UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD – SUITE 102
KING OF PRUSSIA, PA 19406-1415

June 5, 2023

EA-23-037

Thomas Burke, President
Saint Francis Hospital and Medical Center
114 Woodland Street
Hartford, Connecticut 06105-1299

SUBJECT: SAINT FRANCIS HOSPITAL AND MEDICAL CENTER - NRC INSPECTION REPORT NO. 03001246/2022001 AND NOTICES OF VIOLATION

Dear Thomas Burke:

This letter refers to the safety and security inspections conducted on August 22-23, 2022, at your Hartford, Connecticut facility (Inspection Report No. 03001246/2022001, enclosed). This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The enclosed reports present the results of these inspections, as well as the follow-up virtual meeting held February 23, 2023, to confirm the status of the security program once access to computer files was established. An exit meeting was held May 9, 2023, with you and members of your staff to discuss the findings of the inspection.

Based on the results of this inspection, the NRC has determined that four Severity Level IV safety violations and four Severity Level IV security violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Because the issues surrounding the four security violations are related, they are being collectively characterized as a single SL IV Problem. The violations are cited in the non-public enclosed Notice of Violation (Notice) and the circumstances surrounding them and corrective actions taken by your facility are addressed and documented, in part, in the attached inspection report, as well your letter dated October 12, 2022 (ML22318A082) and in the communication dated February 23, 2023 (ML23129A115). The violations are being cited in the Notice because they were identified by the NRC.

Effective management of the radiation safety program is vital for licensees to achieve safe and compliant operations, and during the inspection, the NRC-identified deficiencies were not being appropriately raised and resolved and attributed the cause to a lack of awareness of certain regulatory requirements by the radiation safety officer and radiation safety committee, and an inadequate reporting structure. Therefore, you are required to respond to the specific violations cited in the Notice, and are requested to specifically address: 1) how you plan to improve the

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Upon separation, this cover letter is DECONTROLLED.

management oversight of your radiation safety program; 2) how you plan to monitor the effectiveness of your actions to improve the management oversight of your radiation safety program; and, 3) why you believe your corrective actions for these findings will be successful in preventing similar findings in the future. Please follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response. The NRC review of your response will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC Public Document Room located at NRC Headquarters in Rockville, MD, and from the NRC's document system, the Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. However, the material enclosed herewith contains Security-Related Information as described above. Therefore, the material in the enclosures will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at Robin.Elliott@nrc.gov.

Thank you for your cooperation.

Sincerely,

Anne E. DeFrancisco

Digitally signed by Anne E. DeFrancisco
Date: 2023.06.05 17:15:11 -04'00'

Anne E. DeFrancisco, Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security
Region I

Docket No. 030-01246
License No. 06-00854-03

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03001246/2022001 Safety
3. Notice of Violation (non-public)
4. Inspection Report No. 03001246/2022001 Security (non-public)

cc w/ enclosures
Gregory Hisel, Radiation Safety Officer

cc w/o enclosures 3 & 4
State of Connecticut

SUBJECT: SAINT FRANCIS HOSPITAL AND MEDICAL CENTER - NRC INSPECTION REPORT NO. 03001246/2022001 AND NOTICES OF VIOLATION DATED JUNE 5, 2023

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NOTICE OF VIOLATION - SAFETY

Saint Francis Hospital and Medical Center (SFHMC)
Hartford, Connecticut

Docket No. 030-01246
License No. 06-00854-03

During an NRC inspection conducted on August 22-23, 2022, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. License Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated October 10, 2016 (ADAMS Accession No.: ML16320A261).
The letter states, in part, that for Y-90 therapies, "the written directive shall include the patient or human research subject's name; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the model of spheres (e.g. TheraSphere® or SIR-spheres®) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis." Contrary to the above, between October 2020 and August 2022, SFHMC did not include the treatment site on its written directives for Y-90 therapies. Specifically, the written directive did not include the organ that was treated.
This is a Severity Level IV violation (Enforcement Policy Section 6.3).

B. License Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014 (ADAMS Accession No.: ML14192B052).
The application includes a policy entitled, "Radiation Exposure Monitoring of Personnel" dated 2014, which states, "All personnel working with radiation or radioactive materials shall wear on the trunk of the body a personal dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation (NVLAP) processor."
Contrary to the above, on June 24, 2021, SFHMC did not assure that all personnel working with radioactive materials wear on the trunk of the body a personal dosimeter that is processed and evaluate by an accredited NVLAP processor. Specifically, an authorized user for 10 CFR 35.1000 activities performed a Y-90 therapy and did not wear a personal dosimeter.
This is a Severity Level IV violation (Enforcement Policy Section 6.3).

