Saint Francis HEALTHCARE

July 18, 2024

Nuclear Material Licensing Branch
Region III, U.S. N.R.C.
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Addendum to the 15-Day Report Dated May 22, 2024 for Event No. 57110

To Whom It May Concern:

This letter serves as an addendum to the written report regarding Event No. 57110, which occurred on May 6, 2024, at Saint Francis Medical Center, NRC license No. 24-00158-03.

1) The prescribing physician and Authorized User (AU) was Venkatesh Murugan, M.D.

2) A brief description of the event: A patient received a Y-90 TheraSphere dose to the liver that differed from the prescribed dose by more than 20 percent and by more than 50 rem to the liver. The prescribed dose to the patient's liver was 90 Gy. The estimated dose administered was approximately 360 Gy.

   During the investigation of the above described Medical Event, it was discovered that a second Medical Event occurred. The Y-90 TheraSphere dose also resulted in an unintended dose to an organ or tissue other than the treatment site that was greater than 0.5 Sv and more than 50% over the expected dose to that site. The unintended organ or tissue was the lungs. The second Medical Event was reported to the NRC's Operation Center on July 9, 2024.

   The patient's Y-90 TheraSphere regimen included two dosage administrations on different dates. The first dosage was administered as planned. The second dosage administered was greater than the intended dosage in the written directive, resulting in the second Medical Event. The estimated excess lung dose was calculated to be 2.4 Gy and 165% over the expected lung dose. The patient's cumulative lung dose from both treatments was 4.2 Gy and the planned cumulative lung dose was 1.8 Gy, 0.9 Gy from each of the two dosage administrations.

3) Description of why this event occurred: Through the investigation of this medical event, SFMC identified the following process points that contributed to this Y-90 TheraSphere overdosage.

   a) The AU planned the case with assistance from the local TheraSpheres sales representative. The TheraSphere Y-90 Integrated Treatment Documents, an Excel Workbook that has been provided by the vendor to assist with prescribing and ordering TheraSphere Y-90, was completed and provided by the AU to the Nuclear Medicine Technologist (NMT) via email on April 18th requesting that a 7 GBq vial calibrated for Sunday, April 28th, and a 3 GBq vial calibrated for Sunday, May 5th be ordered. The NMT placed the order. The discrepancy between the prescribed dose and ordered dose was not identified prior to ordering or

administration. On the scheduled day of therapy, the 7 GBq vial provided a dose of approximately 90 Gy, while the 3 GBq vial provided a dose of approximately 273 Gy.

b) The Written Directive (WD) was not signed and dated by the AU prior to the dose administration.
c) On the day of administration, the received vial activities were verified by dose calibrator assay to be within 20% of the ordered activities by the NMT.
d) The 7 GBq vial was designated as Vial A and the 3 GBq vial as Vial B. Each vial was placed into a delivery box labeled with its Vial letter and activity. The vials were delivered to the Radiology Department and the therapy procedure was performed.
e) Post-therapy surveys were performed on each vial, and then a second TheraSphere Y-90 treatment worksheet was completed by the NMT. Upon completion of this second worksheet, the NMT identified that the administered dose was 360 Gy and not the prescribed 90 Gy.
f) The WD, which included the pre and post-therapy data collection, was printed and signed after administering the dose.

4) The effect, if any, on the individual who received the administration: The AU and the referring physician have not observed complications and do not expect future complications from the lung overdosage. A follow-up MRI is scheduled for August. Subsequently, the patient will have follow-up appointments with the referring physician and a colleague of the AU, as the AU no longer works at SFMC.

5) Actions taken or planned to prevent recurrence: After reviewing this event and in consideration of the low annual volumes of Y-90 microsphere cases and anticipated staffing challenges, SFMC has decided to close its Y-90 microsphere program.

Due to this programmatic change, we have:

a) Submitted an amendment request to the NRC to revise 10 CFR 35.1000 Y-90 microspheres, SIR-spheres and TheraSpheres, to "Storage Only" and removed Y-90 SIR-spheres and TheraSpheres as authorized uses of the involved AUs.
   i) The NRC received and processed the amendment request on July 8, 2024, Mail Control Number 641675.
   ii) Currently, we are in the process of decaying and properly disposing of all Y-90 microsphere waste in possession.
b) Once all Y-90 microsphere waste is disposed of, another amendment request will be submitted to completely remove 10 CFR 35.1000 Y-90 microspheres, SIR-spheres and TheraSpheres, from the license.

Due to the preliminary findings from the NRC event inspection on May 14th and 15th and the continuation of administrations of I-131 and other radiopharmaceuticals requiring a WD, we are:

a) Revising policies and procedures, educating the NMT and AUs about the revisions, and maintaining written procedures to provide high confidence that the patient's identity is verified before each administration and that each administration is in accordance with the WD.
b) Revising the necessary procedures to require that a WD be signed and dated by the AU before all administrations requiring a WD.

Additionally, the event was referred to Risk Management for the performance of a Root Cause Analysis in accordance with SFMC policy. The RCA was completed on May 15, 2024.

6) Certification that the licensee notified the individual: The referring physician contacted the patient and communicated the newly realized lung dose overage on July 9, 2024.

If you have any questions regarding this notification, please call Jamie Eisenberg at 314-504-0563.

Sincerely,

Jamie Eisenberg

Jamie Eisenberg, MHA, CNMT
Radiation Safety Officer
Saint Francis Medical Center

Cc: Lisa Newcomer, Vice President of Regional Operations

Martha Pavon

From: Tammy Tomczak
Sent: Monday, July 22, 2024 8:39 AM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Addendum to Event Report 57110
Attachments: Signed SFMC Lung Medical Event Report 071924.pdf

Good morning, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Jamie Eisenberg <eisenberg@medphys-stl.com>
Sent: Thursday, July 18, 2024 1:28 PM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>
Cc: Lisa Newcomer <lnewcomer@sfmc.net>; Deborah Piskura <Deborah.Piskura@nrc.gov>; Laura Dresen <Laura.Dresen@nrc.gov>; Jamie Eisenberg <eisenberg@medphys-stl.com>
Subject: [External_Sender] Addendum to Event Report 57110

Please file the attached document for St. Francis Medical Center, NRC license No. 24-00158-03, as an addendum to event report 57110. This letter serves are the 15-day report for the medical event that was reported on July 9, 2024.

Thank you,
Jamie

Jamie Eisenberg MHA, CNMT
Radiation Safety Officer
For St. Francis Medical Center
314-504-0563
eisenberg@medphys-stl.com