



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

May 7, 2019

Edwin M. Leidholdt, Jr., Ph.D., 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 03034325/2019007 (DNMS) – VA MEDICAL  
CENTER, DURHAM, NORTH CAROLINA

Dear Dr. Leidholdt:

On April 16, 2019, the U.S. Nuclear Regulatory Commission (NRC) completed a routine inspection at the VA Medical Center, Durham, North Carolina. The inspection was limited to a review of activities authorized under Permit No. 32-01134-01. 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 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>).

E. Leidholdt, Jr.,

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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. 32-01134-01

Enclosure:  
IR 03034325/2019007



**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

<b>1. LICENSEE/LOCATION INSPECTED:</b>  Department of Veterans Affairs VA Medical Center 508 Fulton St. Durham, North Carolina 27705  <b>REPORT NUMBER(S)</b> 030-34325/2019007	<b>2. NRC/REGIONAL OFFICE</b>  Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
<b>3. DOCKET NUMBER(S)</b> 030-34325	<b>4. LICENSE NUMBER(S)</b> 03-23853-01VA	<b>5. DATE(S) OF INSPECTION</b> April 16, 2019

**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	Deborah A. Piskura, Senior Health Physicist	<i>Deborah A. Piskura</i>	5/7/2019
BRANCH CHIEF	Patricia J. Pelke, Chief, MLB	<i>Patricia J. Pelke</i>	5/7/2019

**Docket File Information**

**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

**1. LICENSEE/LOCATION INSPECTED:**

Department of Veterans Affairs  
VA Medical Center  
508 Fulton St.  
Durham, North Carolina 27705

REPORT NUMBER(S) 030-34325/2019007

**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 16, 2019

**6. INSPECTION PROCEDURES USED**

87130, 87131 & 87132

**7. INSPECTION FOCUS AREAS**

03.01 - 03.07

**SUPPLEMENTAL INSPECTION INFORMATION**

**1. PROGRAM CODE(S)**

03614

**2. PRIORITY**

2

**3. LICENSEE CONTACT**

Ed Leidholdt, Ph.D., Director, NHPP

**4. TELEPHONE NUMBER**

(707) 562-8374

**Main Office Inspection**

**Next Inspection Date:**

N/A

**Field Office Inspection** VA Medical Center, Durham, NC

**Temporary Job Site Inspection**

**PROGRAM SCOPE**

The Durham VA Medical Center (permittee) of the DVA was authorized to use licensed material with atomic numbers 1-83, F-18, Mo-99/Tc-99m, I-131, and Xe-133 under Permit No. 32-01134-01. The permittee's use of licensed materials was limited to diagnostic, radiopharmaceutical therapy, and permanent prostate implants; laboratory R&D using licensed material was inactive at this time. Although the permittee was authorized for Ra-223 and Sm-153, these radiopharmaceuticals had not be administered. The permit authorized two locations of use, the main hospital and a temporary location for shielding evaluations. The radiation safety program was managed by a dedicated full-time RSO with support by the Chief Nuclear Medicine Technologist functioning as an assistant RSO.

Nuclear medicine studies were performed daily. The nuclear medicine department was staffed with seven FT technologists who performed approximately 300 diagnostic procedures per month. The permittee received unit doses only; the department administered a full spectrum of diagnostic studies. The permittee operated separate nuclear cardiology and PET departments within the hospital. The cardiac and PET studies were performed daily by technologists who rotated from the main nuclear medicine department. The hospital maintained an active therapeutic radiopharmaceutical program limited to I-131 treatments; the majority of these patients were released under the provisions of 10 CFR 35.75.

The licensed activities in radiation oncology were limited to permanent prostate I-125 implants. The licensee utilized the services of professional staff from the Duke University Healthcare system on a contractual basis. In 2018, the permittee performed two I-125 permanent prostate implants. No implants were administered year to date 2019.

**Docket File Information (Continued)**  
**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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Durham, North Carolina 27705

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5. DATE(S) OF INSPECTION

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**PROGRAM SCOPE**

This inspection consisted of interviews with selected permittee personnel, a review of selected records, tours of the nuclear medicine, cardiology, and PET departments, and independent measurements. The inspector observed permittee staff perform dose calibrator QA checks and administer several diagnostic dosages. The inspector reviewed written directives for several radiopharmaceutical treatments. The inspector also reviewed permanent prostate implant written directives and pre- and post-treatment plans for the two cases implanted in 2018. The inspection included observations of security of byproduct material, surveys, use of personnel monitoring, and postings. At the time of this inspection, the permittee had an I-131 patient who was being treated as an inpatient. The inspector observed the use of access controls, personnel monitoring and protective clothing, patient and patient room surveys, nursing instructions, and patient room postings by the permittee. The inspector performed surveys in the adjacent patient room and hallways to confirm that the radiation levels were within Part 20 limits.

No violations of NRC requirements were identified during this inspection.

An exit meeting was held with hospital and NHPP staff at the conclusion of the onsite inspection.

E. Leidholdt, Jr.,

Letter to Edwin M. Leidholdt, Jr., Ph.D., from Patricia J. Pelke dated May 7, 2019.

SUBJECT: NRC INSPECTION REPORT 03034325/2019007 (DNMS) – VA MEDICAL CENTER, DURHAM, NORTH CAROLINA

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OFFICE	RIII DNMS	C	RIII DNMS	C	RIII-DNMS	C	RIII	
NAME	DPiskura:ps		BParker		PJPelke			
DATE	05/07/19		05/03/19		05/07/19			

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