



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2056 WESTINGS AVENUE, SUITE 400
NAPERVILLE, IL 60563-2657

March 20, 2025

EA-24-114
EAF-RIII-2024-0018
EN 57110
NMED NO. 240165 (Closed)

Justin Davison
President and Chief Executive Officer
Saint Francis Medical Center
211 Saint Francis Drive
Cape Girardeau, MO 63703

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$14,400, NRC REACTIVE INSPECTION REPORT NO. 03002269-2024001 (DRSS)
– SAINT FRANCIS MEDICAL CENTER

Dear Justin Davison:

This letter refers to the inspection conducted on May 14-15, 2024, at your Cape Girardeau, Missouri, facility. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a medical event that occurred on May 6, 2024; your staff reported this medical event to the NRC on May 7, 2024 (Event Notification 57110). The medical event involved an overdose to the treatment site utilizing yttrium-90 microspheres within the TheraSphere™ brachytherapy system. The inspectors, Deborah Piskura and Laura Dresen, as well as Rhex Edwards, conducted a final exit briefing with Lisa Newcomer and members of your staff on November 7, 2024, to discuss the circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action. The inspection report was issued on December 6, 2024, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML24318C454. ADAMS is accessible from the NRC website at <https://www.nrc.gov/reading-rm/adams.html>.

In the December 6, 2024, letter transmitting the inspection report, we informed you that four apparent violations were being considered for escalated enforcement action, including a civil penalty. In the letter, we provided you the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference (PEC) or engaging the NRC in Alternative Dispute Resolution (ADR) mediation. In a letter dated December 13, 2024, (ML24351A083), Lisa Newcomer responded to the letter informing us of your decision to attend a PEC.

On February 4, 2025, a PEC was conducted in the Region III office with members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions.

Based on the information developed during the inspection, the information that you provided during the conference (ML25035A101), and the information you provided in your February 11, 2025, letter (ML25052A141), the NRC has determined that violations of NRC requirements occurred and is proceeding with enforcement action. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and the circumstances surrounding them are described in detail in the subject inspection report.

During a palliative treatment of a liver tumor on May 6, 2024, you overdosed the treatment site by approximately 300 percent using yttrium-90 microspheres within the TheraSphere™ delivery set. The authorized user prescribed a palliative dose of 90 Gray to the tumor within the left lobe of the liver. The authorized user worked with a representative from the device manufacturer to plan this treatment. A medical event occurred due to a lack of management oversight of the yttrium-90 program. Contributing to this was unclear email communications and instructions from the authorized user prior to nuclear medicine staff ordering the microspheres from the device manufacturer. Your nuclear medicine staff ordered two dosages of yttrium-90 TheraSphere™ which were administered to the patient on May 6, 2024, resulting in a dose of 300 percent greater than prescribed. This administration also resulted in an unintended dose to the patient's lungs of 232 percent greater than initially planned from this treatment. You concluded that the medical event would not result in adverse health consequences for the patient. You reported this event to the NRC on May 7, 2024 (EN 57110) and provided a written report of the event on May 22, 2024 (ML24150A053).

Following the event, the NRC retained the services of a medical consultant. The medical consultant indicated the delivered dose exceeded the threshold for potential health effects on the liver. However, the patient's medical oncologist indicated that as of January 27th, 2025, the patient did not have any identifiable health effects on the liver as a result of the procedure, and the patient has been able to continue with their treatment plan for their underlying condition.

Four violations were identified regarding your failure to: (1) have written directives dated and signed by an authorized user before the administration of therapeutic doses of radiation from byproduct material; (2) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; (3) provide training in your procedures to individuals involved in yttrium-90 microspheres administrations, commensurate with the individual's duties to be performed; and (4) through the Radiation Safety Officer, ensure that the radiation safety activities were being performed in accordance with Licensee-approved procedures and regulatory requirements, specifically related to yttrium-90 microspheres administrations.

