DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration (VHA)
National Health Physics Program (NHPP)
2200 Fort Roots Drive
North Little Rock, AR 72114

August 29, 2024

Bryan Parker
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: Report of medical event, NRC License No. 03-23853-01VA

Dear Mr. Parker:

Pursuant to 10 CFR 35.3045, we are providing a written report regarding a medical event that occurred at the VA Boston Healthcare System, Boston, Massachusetts. A brief description of the event, possible causes of the event, actions taken to prevent recurrence, and other required information are contained in the enclosure. The medical facility holds VHA Permit Number 20-00671-02 under our master material license.

The medical event occurred and was discovered on August 20, 2024. The event involved treatment of a patient with yttrium-90 microspheres. A single vial of microspheres was administered. Measurements made after the administration indicated that only about 63 percent of the prescribed activity was delivered. We notified the NRC Operations Center by telephone on August 21, 2024; the event was assigned Event Number 57280.

We are conducting an inspection to evaluate the circumstances of the medical event, actions to prevent recurrence, and regulatory compliance. Please contact me, at 501-257-1571, if you have any questions about this matter.

Sincerely,

EDWIN LEIDHOLDT

Digitally signed by EDWIN LEIDHOLDT
Date: 2024.08.29 13:05:52 -07'00'

Edwin M. Leidholdt Jr., Ph.D., FACR
Executive Director, VHA National Health Physics Program (11SPEC12)

Enclosure

Department of Veterans Affairs

Memorandum

Date: August 29, 2024

From: Director (523/00); VA Boston Healthcare System, Boston, Massachusetts

Subj: Report of Medical Event

To: Executive Director, VHA National Health Physics Program (11SPEC12)

1. This memorandum is our written report of a medical event (ME) to the National Health Physics Program (NHPP) pursuant to 10 CFR 35.3045. The ME was initially reported by the Radiation Safety Officer (RSO) to NHPP by telephone on August 20, 2024, at 3:05 PM EDT. The following information is provided pursuant to 10 CFR 35.3045:

    a. Permittee's name: VA Boston Healthcare System, VHA Permit Number 20-00671-02

    b. Name of prescribing physician: Yamin Dou, M.D.

    c. Brief description of event:

    A decision was made to treat a 72-year old patient with hepatocellular carcinoma with Y-90 microspheres. A written directive was prepared prescribing 42.9 mCi of Y-90 TheraSphere microspheres to the right lobe of the patient's liver. The written directive was signed by an authorized user (AU) physician. The AU and an interventional radiologist (IR) were in the procedure room during the procedure.

    The target lesion in Segment 7 has multiple branches of blood supply and IR was unable to target it with a single branch. Therefore, the entire right lobe was infused. The target lesion received about one-third of the total infusion. The desired dose to the target lesion was 200 Gy calculated by the vendor, Boston Scientific. The patient received 63.4% of the dose which is equivalent to 126 Gy to the target Segment 7 lesion.
    The patient was administered Y-90 TheraSphere microspheres to the right lobe of the patient's liver at approximately 1:00 pm EDT on August 20, 2024. The manufacturer's procedural checklist was utilized to guide the procedure using the manufacturer-provided administration kit. The microcatheter was flushed with a 5 cc syringe of normal saline solution immediately prior to connecting to the TheraSphere administration kit. Initially, the administration proceeded per the manufacturer's protocol with no issues. After the first 20 cc of saline was infused through the administration kit, the IR noted that there was greater resistance during