C. License Condition 16A of License No. 06-00854-03 requires, in part, that sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months.
Contrary to the above, between March 2021 and August 2022, SFHMC did not test sealed sources for leakage and/or contamination at intervals not to exceed 6 months. Specifically, during this period leak tests were performed at intervals of seven and ten months.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

D. 10 CFR 20.1201(f), requires, in part, that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

Contrary to the above, from October 2020 to August 2022, SFHMC did not reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the Nuclear Medicine department employed per diem employees and have not obtained information regarding radiation exposures received at other employers to reduce the allowed exposure at SFHMC.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

Pursuant to the provisions of 10 CFR 2.201, Saint Francis Hospital and Medical Center (SFHMC) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-23-037" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your 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 please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described

in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated This 5th day of June 2023

Enclosure 1

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03001246/2022001
Docket No.	03001246
License No.	06-00854-03
Licensee:	Saint Francis Hospital and Medical Center
Address:	114 Woodland Street Hartford, Connecticut 06105-1299
Inspection Dates:	August 22-23, 2022, in office review through April 27, 2023
Exit Meeting:	May 9, 2023

Inspector:

Robin L. Elliott June 1, 2023

Robin L. Elliott date
Senior Health Physicist
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Approved By:

Anne DeFrancisco June 5, 2023

Anne DeFrancisco date
Chief
Medical and Licensing Assistance Branch
Division of Radiological Safety and Security

Enclosure 2
Inspection Report No. 03001246/2022001

EXECUTIVE SUMMARY

Saint Francis Hospital and Medical Center
NRC Inspection Report No. 03001246/2022001

A routine announced safety inspection was performed at Saint Francis Hospital and Medical Center (SFHMC), on August 22-23, 2022. In office review concluded on May 9, 2023, with the exit meeting. The inspection was conducted with regard to NRC radioactive materials license number 06-00854-03; the inspection was performed in accordance with inspection procedures 87131, 87132, 87122. The inspection focused on the performance of the licensee's program through direct observation of work activities, interviews with licensee workers, demonstrations by workers performing licensed activities, independent measurements of radiation conditions at the licensee's facilities, and a review of selected records.

During the inspection four severity Level IV violations were identified. The violations involved: 1) the failure to include the organ treated for Y-90 microsphere therapies; 2) the failure of an Authorized User to wear dosimetry during a Y-90 therapy treatment; 3) the failure to perform leak tests on the blood irradiator at the required six-month interval; and 4) the failure to obtain occupational radiation exposures for per diem employees.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed the organization and scope of SFHMC's programs through direct observation of work activities, interviews with licensee workers, and review of selected records.

b. Observations and Findings

SFHMC was a large community hospital that was authorized for 35.100, 35.200, 35.300, 35.400, 35.600 high dose rate remote afterloader (HDR), 35.1000 microspheres, various sealed sources in storage and for instrument calibration and a self-shielded blood irradiator. The program was supervised by a Radiation Safety Committee (RSC) which met quarterly. The Radiation Safety Officer (RSO) was a consultant health physicist that was on site regularly and was supported by a full-time Assistant RSO. The RSO performed the annual program review of the radiation safety program.

The Nuclear Medicine (NM) Department consisted of three areas: general nuclear medicine, cardiology and positron emission tomography (PET). There were three cameras in general nuclear medicine, two cameras in cardiology and one camera in PET. There were two treadmills in cardiology. There was one hot lab in each nuclear medicine location. The department was staffed with six full-time nuclear medicine technologists (NMT) and two per diem NMTs all of whom rotated through all three areas.

The Radiation Oncology (RO) Department was staffed with two full-time authorized medical physicists (AMP) and three locum AMPs. There were three authorized users (AU) for 35.400, four AUs for 35.600 HDR and two AUs for 35.1000 (microspheres). Gynecological treatments composed the majority of the HDR oncology procedures. Radium-223 (Ra-223) Xofigo therapies were performed in the RO department under the supervision of two AUs. A strontium-90 (Sr-90) eye applicator remained in storage.

The Blood Bank utilized a gamma irradiator to sterilize blood samples. It was staffed 24 hours a day, 365 days a year. A manager of the area monitored the use of the irradiator and arranged for all required maintenance.