Each of these violations represented a substantial programmatic failure to implement written directives or procedures for administrations requiring a written directive or a failure to train personnel in those procedures, and these failures resulted in an actual consequence, a medical event. Fortunately, based on the referring physician's medical evaluation of the patient, the medical event did not result in serious injury or loss of life. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level (SL) II problem. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Because the violations were categorized as a Severity Level II problem, the NRC considered whether credit was warranted for Identification and Corrective Action in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The NRC determined that credit was not warranted for Identification because the violations were identified by the NRC during inspection of a reported medical event. The NRC determined that credit was warranted for Corrective Action because you took prompt and comprehensive corrective actions following the medical event and the identification of the violations. These corrective actions included:

- suspending the yttrium-90 program and amending the license to authorize yttrium-90 for storage only pending disposal;
- revising Licensee policy “Administration of Dosages Requiring a Written Directive” to remove outdated references to 10 CFR Part 35, update the radiopharmaceuticals the Licensee administers that require a written directive, add content to promote safety culture, and revise the medical event determination content to align with 10 CFR 35.3045;
- updating and providing training to nuclear medicine staff on the requirement for written directives to be filled out, signed, and dated by the authorized user prior to the administration; and
- committing to provide training to authorized users and nuclear medicine technologists on any therapeutic radiopharmaceuticals requiring written directives prior to performing the initial administration and annually thereafter.

Therefore, to emphasize the importance of management oversight of the yttrium-90 program and of prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$14,400 for the SL II problem (\$14,400 is the amount assigned to “medical” (Line “e”) in Table A of Section 8.0 of the Enforcement Policy and modified by Table B of the same section). In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

You may pay the proposed civil penalty in accordance with NUREG/BR-0254 which can be found on the NRC’s website at <https://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0254/index.html>. When using NUREG/BR-0254 to pay the civil penalty, the invoice number should be used as the “enforcement action identifier” when submitting your payment through one of the approved methods listed in the brochure. The NRC may consider a request for additional time to pay the proposed civil penalty, including the option to enter into an installment agreement, if payment of the civil penalty as a lump sum in the required timeframe would pose a financial hardship. To request additional time to pay, you must submit a written request, with appropriate justification explaining your financial hardship, to NRCCollections.Resource@nrc.gov. All requests should be submitted in sufficient time to allow the NRC the ability to review your request for additional time to pay before the 30-day payment period expires.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the “mediator”) works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral

mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. **If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Diana Betancourt-Roldan, Enforcement Officer at 630-810-4373 within 10 days of the date of this letter.** You may also contact both ICR and Diana Betancourt-Roldan for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil penalties and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report No. 03002269/2024001 (DRSS) (ML24318C454), your PEC presentation (ML25035A101), and your letter dated February 11, 2025 (ML25052A141). Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/current.html>.

If you have any questions concerning this matter, please contact Diana Betancourt-Roldan of my staff at 630-810-4373.

Sincerely,



Signed by Giessner, Jack
on 03/20/25

John B. Giessner
Regional Administrator

Docket No. 030-02269
License No. 24-00158-03

Enclosure: Notice of Violation and Proposed
Imposition of Civil Penalty
Civil Penalty Invoice No.
EAF-RIII-2024-0018

cc w/encl: Lisa Newcomer, RRT, MBA, FACHE,
Vice President, Regional Operations
Jamie C. Eisenberg, MHA, CNMT,
Radiation Safety Officer
State of Missouri

Letter to J. Davison from J. Giessner dated March 20, 2025.

