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 |
|---|---|
| Department of Veterans Affairs<br>Under Secretary of Health<br>Washington, D.C. 20420<br>Location: VA St. Louis Health Care System, St. Louis, MO<br><br>REPORT NUMBER(S) 030-34325/2018001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 030-34325 | 03-23853-01VA | July 9 - December 19, 2018 |

**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 | Kevin Null/Deborah Piskura | | 1/18/2019 |
| BRANCH CHIEF | Patricia J. Pelke | | 1/18/2019 |

NRC FORM 591M PART 3
(07-2012)
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U.S. NUCLEAR REGULATORY COMMISSION

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| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS |
|---|---|
| 87131, and 87134 | All |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 02110 | 2 | Ed Leidholdt, Ph.D. | (707) 562-8374 |

☑ Main Office Inspection  Next Inspection Date: n/a

☑ Field Office Inspection

☐ Temporary Job Site Inspection

## PROGRAM SCOPE

VA St. Louis

This location was inspected on July 9, 2018.
This permittee of the DVA was authorized to use licensed material with atomic numbers 1-83, F-18, Mo-99/Tc-99m, I-131, Xe-133, Lu-177 and Ra-113. The permit authorized six locations of use. The radiation safety program was managed by a dedicated full-time RSO and supported by an assistant RSO.

At the St. Louis Hospital (main) nuclear medicine studies were performed daily. The nuclear medicine department was staffed with three FT technologists who performed approximately 130-150 diagnostic procedures per month. The permittee received unit doses and bulk Tc-99m for kit preparation; the department administered a full spectrum of diagnostic studies. The permittee operated a separate PET department within the hospital. The PET studies were performed daily by two FT technologists. The hospital maintained an active therapeutic radiopharmaceutical program including I-131 and Ra-223 treatments; all patients were released under the provisions of 10 CFR 35.75.

Performance Observations

This inspection consisted of interviews with selected licensee personnel, a review of selected records, a tour of the nuclear medicine and PET departments, and independent measurements. The inspector observed the permittee staff perform dose calibrator QA checks and administer several diagnostic dosages. The inspector reviewed the patients' written directives for several radiopharmaceutical therapy treatments. The inspection included observations of security of byproduct material, use of personnel monitoring, and postings.

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☑ Main Office Inspection  Next Inspection Date: n/a

☑ Field Office Inspection

☐ Temporary Job Site Inspection

## PROGRAM SCOPE

VA Marion, IL

This location was inspected on August 2, 2018.
At the Marion, IL Hospital nuclear medicine studies were performed daily. The nuclear medicine department was staffed with two FT technologists who performed approximately 100-150 (and trending higher) diagnostic procedures per month. The permtittee received unit doses only; the department administered a full spectrum of diagnostic studies. The hospital's use of therapeutic radiopharmaceuticals was limited to I-131 whole body CA follow up studies.

Performance Observations

This inspection consisted of interviews with selected licensee personnel, a review of selected records, a tour of the nuclear medicine department, and independent measurements. The inspector observed the permittee staff perform dose calibrator QA checks and administer one diagnostic dosage. The inspection included observations of security of byproduct material, confirmatory source inventories, use of personnel monitoring, and postings.

NRC FORM 591M PART 3
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☑ Field Office Inspection

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## PROGRAM SCOPE

VA Wichita
This location was inspected on October 15, 2018, with continuing followup through October 30, 2018.
This was a routine, unannounced inspection of a permittee under the Department of Veterans Affairs (DVA) Master Materials License (MML). The facility was an 81 bed medical center under the St. Louis VA permit that operated an active nuclear medicine department, including PET/CT diagnostic imaging. The permit authorized broad scope activities and was assigned a program code 02110 (medical broad scope) by the DVA. The RSO on the permit was located at the St. Louis VA facility, and conducted an audit of permitted activities at the Wichita facility two times per year. The Wichita VA nuclear medicine department was staffed by four full-time certified nuclear medicine technologists (CNMT). Two CNMT's conducted diagnostic nuclear medicine studies in the medical center's cardiology department, and the other two CNMT's conducted PET diagnostic studies in the PET/CT department. The cardiology department, where about 7 diagnostic studies were conducted per day, had 2 imaging rooms and a hot lab. The PET department performed about 2 - 3 studies per day, and had one imaging room and one hot lab. The facility received diagnostic unit doses from a local radiopharmacy, and did not perform any radiopharmaceutical or sealed source therapy procedures.

Performance Observations

The inspector interviewed three CNMT's and observed the preparation, handling, and injection of radionuclides for diagnostic procedures, as well as the use of protective clothing, and whole body and extremity dosimetry. The inspector toured both nuclear medicine departments and observed the use of access-controlled coded entry systems for both hot labs. The inspector also noted the availability of calibrated survey meters and associated radiation protection equipment, e.g., remote handling tools, syringe shields, dose calibrators, and lead shielding.

The inspector reviewed a select sampling of records related to the use, storage, and disposal of permitted radionuclides in both nuclear medicine departments. This included results of the permittee's occupational dosimetry for calendar years 2017 and 2018 to date, records of survey meter calibration, and waste disposal records.

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## PROGRAM SCOPE

(cont'd. from previous page)
The inspector also observed two CNMT's demonstrate how smears for contamination of incoming packages and restricted areas were performed. The inspector reviewed a random selection of documented results of these surveys, instrumentation used to analyze smears, and associated instrument calibration procedures.

From October 15 - 30, the inspector conducted an additional review of results of package and area smears taken in the nuclear medicine department in cardiology. The review pertained to a follow-up on what appeared to be elevated background counts when compared to sample counts. The well counter was located in a patient imaging room. Background radiation from injected patients may have contributed to the high background values. There was no indication that the permittee failed to comply with its permit or regulatory requirements.

The inspector discussed the issue with the RSO. The RSO stated that the radiation safety office was planing to conduct a regularly scheduled audit of the Wichita location before the end of the year. The RSO also indicated that he was in the process of reviewing smear analysis procedures used at each location under their permit to assure consistency. The PET department conducted and analyzed its smears independent of the cardiology department. No issues were identified in the PET department. Permittee staff committed to using the well counter in the PET department to analyze smears taken in the cardiology department until the issue is resolved.

The inspector followed-up on an event (EN 52779 and NMED item number 170282) that was reported by the licensee on May 31, 2017. The event pertained to receipt of a package that contained unit doses of fluorine-18 (F-18). The package had removable contamination which exceeded the reporting threshold. The permittee later concluded that an F-18 unit dose was in the dose calibrator when the CNMT was counting a package smear, and that the well counter was picking up radiation from the F-18 unit dose. The inspector noted that the dose calibrator and well counter were adjacent to each other.

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## PROGRAM SCOPE

(cont'd. from previous page)
The inspector observed a CNMT count a blank smear in the well counter while an F-18 unit dose was in the dose calibrator. The CNMT also counted the blank smear in the well counter without an F-18 unit dose in the dose calibrator. The inspector confirmed that the well counter detected the F-18 and contributed significantly to instrument readings. The inspector also confirmed that the licensee and permittee took corrective actions described in NMED item number 170282.

No violations of NRC requirements were identified.