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
Saint Francis Medical Center 211 Saint Francis Dr. Cape Girardeau, MO 63703 REPORT NUMBER(S) 2018001	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
030-02269	24-00158-03	5/14/2018 to 6/06/2018

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)

Contrary to Title 10 of the Code of Federal Regulations (CFR) 35.2075 (a) and (c), from June 23, 2016 to May 14, 2018, the licensee failed to retain a record of the basis for authorizing the release of an individual in accordance with 10 CFR 35.75 for 3 years after the date of release of the individual. Specifically, the licensee did not retain the records for the release criteria of any of its iodine-131 administrations during this time period.

The cause of the violation was that the licensee was not aware of the requirement. As corrective action, the licensee performed calculations using Regulatory Guide 8.39 and determined that none of the patients exceeded the 5 mSv limit. The licensee retrained the staff on of the release criteria requirement and committed to retain records.

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	Greg K. Rushing		6/22/18
NRC INSPECTOR	Luis Nieves Folch		6/22/18
BRANCH CHIEF	Aaron T. McCraw		6/22/18

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

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87131	03.01-03.08

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
02240	2	Mark L. Gates, M.D., RSO	(573) 331-3000

☑ Main Office Inspection Next Inspection Date: May 14, 2020

☐ Field Office Inspection

☐ Temporary Job Site Inspection

PROGRAM SCOPE

This was a routine, unannounced inspection of a 300-bed hospital authorized to use byproduct material under 10 CFR 35.100, 200, 300, 500 and 1000(Y-90) at its campus in Cape Girardeau, Missouri. At the time of the inspection, the licensee performed a comprehensive spectrum of diagnostic and therapeutic administrations of radiopharmaceuticals, including 15 diagnostic procedures daily, 15 cardiac stress tests daily, 4 FDG(Intego machine) infusions daily, and 5 Y-90 Sir-Spheres in 2017. The licensee does not possess any sources under its 35.500 authorization. The licensee staffs their department with four full-time technologists in their three hot labs from Mondays to Fridays. The licensee retains a consultant health physicist to perform annual audits of the radiation safety program.

PERFORMANCE OBSERVATIONS

The inspector toured the nuclear medicine laboratory and observed a nuclear medicine technologist (NMT) demonstrate package receipt surveys and instrument quality control checks. The NMT demonstrated preparation and administration of radioactive material, because there were no patients administrations scheduled at the time of the inspection. The inspector performed independent surveys of the hot lab and other areas of the nuclear medicine department and found no contamination or exposures to members of the public distinguishable from background. The NMT demonstrated adequate knowledge of radiation safety principles and practices through interviews. The inspector reviewed quarterly audit reports, spill reports, documentation of package receipt, area surveys, instrument quality control, waste disposal, and employee training. The inspector also reviewed monthly dosimetry reports, which indicated annual whole-body and extremity doses below regulatory limits.

During the last inspection one violation was identified for an Authorized User's failure to sign and date a written directive. The inspector reviewed the corrective actions taken by the licensee by reviewing written directives and interviewing staff. The inspector identified no evidence to suggest that the violation reccurred and closed the previous violation.

One violation was identified during this inspection, concerning the licensee's failure to retain a record of the basis for authorizing the release of individuals following administrations of iodine-131, as documented on Part 1 of this Form.