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

July 27, 2022

Edwin M. Leidholdt, Ph.D. Director
National Health Physics Program (115 HP/NLR)
Department of Veterans Affairs
Veterans Health Administration
2200 Fort Roots Drive
Building 101
North Little Rock, AR 72114

SUBJECT: NRC INSPECTION REPORT 03034325/2022005(DNMS) – VA MEDICAL CENTER, GAINESVILLE, FLORIDA

Dear Dr. Leidholdt:

On May 31, 2022, the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at the VA Medical Center, Gainesville, Florida. The inspection was limited to a review of activities authorized under Permit Number 09-12467-02. 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 Public Document Room or the NRC's Agencywide Documents Access and Management System (ADAMS, accessible from the NRC Web site 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,

Michael M. LaFranzo

Digitally signed by Michael M. LaFranzo
Date: 2022.07.27 13:49:03 -05'00'

Michael LaFranzo, Acting Chief
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket No. 030-34325
License No. 03-23853-01VA
Permit No. 09-12467-02

Enclosure:
IR 03034325/2022005

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
North Florida/South Georgia Veterans Health System 1601 S.W. Archer Road Gainesville, Florida 32608-1197 REPORT NUMBER(S) 2022005	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	May 31, 2022

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)

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	Luis Nieves	Luis A. Nieves Folch Digitally signed by Luis A. Nieves Folch Date: 2022.06.10 09:49:25 -05'00'	
BRANCH CHIEF	Michael LaFranzo	Michael M. LaFranzo Digitally signed by Michael M. LaFranzo Date: 2022.07.27 13:47:36 -05'00'	

NRC FORM 591M PART 2
(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
North Florida/South Georgia Veterans Health System 1601 S.W. Archer Road Gainesville, Florida 32608-1197 REPORT NUMBER(S) 2022005	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	May 31, 2022

(Continued)

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-34325	03-23853-01VA	May 31, 2022

6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER

☐ Main Office Inspection Next Inspection Date: _____

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

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PROGRAM SCOPE

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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☐ Main Office Inspection Next Inspection Date: _____

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
North Florida/South Georgia VA Health	030-34325	

4. Report Number(s):	5. Date(s) of Inspection:
2022005	May 31, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Luis Nieves	02120	3	02120

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Kathleen Thomas, M.S., RSO	kathleen.thomas@va.gov	352-548-6514

13. Inspection Type:		14. Locations Inspected:		15. Next Inspection Date (MM/DD/YYYY):	
☑ Routine	☑ Announced	☑ Main Office	☑ Field Office	☐ Normal	☐ Extended
☐ Non-Routine	☐ Unannounced	☐ Temporary Job Site	☐ Remote	☐ Reduced	☐ No change
☐ Initial					

16. Scope and Observations:

This was an announced, routine inspection of a Veterans Affairs hospital in Gainesville and Lake City, Florida, authorized to use unsealed byproduct material for diagnostic and therapeutic procedures.

At the Gainesville location the hospital was approved for a variety of diagnostic and therapeutic isotopes including Rubidium 82, Iodine131, Lutetium 177, and Radium 223. The licensee had one hot lab and was staff with 8 Nuclear Medical Technicians (NMT) who perform approximately 25 patients total per day 10 FDG and 10 Rb-82. The licensee perform five I-131 administration in 2022. The licensee has never administer Lutetium 177 and the last time a Radium 223 dose was administer was back in 2017.

At the Lake City location the licensee only performed diagnostic procedures mainly heart studies and gallium scans approximately nine per day. The Nuclear Medicine Department was staff with two NMT.

PERFOMANCE OBSERVATIONS

The inspector toured the nuclear medicine hot lab at two locations and discussed with an NMT package receipt, surveys, and instrument quality control checks. The inspector observed one rest test using Rb-82. The NMT and RSO demonstrated adequate knowledge of radiation safety principles and practices though interviews. The inspector reviewed quarterly audit reports, instrument quality control, inventory, written directives, dose calibrator linearity and accuracy, and training. The inspector also reviewed monthly dosimetry reports which indicated annual whole-body and extremity doses were below regulatory limits.

Regarding the licensee's use of a Bracco Cardiogen-82 Rb-82 generator, Title 10 of the Code of Federal Regulations (10 CFR) 35.60 requires a licensee to calibrate the instrument used to measure the activity of the dosage administered to each patient of human research subject. This calibration may either be performed in accordance with nationally recognized standards of calibration or with instructions provided by the manufacturer. However, there are currently neither nationally recognized standards nor specific calibration procedure for calibration the Cardiogen-82 detectors in a dynamic mode (i.e., while liquids are flowing by the detector). Until such standards of procedures are developed, compliance with 10 CFR 35.60 is not possible.

In addition, 10 CFR 35.63 requires a licensee to determine the activity of each dosage administered before medical use. Due to the 76-second half-life of Rb-82 and direct infusion into the patient, users of the Cardiogen-82 generator system are unable to measure patient dosages of Rb-82 prior to administration.

Materials Inspection Record (Continued)

On several occasions as of May 31, 2022, the licensee used a Bracco Cadiogen-82 Rb-82 generator for cardiac imaging and could not comply with 35.60 (calibration of instruments used to measure the activity of unsealed byproduct material, in this case detectors associated with Rb-82 generator systems) and 10 CFR 35.63 (determination of dosages of unsealed byproduct material for medical use, in this case Rb-82).

The licensee used documentation of the infusion cart maintenance performed by the manufacturer to document the completion and results of the infusion rate and the radiation detector test semi-annually to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications. The authorized users (AUs) for medical uses under 10 CFR 35.200 who used Rb-82 chloride successfully completed the manufacturer’s training specific to the manufacturer and model of generator and infusion cart that was used, which included: (1) elution and quality control procedures needed to determine Rb-82 activity and the strontium-82 and strontium-85 breakthrough levels; (2) dose calibrator calibration procedures; and (3) safety procedure for the clinical use of Rb-82 chloride. The licensee’s quality control procedure for calibration of the radiation detector in the infusion cart included: (1) performance of the Rb-82 activity constancy check comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to adjust the infusion cart readout setting; and (3) when these tests are required by the manufacturer. The licensee maintained documentation that all AUs using Rb-82 have satisfactory completed such training. The licensee also recorded the activity of each dosage administered, as provided by the infusion cart.

Although the inspector identified violations of 10 CFR 35.60 and 35.63, the licensee met all of the criteria in EGM 13-003 (available at ww.nrc.gov) for use of enforcement discretion; therefore, the NRC is exercising enforcement discretion and will not issue any enforcement action for these violations.

No other violations of NRC requirements were identified during this inspection.