



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

May 10, 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 03034325/2016002(DNMS) – MIAMI VA
HEALTHCARE SYSTEM, MIAMI, FLORIDA

Dear Mr. Adams:

On April 20 - 21, 2016, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the Miami VA Healthcare System, Miami, Florida. The inspection was limited to a review of activities authorized under Permit Number 09-00239-06. 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.

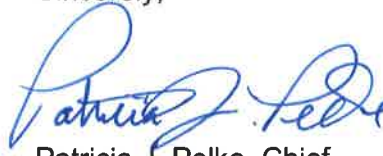
In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management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

C. Adams

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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.: 09-00239-06

Enclosure:
IR 03034325/2016002(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
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No.: 030-34325
License No.: 03-23853-01VA
Permit No.: 09-00239-06

Enclosure:
IR 03034325/2016002(DNMS)

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DATE	5/6/2016		5/6/2016		5/10/2016			

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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: Miami VA Healthcare System

REPORT NUMBER(S)

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

April 20 - 21, 2016

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	Robin Elliott		5/10/2016
BRANCH CHIEF	Patricia Pelke		5/10/2016

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Department of Veterans Affairs
Under Secretary for Health
Washington, D.C.
Location: Miami VA Healthcare System

REPORT NUMBER(S)

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

April 20 - 21, 2016

6. INSPECTION PROCEDURES USED

87131, 87126

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02120, 03610

2. PRIORITY

3

3. LICENSEE CONTACT

Craig Adams

4. TELEPHONE NUMBER

(501) 257-1573

☐ Main Office Inspection

Next Inspection Date: N/A

☒ Field Office Inspection Miami, FL

☐ Temporary Job Site Inspection

PROGRAM SCOPE

The permittee is a medical facility authorized for 35.100, 35.200, and 35.300 materials, and broad-scope medical related research activities. These uses were supervised by an active Radiation Safety Committee (RSC) that met quarterly and had representation from each area that used permitted material, as well as other areas not regulated by the NRC. The RSC reported to the Environment of Care Committee. The radiation safety program was staffed by a full-time Radiation Safety Officer (RSO), who had access to executive management.

The Nuclear Medicine (NM) program which was staffed with five Authorized Users (AU) and five Nuclear Medicine Technologists (NMTs), typically performed 15 NM studies per day and seven PET scans per day. The program participated in hosting rotations for NM students from Broward Community College, Miami Dade College, and Keiser College training them for a six week period. Their facilities consisted of three cameras, two treadmills, one uptake probe, and two hot labs (one for NM and one for PET). The PET facilities were located in a trailer adjacent to the main hospital facility. A project has begun to move the PET facility to the third floor of the hospital in the near future. The NMTs rotated shifts performing PET scans to limit their exposure. Radiopharmaceuticals (primarily technetium-99M, iodine-131, iodine-123, FDG) were obtained in unit doses only from Cardinal Health located in Miami Lakes. All doses were assayed in the dose calibrator prior to administration. In 2015, 12 iodine-131 therapies were performed, one of which was administered as an in-patient treatment. Thus far in 2016, four therapies have been performed. Therapies were performed using capsules only. Written directives were reviewed and contained the information as required in 10 CFR 35.40. In addition, they included verification procedures as required in 10 CFR 35.41. Patients were provided written instructions, and patient release calculations were performed in accordance with 10 CFR 35.75. For in-patient treatments, staff associated with patient care received training, were monitored, and appropriate surveys were performed. All waste materials were collected and stored for decay prior to disposal.

The research activities were conducted by five Principal Investigators. Isotopes that were authorized for use were chromium-51, hydrogen-3 and iodine-125. Isotopes that were in inventory were chromium-51 and hydrogen-3; no work had begun with iodine-125. Approximately 100 microcuries of chromium-51 was being used daily in one laboratory. In this facility, work was performed behind lead blocks and 1.5 inch plexiglass shields, and remote handling devices were used.

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION (Continued)

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Under Secretary for Health Washington, D.C. Location: Miami VA Healthcare System REPORT NUMBER(S)		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 April 20 - 21, 2016	

PROGRAM SCOPE (Continued)

Lab coats, gloves, and dosimeters were worn. A survey meter was present for surveying during work and at the end of the day. In all laboratories, stock material was stored in a locked refrigerator, waste material was stored in a locked cabinet, and work areas were demarcated with "caution radioactive material" tape.

The inspector observed a variety of activities in NM including: package receipt, dose preparation, injection, patient positioning and interaction, and surveying. The inspector also observed a researcher working with chromium-51. The inspector interviewed workers regarding their use and control of licensed material. All personnel observed and interviewed were knowledgeable and demonstrated good radiation safety practices. Independent measurements taken in NM, at the PET trailer, in research laboratories, and in the waste storage facility were all consistent with licensee postings and within regulatory limits. Records reviewed included: Audits, RSC minutes, dosimetry reports, instrument calibrations, survey records, leak tests and inventories, approval of research AUs, and written directives. No concerns were noted. A recommendation was made to keep a signed copy of the written instructions provided to iodine-131 therapy patients in their file along with the patient release calculations, as commitments made by the patient factor into the calculations.

The inspector reviewed the NRC's medical toolkit page with the RSO and instructed him on how to enroll for the Medical List Server. In the exit meeting, the inspector reviewed the Safety Culture Policy Statement, the brochure, provided copies of the "Trait Talk" Newsletters and explained about the availability of the educational resource that is posted on the website nrc.gov/about-nrc/safety-culture.html.

Within the scope of this inspection, no violations were identified.