2. Review of Licensed Activities

a. Inspection Scope

The inspectors reviewed licensed activities through direct observation of work activities, interviews with workers, demonstrations by workers performing tasks regulated by NRC, and a review of selected records.

b. Direct Observations, Interviews, and Records Review

The inspectors toured all the NM facilities and observations included: package receipt, dose preparation, injection, scanning, patient interaction, security of licensed material, surveys, and waste disposal. Interviews were conducted with the RSO, Assistant RSO, NMTs, and representatives of administration. NM performed approximately 20 procedures per day including a wide variety of general studies. Unit doses were used for all scheduled tests and received from Cardinal Health or Sofie. Radionuclides used included Tc-99m, Fluorine-18, Gallium-68, Xenon-133, Indium-111, Iodine-123, Iodine-131 (I-131), Ra-223 and Sr-90. All doses were assayed prior to administration.

The inspectors toured the RO department including the HDR vault and control room, and sealed source storage. RO performed 10 CFR 35.300 activities: Xofigo therapy, 10 CFR 35.400 activities: Prostate implants, 10 CFR 35.600 activities: HDR for gynecological cancer treatments using only vaginal cylinders, and 10 CFR 35.1000 activities: Y-90 microsphere treatments. In 2021, six patients received Xofigio therapy which consisted of regime of six injections. Typically, three to six patients were treated per year. Since October 2020, five prostate implants were performed and during the inspection, the licensee submitted an amendment request to terminate the program. The last implant was performed in February 2022; used seeds were stored in the RO hot lab for decay after which they were disposed. The Sr-90 eye applicator remained in storage pending disposal. The RO hot lab also included the following sources in-storage: two Sm-153 sources, an Eu-154 source and a C-14 source. SFHMC was in the process of working with a contractor to dispose of these legacy sources which was expected to occur in November 2022. Greater than 30 patients per year were treated with the HDR receiving three to five fractions each. The inspector observed a spot check and no concerns were noted. The HDR was adequately secured as were all the keys for the HDR unit and console. For Y-90 TheraSpheres, ten treatments had been performed since the last inspection, six of which were done in 2021.

Blood bank staff received irradiator training prior to working in the facility and completed a logbook entry when the irradiator was used. There were no incidents reported involving the irradiator since the last inspection. Maintenance is scheduled every two years and the last visit was May 28, 2021. Emergency procedures and contact information were posted at the irradiator. Two area dosimeters were mounted at the facility which confirmed that radiation levels did not exceed the public dose limit. The inspector performed a radiation survey of the facility which yielded measurements consistent with the licensee postings.

Records Review

The following records were reviewed: irradiator use logs, emergency postings, maintenance logs, written directives, patient release instructions, patient release calculations, written procedures for: radioactive waste disposal and restricted area survey procedures, daily area surveys, weekly area wipes, package receipt, package return, sealed source inventories, sealed source leak tests, dosimetry, waste disposal, instrument calibration, dose calibrator calibrations, annual audits, radiation safety training, and DOT/HAZMAT training. Some records were maintained electronically, and some were maintained on paper.

The following is a summary of the findings from the records review:

1) The written directives for TheraSphere treatments did not include the target organ, although they did identify the location within the liver for the intended treatment. The licensee modified their form to include the target organ.
2) One of the AUs performed a Y-90 treatment on June 24, 2021, without wearing a dosimeter. The dosimeter for the wear period when the therapy was delivered was returned as unused. This was cited as a SL IV violation.
3) With respect to Y-90 waste management, the licensee was not documenting the release survey as required by 10 CFR 35.2092. The waste log only recorded the meter used for surveying the waste upon entry and not an identification of the survey meter and date upon release in addition to the reading. The licensee modified the waste log to record all required information.
4) Leak tests performed on the irradiator were not done within the six-month required frequency: 3/22/2021, 10/21/2021 and 8/17/2022, resulting in a 7-month and 10-month frequency respectively. This was cited as a SL IV violation.
5) The licensee employs per diem employees but was not reaching out to obtain occupational radiation exposures from other employers to add to their SFHMC exposure. None were close to receiving the occupational exposure limit; however, the licensee is required to sum all occupational exposures. This was cited as a SL IV violation.
6) The Radiation Safety Committee did not meet in the 3rd quarter of 2021. The licensee had a deficiency in the security program which may have been addressed sooner had this meeting been held.

Close out of Previous Violations

During the 2020 inspection, the following violations were identified:

1. 10 CFR Part 35.2092 was cited for failure to maintain records for the disposal of Ra-223 waste.

2. 10 CFR Part 35.61 was cited for failure to calibrate annually the survey meter used to perform surveys during Y-90 procedures.

