



SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Department of Veterans Affairs Southeast Louisiana Veterans Health Care System 2400 Canal Street New Orleans, LA REPORT NUMBER(S) 2019-003		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 January 28, 2019
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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 VonEhr/Bryan A. Parker		2/27/2019
BRANCH CHIEF	Patricia J. Pelke		2/27/2019

Docket File Information
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January 28, 2019

6. INSPECTION PROCEDURES USED

87131

7. INSPECTION FOCUS AREAS

All

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02120

2. PRIORITY

3

3. LICENSEE CONTACT

Dr. Jason Samii, M.D., Ph.D.

4. TELEPHONE NUMBER

☐ Main Office Inspection

Next Inspection Date:

N/A

☒ Field Office Inspection 2400 Canal Street, New Orleans, LA

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of activities under Permit No. 17-00629-01 of the Department of Veterans Affairs, the Southeast Louisiana Veterans Health Care System located in New Orleans, LA. The permittee's facility is a new construction, having entered operations in September 2017, and is gradually adding staff and new licensed modalities to become a complete healthcare center. At the time of the inspection, the permit was on Amendment No. 6, which authorized 35.100-300 use of licensed radioactive material, in addition to Tc-99m for use in shielding evaluations.

The inspection started with the nuclear medicine staff at 6:30 am, which is the normal starting time for QA/QC operations. The inspector observed the staff prepare the dose calibrator, conduct constancy, and conduct QC on the imaging equipment using 10 CFR 35.65 authorized sealed sources. Through interviews and observations, the inspector determined the staff to be competent and knowledgeable regarding their responsibilities with respect to nuclear medicine operations, procedures, protocols, and requirements.

The inspector observed the receipt of licensed material via a local radiopharmacy, which was wiped, surveyed, and logged by the licensee, with no issues identified. The inspector observed the correct use of calibrated survey instruments throughout the inspection. The inspector also reviewed with the RSO and Authorized User (one of three) the practices and procedures in use at the facility for therapeutic (35.300) uses of unsealed radioactive material. Since the opening of the facility, only 5 uses under 35.300 were recorded, all authorized under the current RSO, Dr. Jason Samii, and all involving I-131. The licensee has not yet begun use for Ra-223 Xofigo, but discussed the regulatory challenges with the inspector in hopes of using Xofigo in the near future. The five written directives for the above administrations were all reviewed, in addition to patient release criteria and other associated records and requirements, with no issues identified. The permittee reviews the written directives following administration to identify any medical events.

The inspector interviewed multiple technologists, and observed the administration of 10 CFR 35.200 licensed materials, with no issues identified.



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Dr. Jason Samii, M.D., Ph.D.

4. TELEPHONE NUMBER

☐ Main Office Inspection

Next Inspection Date: N/A

☒ Field Office Inspection 2400 Canal Street, New Orleans, LA☐ Temporary Job Site Inspection**PROGRAM SCOPE**

The inspector briefly discussed the new 10 CFR Part 35 rules, and that they were in effect as of mid-January 2019. The inspector also discussed staff refresher training, with no issues identified.

The licensee has not yet finalized a contract for a computer-based information system to record the licensed activities, and therefore all records reviewed during the inspection were on paper.

As part of the licensee's annual program review, records such as inventories, leak tests, QA/QC, and other supporting documents were reviewed, with no issues identified.

The permittee had self-identified a permitting issue outside the scope of this inspection, wherein the permit in effect at the time did not authorize the use of Tc-99m for shielding evaluations, an activity that had been carried out. The permittee requested and received an amendment to the permit authorizing this activity on December 3, 2018.

No violations were identified. An entrance meeting and preliminary exit meeting were provided to on-site administration. In addition, the inspector was accompanied by Ms. Elizabeth Levy and Ms. Angela Jackson of the State of Louisiana, Emergency and Radiological Services Division, Office of Environmental Compliance, Department of Environmental Quality.