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
 \$14,400, NRC REACTIVE INSPECTION REPORT NO. 03002269-2024001 (DRSS)
 – SAINT FRANCIS MEDICAL CENTER

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OFFICE	RIII-EICS		RIII-DRSS		RIII-EICS		OE	
NAME	JDraper:bw		REdwards		DCurtis		JPeralta for DPelton	
DATE	2/26/2025		2/28/2/25		3/3/2025		3/17/2025	
OFFICE	NMSS		OGC for NLO		RIII-EICS		RIII-ORA	
NAME	MBurgess		RAugustus		DBetancourt-Roldan		JGiessner	
DATE	3/17/2025		3/17/2025		3/20/2025		3/20/2025	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Saint Francis Medical Center
Cape Girardeau, Missouri

Docket No. 030-02269
License No. 24-00158-03
EA-24-114
EAF-RIII-2024-0018

During an NRC inspection conducted on May 14-15, 2024, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

Contrary to the above, prior to May 6, 2024, the Licensee failed to have a written directive that was dated and signed by an authorized user before the administration of a therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. Specifically, between 2023 and May 6, 2024, the Licensee administered 10 therapeutic dosages of yttrium-90 microspheres and did not have written directives that were dated and signed by the authorized user before the administration of these therapeutic dosages.

- B. Title 10 CFR 35.41(a) states that, for any administration requiring a written directive, the Licensee shall develop, implement, and maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive.

Contrary to the above, as of May 6, 2024, the Licensee did not develop, implement, or maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive. Specifically, the Licensee did not develop, implement, or maintain written procedures for administering yttrium-90 microspheres.

- C. License Condition 14.C. of License No. 24-00158-03, Amendment No. 83 provides: "Except as specifically provided otherwise in this license, the Licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the Licensee's letter dated March 7, 2017."

The Licensee's letter dated March 7, 2017, states, in part that "we [the Licensee] commit to provide training to all individuals involved in Y-90 SIR.Spheres and TheraSpheres™ use, commensurate with the individual's duties to be performed. This training will be provided to all individuals preparing, measuring, performing dosimetry calculations, and administering microspheres."

Enclosure

Contrary to the above, prior to May 6, 2024, the Licensee failed to provide training to all individuals involved in yttrium-90 microsphere use, commensurate with the individual's duties to be performed. Specifically, the Licensee failed to provide training in the Licensee's TheraSphere™ use that was commensurate with the duties to be performed by individuals, including the nuclear medicine staff, who were involved with ordering, preparing, measuring, and performing dosimetry calculations for yttrium-90 microspheres administrations.

- D. Title 10 CFR 35.24(b) states, in part, that a Licensee's management shall appoint a Radiation Safety Officer who agrees, in writing, to be responsible for implementing the radiation protection program. The Licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with Licensee-approved procedures and regulatory requirements.

Contrary to the above, prior to May 6, 2024, the Licensee, through the Radiation Safety Officer, failed to ensure that radiation safety activities were being performed in accordance with Licensee-approved procedures and regulatory requirements. Specifically, the Radiation Safety Officer failed to assure training occurred consistent with License Condition 14.c and assure compliance with the requirements of 10 CFR 35.40(a) to provide signed and dated written directives. Further, the Radiation Safety Officer failed to assure that the Licensee's policies and procedures provided high confidence that (a) the patient's or human research subject's identity is verified before each administration and (b) each administration is in accordance with the written directive (quality management program), including the use of yttrium-90, in accordance with regulatory requirements.

This is a Severity Level II problem (Enforcement Policy Section 6.3.b.3).
Civil Penalty - \$14,400. (EA-24-114) (EAF-RIII-2024-0018)

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective steps that have been taken and the results achieved; and (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved is already adequately addressed on the docket in Inspection Report No. 03002269/2024001 (DRSS) (ML24318C454), the Licensee's PEC presentation (ML25035A101), and the Licensee's letter dated February 11, 2025 (ML25052A141). However, if the description therein does not accurately reflect the Licensee's position or its corrective actions, the Licensee is required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if the Licensee chooses to respond, the Licensee must clearly mark its response as a Reply to a Notice of Violation, and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region III and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above by submitting the payment in accordance with NUREG/BR-0254.

The Licensee may protest the imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the

Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an “Answer to a Notice of Violation” and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201 but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: David Pelton, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III and the Document Control Center, Washington, DC 20555-0001.