3. 10 CFR Part 35.24(f) was cited for failure to have a Nursing representative on the RSC.

4. Condition 18 of License No. 06-00854-03 for failure to maintain an inventory of the total quantity of radioactive materials stored at SFHMC as used for NM and RO activities, and for not conducting quarterly surveys of the sealed source and brachytherapy storage areas with a survey meter.

All violations were reviewed and SFHMC had implemented corrective actions as submitted in the January 6, 2021, letter (ML21029A141). This closes all the above violations.

Independent Radiation Measurements

Independent radiation surveys were conducted in the irradiator room, sealed source storage area, HDR console, hot labs, camera rooms, injection areas and outside PET quiet rooms; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

Instrument type: Model # 2401-P
NRC S/N: 281068 calibration expiration date: December 17, 2022

c. Conclusions

During this inspection, four severity level IV violations of NRC requirements were identified. The following are the violations:

1. License Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the letter dated October 10, 2016 (ADAMS Accession No.: ML16320A261).

   The letter states, in part, that for Y-90 therapies, "the written directive shall include the patient or human research subject's name; the treatment site; the radionuclide (including the physical form [Y-90 microspheres]); the model of spheres (e.g. TheraSphere® or SIR-spheres®) or manufacturer; the prescribed dose or activity; and, if appropriate for the type of microsphere used, the statement "or dose or activity delivered at stasis."

   Contrary to the above, between October 2020 and August 2022, SFHMC did not include the treatment site on its written directives for Y-90 therapies. Specifically, the written directive did not include the organ that was treated.

2. License Condition 18 of License No. 06-00854-03 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 30, 2014 (ADAMS Accession No.: ML14192B052).

   The application includes a policy entitled, "Radiation Exposure Monitoring of Personnel" dated 2014, which states, "All personnel working with radiation or radioactive materials shall wear on the trunk of the body a personal dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation (NVLAP) processor."

   Contrary to the above, on June 24, 2021, SFHMC did not assure that all personnel working with radioactive materials wear on the trunk of the body a personal dosimeter that is processed and evaluate by an accredited NVLAP processor. Specifically, an authorized user for 10 CFR 35.1000 activities performed a Y-90 therapy and did not wear a personal dosimeter.

3. License Condition 16A of License No. 06-00854-03 requires, in part, that sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months.

Contrary to the above, between March 2021 and August 2022, SFHMC did not test sealed sources for leakage and/or contamination at intervals not to exceed 6 months. Specifically, during this period leak tests were performed at intervals of seven and ten months.

4. 10 CFR 20.1201(f), requires, in part, that the licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person.

   Contrary to the above, from October 2020 to August 2022, SFHMC did not reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. Specifically, the Nuclear Medicine department employed per diem employees and did not obtain information regarding radiation exposures received at other employers to reduce their allowed exposure at SFHMC.

3. Exit Meeting

On May 9, 2023, the inspectors conducted an exit meeting by telephone with SFHMC. The inspection finding and violations were discussed. SFHMC acknowledged the inspection findings and discussed corrective and preventative actions communicated via email on October 12, 2022 (ML22318A082).

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
+ Individual(s) present for onsite inspection debrief on August 23, 2022
^ Individual(s) present for virtual exit meeting on May 9, 2023

#+^ Anne Bilisko, Supervisor of Nuclear Medicine
+^ Thomas Burke, President
+ Terry Caruso, Radiation Oncology Manager
#+^ Gregory Hisel, Radiation Safety Officer
+ Aaron Jones, Authorized Medical Physicist
+ Tony Murtha, Director Radiation Oncology
+^ George Pavlonnis, Authorized Medical Physicist
#+ Michael Reynolds, Director Radiology
+ Erin Sculley, Authorized Medical Physicist
+^ Thomas Shapiro, Chief Medical Officer
#+ Darren Strickland, State of CT

INSPECTION PROCEDURES USED

IP 87131, Nuclear Medicine Programs, Written Directive Required
IP 87132, Brachytherapy Programs
IP 87122, Irradiator Programs
TheraSphere and SIRSpheres Yttrium-90 Microspheres Licensing guidance

LIST OF ACRONYMS USED

AMP	Authorized Medical Physicist
AU	Authorized User
CFR	Code of Federal Regulations
HDR	High Dose Rate Remote After Loader
NM	Nuclear Medicine
NMT	Nuclear Medicine Technologist
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RO	Radiation Oncology
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SFHMC	Saint Francis Hospital and Medical Center
SLIV	Severity Level IV