NRC FORM 591M
(09-11-2024)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Saint Francis Medical Center 211 Saint Francis Dr. Cape Girardeau, MO 63703 **Report Number(s)** 2025001	Region III U. S. Nuclear Regulatory Commission 2056 Westings Avenue, Suite 400 Naperville, IL 60563-2657

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-02269	24-00158-03	May 21, 2025

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

Contrary to 10 CFR 35.70(a), on April 4, 2024, and June 13, 2024, the licensee failed to perform the end-of-the day areas survey where unsealed byproduct material requiring a written directive was prepared for use or administered. As corrective action, licensee retrained the nuclear medicine technologists on performing the end-of-the day areas survey when unsealed byproduct material requiring a written directive is used or administered.

B. The following violation(s) is/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 AND DATE
LICENSEE'S REPRESENTATIVE		
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	ZAHID SULAIMAN Digitally signed by ZAHID SULAIMAN Date: 2025.06.09 15:26:06 -05'00'
BRANCH CHIEF	Rhex A. Edwards, Chief, MIB	Digitally signed by RHEX EDWARDS Date: 2025.06.10 16:13:39 -05'00'

Add Continuation Page

NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Saint Francis Medical Center	030-02269	24-00158-03

4. Report Number(s):	5. Date(s) of Inspection:
2025001	May 21, 2025

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Zahid Sulaiman, Health Physicist	02240	2	87130

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Gwen Long, Manager-Imaging Services	glong@sfmc.net	(573) 331-5175

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☐ Hybrid	
☑ Routine	☑ Main Office	05/21/2027
☐ Announced	☐ Field Office	☑ Normal
☐ Non-Routine	☐ Temporary Job Site	☐ Extended
☑ Unannounced	☐ Remote	☐ Reduced
		☐ No change

16. Location(s) Inspected List:

Main Hospital: 211 Saint Francis Dr., Cape Girardeau, MO 63703

17. Scope and Observations:

This was an unannounced routine inspection of a 306-bed hospital authorized to use byproduct materials for medical purposes permitted by 10 CFR 35.100, 35.200, 35.300, and 35.1000 (Y-90, TheraSpheres and SIR-Spheres, for possession and storage only with intent to dispose). The nuclear medicine department was staffed with five full-time nuclear medicine technologists (NMTs) who rotate between the nuclear medicine, PET clinic, and Heart clinic. The NMTs performed approximately 5-8 diagnostic doses, 7-9 fluorine-18 doses for PET/CT scan, and 8-13 cardiac stress tests daily. The diagnostic administrations included various imaging procedures using technetium-99m (Tc-99m), primarily for cardiac stress test, bone scans, HIDA, lung scan, and gastric emptying studies. The NMT also performed approximately 15-20 iodine-131 hyperthyroid and thyroid ablation annually. The licensee suspended the medical use of Y-90 program and amended the license. The license amendment #86 dated April 25, 2025, put the Y-90 microspheres for possession and storage only with intent to dispose. Prior to suspending the Y-90 program, the licensee performed approximately 10-15 Y-90 microspheres treatments annually.

PERFORMANCE OBSERVATIONS

This inspection consisted of a tour of the nuclear medicine department, PET clinic, and heart clinic; interviews with select licensee personnel; a review of select records; an observation of security of the materials; and independent measurements. The inspector observed three diagnostic administrations of licensed materials including dose preparation and disposal. The inspector verified the location of sealed sources from the licensee's most recent inventory, and all sources were accounted for. The inspector had the NMT demonstrate the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, and spill response with no issue noted. The inspector had the NMT describe and demonstrate the Y-90 dose preparation, pre/post vial dose measurement, and dose calculation to the treatment sites. The inspector reviewed selected written directives and treatment plans for various radiation therapy procedures. During this inspection, the inspector noted several written directives were not dated and signed by the authorized user before the administration of these therapeutic dosages, this violation was identified and document in the reactive inspection (inspection report # 030-02269/2024001), a SLIII violation of 10 CFR 35.40(a) was issued

Materials Inspection Record (Continued)

during the reactive inspection. Through these demonstrations and discussions, the inspector found that the licensee personnel were knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: quarterly program audits, radiation safety committee minutes, written directives, package receipts, waste disposal records, DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, spill report, sealed source leak tests and inventory, daily area surveys, weekly wipe tests, and dosimetry records. The inspectors performed independent and confirmatory radiation measurements which indicated results consistent with licensee survey records and postings.

At the time of this inspection, the inspector did not review the corrective actions related to reactive inspection report # 030-02269/2024001, issued on March 20, 2025. These corrective actions will be reviewed during the non-routine enforcement follow-up inspection.

During a document review, the inspector noted that the licensee had identified a violation for failing to perform the end-of-the day areas survey where unsealed byproduct material requiring a written directive was prepared for use or administered. Specifically, on April 4, 2024, and June 13, 2024, the licensee failed to conduct the required end-of-the day area surveys where the unsealed byproduct materials requiring a written directive was used or administered. As a corrective action, the licensee retrained the nuclear medicine technologists on performing the end-of-the day area surveys as required by 10 CFR 35.70(a). This violation was assessed as Severity Level IV (SLIV) per NRC Enforcement Policy section 6.3.d.3 because it was a failure to follow a procedure. It was also determined to be an isolated incident, that did not demonstrate programmatic weakness, and had limited consequences similar to Enforcement Policy section 6.3.d.1. Since this SLIV violation was licensee self-identified, non-repetitive, non-willful, and corrective action has already been implemented to prevent recurrence, it met the criteria to be considered as a NCV per section 2.3.2.b of the NRC Enforcement Policy

Signature and Date - Branch Chief

Digitally signed by RHEX EDWARDS
Date: 2025.06.10 16:11:34 -05'00'