If the Licensee chooses to respond, the response will be made available electronically for public inspection in the NRC Public Document Room or in ADAMS. To the extent possible, the Licensee’s response should not include any personal privacy, proprietary, classified or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then the Licensee should provide a bracketed copy of its response that identifies the information that should be protected and a redacted copy of the response that deletes such information. If the Licensee requests that such material is withheld from public disclosure, it must specifically identify the portions of the response that it seeks to have withheld and provide in detail the bases for the claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

In accordance with 10 CFR 19.11, the Licensee may be required to post this Notice within two working days of receipt.

Dated this 20th day of March 2025.



Saint Francis Medical Center
211 ST. FRANCIS DRIVE
CAPE GIRARDEAU, MO 63703



03/20/2025

Address/Customer Information

Saint Francis Medical Center
211 ST. FRANCIS DRIVE
CAPE GIRARDEAU, MO 63703

Customer Codes

Account Code: L00000830/1

Bill Information

Bill Number: EAF-RIII-2024-0018
Amount Due: \$14,400.00
Due Date: 04/19/2025

Contact Us

Phone Number: 301-415-7554
Fax Number: 301-415-4135
Email Address: Fees.Resource@nrc.gov

Remit Payment Online at:

www.pay.gov
(see NUREG/BR-0254,
Payment Methods brochure for
other electronic payment options)

Bill Summary

Initial Charges	\$14,400.00
Discount	0.00
Surcharge	0.00
Interest Charges	0.00
Penalty Charges	0.00
Admin Charges	0.00
Bill Amount	\$14,400.00
Collected	0.00
Applied Credit	0.00
Adjustments	0.00
Amount Due	\$14,400.00

Credit Summary

Applied Credit	\$0.00
Unapplied Credit	0.00
Credit Total	\$0.00

Comments:

For questions, contact the NRC Financial Services and Operations Branch at (301) 415-7554 or by email at Fees.Resource@nrc.gov. For NRC debt collection procedures, including interest and penalty provisions, see 31 U.S.C. 3717, 4 CFR 101-105 and 10 CFR 15.

If this invoice is related to an Order Imposing a Civil Penalty, Saint Francis Medical Center is required to pay the Civil Penalty within 30 days of the Order date. If payment is in response to a Notice of Violation and Proposed Imposition of a Civil Penalty, please follow the instructions in the Notice. The NRC may consider a request for additional time to pay the Civil Penalty, including the option to enter into an installment agreement, if appropriate. All requests for additional time to pay an invoice must be submitted in writing, with appropriate justification, to NRCCollections.Resource@nrc.gov, and should be submitted sufficiently ahead of time to allow the NRC time to review the request for additional time to pay within the 30-day payment period. This Invoice is related to the Civil Penalty proposed or imposed under EAF-RIII-2024-0018 issued to Saint Francis Medical Center. Please include this reference number on your payment method (see attached Payments Methods Brochure).

Please see the NUREG/BR-0254, Payment Methods brochure for instructions on how to make domestic and international payments. EFFECTIVE OCTOBER 1, 2024, THE NRC WILL ONLY ACCEPT ELECTRONIC PAYMENT METHODS. PAPER METHODS OF PAYMENT, INCLUDING CHECKS, WILL NO LONGER BE ACCEPTED. Please refer to the terms and conditions brochure for information on interest, penalties, and administrative fees associated with delinquent payments. Please reference the invoice number on the remittance.

Customer Information

L00000830/1
Saint Francis Medical Center
211 ST. FRANCIS DRIVE
CAPE GIRARDEAU, MO 63703

Change of Address:

Phone: _____

Remit Payment Online at:

www.pay.gov
(see NUREG/BR-0254,
Payment Methods brochure for
other electronic payment options)

This Payment References the following Bill:

EAF-RIII-2024-0018

Outstanding Amount Due: \$14,400.00

Amount Enclosed: _____