31, 2016 and September 1, 2016
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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 violation(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)

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	Jason Dykert		9/22/2016
BRANCH CHIEF	Patricia J. Pelke		9/22/2016

Docket File Information

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3. DOCKET NUMBER(S) 030-34325	4. LICENSE NUMBER(S) 03-23853-01VA	5. DATE(S) OF INSPECTION August 31, 2016 and September 1, 2016
6. INSPECTION PROCEDURES USED 87134	7. INSPECTION FOCUS AREAS 02.01 - 02.07	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02110	2. PRIORITY 2	3. LICENSEE CONTACT Craig Adams, NHPP	4. TELEPHONE NUMBER (501) 257-1573
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- Main Office Inspection Next Inspection Date: N/A
- Field Office Inspection Dallas, Texas and Fort Worth, Texas
- Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine unannounced inspection of the Department of Veterans Affairs MML permittee VA North Texas Health Care System, which operates as a medical broad scope institution. Current activities performed under the permit included diagnostic and therapeutic nuclear medicine (35.100, 35.200 & 35.300) and one laboratory performing limited research activities with iodine-125. The hospital has five Authorized Users, eight certified nuclear medicine technologists, three PET technologists, and three radiation safety staff members. The radiation safety officer (RSO) reports to the Chief of Safety and Service who reports to the Hospital Assistant Director. The RSO and radiation safety staff members provide radiation protection program management for the hospital, including permit management, radiation safety training, dose calibrator and well counter calibrations, survey meter calibration, sealed source procurement and disposal activities, inventories and leak tests, ALARA dosimetry reviews, quarterly internal program audits, Radiation Safety Committee (RSC) support, radiation producing and monitoring equipment service and contract support, incidents and medical event review, in addition to many other ancillary duties. The RSC meets at least twice per year, and provides additional oversight, dosimetry review, authorized user review and approval, medical physics services and contracts, and reviews/approves any changes to the radiation protection program that could affect overall safety.

Nuclear medicine operates Monday through Saturday 7am - 6pm, utilizes technetium-99m and other permitted isotopes in unit dose or capsule form delivered from Cardinal Health, a Bracco CardioGen-82 PET rubidium-82 dose calibrator and delivery system, a Medrad Intego PET infusion system that houses bulk doses of fluorine-18, iodine-123 for DaT scans, in addition to administering radium-223 (Ra-223) (Xofigo) and iodine-131 (I-131) for diagnostic and therapeutic doses. The hospital performs 20-40 diagnostic imaging procedures per day, 5-10 of them with PET, and 2-4 therapeutic procedures per month. There are two SPECT cameras, two SPECT-CT cameras, one PET camera, one hot lab for unit doses and a separate hot lab and treatment area for the PET doses, in addition to an iodine thyroid studies room and waste storage room. There are inpatient services for thyroid ablations, and a separate isolated room with specifically trained nursing staff is provided. Twenty-one sealed sources used for instrument calibration purposes have the required current leak tests.

Docket File Information (Continued)

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Department of Veterans Affairs
Under Secretary for Health
Washington, D.C.
Location: VA North Texas Health Care System
Dallas, Texas

REPORT NUMBER(S) 2016013

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-34325

4. LICENSE NUMBER(S)

03-23853-01VA

5. DATE(S) OF INSPECTION

August 31, 2016 and
September 1, 2016

PROGRAM SCOPE

The Fort Worth facility is an outpatient clinic only and has one SPECT camera and one technologist administers doses there one day per week. The hot lab and camera area are secured with two barriers. Radiation surveys indicated exposures were within regulatory limits and that the permittee's postings were adequate.

The inspector observed a patient treatment which utilized the Medrad Intego PET infusion system. The technologist verified the patient ID, performed and demonstrated the daily QA/QC for the machine to verify activity and determine the dosage delivered to the patient, prepared and finalized the required records, appropriately handled and disposed of the dose delivery tubing with ALARA techniques, and performed the required area surveys at the end of treatments.

The inspector interviewed an authorized user about their role in supervision and training of the technologists. The inspector interviewed four different technologists who demonstrated and performed tasks in various areas of the nuclear medicine department. All of the staff interviewed were knowledgeable in and practiced appropriate radiation safety principles when using syringe shields, protective cloths and PPE, accepting new package receipt, labeling vials and syringes, performing area surveys and weekly wipes, controlling access to the hot lab, discussing spill response, maintaining ALARA and administering doses.

Written directives for I-131 use and Ra-223 therapy were selectively reviewed for 2015 and 2016, no issues were noted. Paper records and electronic records are kept for all procedures requiring a written directive. Written directives were reviewed by the radiation safety staff, the nuclear medicine staff, and discussed at RSC meetings for events or issues.

The inspector independently performed radiation surveys in both hot labs, selected treatment rooms, waste disposal area, iodine treatment room, hallways, and in the research laboratory where permitted materials were used with a Ludlum 2401-P survey meter, s/n 197217, calibration due 4/5/2017. Measurements indicated that exposure rates were within regulatory limits and that postings and signs were adequate.

The inspector reviewed the permittee's on-line training management system and a few selected records to verify required training was up to date. Other records were reviewed, including quarterly program audits, RSC minutes, accreditation training certificates and preceptor statements for the Authorized Users on the permit, sealed source leak tests and physical inventories, instrument calibrations, QA/QC records and activities for the dose delivery systems in nuclear medicine, receipt and transfer records, patient release instructions and basis for release records and calculations in accordance with 10 CFR 35.75, area surveys and weekly wipe test records, and selected procedure protocols for current revisions. No concerns were identified.

Waste held for decay in storage was observed and discussed, appropriate background levels were surveyed and performed to verify waste radiation levels were documented before the waste was disposed of as bio-hazardous.

Dosimetry records were reviewed and the highest whole body dose reviewed was 350 millirem in 2015 and currently at 201 millirem in 2016 for the nuclear medicine staff.

Docket File Information (Continued)

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PROGRAM SCOPE

An exit meeting was held with the Hospital Director, Assistant Hospital Director, Associate Director, Hospital Chief of Staff, Deputy Chief of Staff, Acting Director of Nuclear Medicine, Chief of Safety and Service, Chief of Nuclear Medicine, Chair of the Radiation Safety Committee, Hospital Compliance Officer, Acting Assistant Director for outpatient services, Radiation Safety Officer, Radiation Safety Staff Health Physicist, Interim Chief of Quality Safety and Value, Interim Associate Director of Patient Care Services and the Administrative Officer for Nuclear Medicine to discuss the results of the inspection. No violations were identified.