administration through the kit than what has been typically encountered. Additionally, during the first 20 cc saline flush, we noticed a significant amount of saline went into the overflow bottle. A second overflow bottle was used to replace the initial overflow bottle. At this point, the administration was paused, and the tubing and connections were visually inspected. No cause for resistance was found. It was suspected that there was a kink in the microcatheter near or in the Touhy-Borst adapter/microcatheter connection. Attempts were made to loosen the connection without perceived benefit. The AU and IR disconnected the administration kit from the microcatheter. The IR then flushed the microcatheter in an effort to administer any residual dose within the microcatheter. The dosimeter reading outside the shield housing was 0.1 mR/h (initial reading was 4.6 mR/h). The AU and IR decided to finish the administration. After the attempt to clear the microcatheter of microspheres, it was partially withdrawn which allowed visual inspection of the Touhy-Borst adapter/microcatheter connection revealing a kink in the microcatheter. The administration kit and microcatheter were placed in a shielded Nalgene waste container. The final dosimeter reading outside the shield housing was 0.0 mR/hr and no contamination was found.

Pre-procedure, the Chief Nuclear Medicine Technologist measured the manufacturer's supplied dosage to be 39.8 mCi at 12:32 pm which was within the 10% allowed variability from the prescribed dosage. Following the administration, the RSO performed measurements of the waste container revealing approximately 12.6 mCi residual activity within the administration kit and procedure waste and calculated that the patient received approximately 63% of the prescribed activity (the prescribed activity was 42.9 mCi); the administered activity was estimated to be 27.2 mCi). Additionally, the estimated desired dose to target volume was 76 Gy and the estimated dose delivered to the perfused liver tissue was 48.2 Gy.

After discovery of this medical event, the RSO notified NHPP at approximately 2:10 PM. At approximately, 4:10 PM the AU, IR, and RSO informed the patient and their wife of the event. The following day, 8/21/24 at approximately 9:40 AM the IR attempted to inform the referring physician. The referring physician was on leave, but the IR was able to notify, at approximately 10:00 AM on 8/21/24, the covering physician, who confirmed receipt of the notification.

d. Why the event occurred:

A cause of the event has not been established with certainty. Preliminary analysis indicates that, due to a kink in the microcatheter, flow of Y-90 microspheres through the administration kit tubing into the patient via the microcatheter was restricted, resulting in an underdose to the patient.

e. The effect on the individual who received the administration:

No short-term harm is anticipated. The patient is scheduled for an additional administration on 9/5/2024.

f. Actions that have been taken or are planned to prevent recurrence:

The same day as the Y-90 TheraSpheres were administered, the manufacturer was notified. The manufacturer will analyze the administration kit and microcatheter after the items have decayed and can be released by VA Boston.

NHPP plans to perform a reactive inspection to independently assess causes and review the procedure for regulatory compliance.

Planned actions to prevent recurrence:

The IR will 1) visually inspect the lines including the microcatheter for any visible kinks, 2) verify the microcatheter flushes with a 20 cc saline syringe prior to connecting to the administration kit (5 cc saline syringe was used previously), and 3) if high resistance is encountered the administration will be paused to see if any activity has left the shielded housing. If none has left the housing, the IR will disconnect the system and replace the microcatheter. If activity has left the housing, the IR will continue to administer the activity per the Instructions for Use so long as there is no evidence of a spill.

g. Certification that the permittee notified the individual (or the individual's responsible relative or guardian):

We certify that we notified the patient in accordance with 10 CFR 35.3045.

2. Please let us know if you require further information regarding this matter.

DocuSigned by:

8/29/2024

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Vincent Ng.
Director, VA Boston Healthcare System

From:	Edwards, Mark W.
To:	Bryan Parker
Cc:	Leidholdt, Ed; Abell, Clinton E.; Kidwell, Calvin B; Wiebeck, Kim C.; Edwards, Mark W.
Subject:	[External_Sender] 2024 08 29 Boston Event Letter to NRC (Event No. 57280)
Date:	Thursday, August 29, 2024 3:17:14 PM
Attachments:	2024 08 29 Boston Event Ltr to NRC (Event No. 57280).pdf
Importance:	High

Mr. Parker,

On behalf of Dr. Leidholdt.

Please find attached copy of a written report regarding a medical event that occurred at the VA Boston Healthcare System, Boston, Massachusetts; Permit No. 20-00671-02.

Would you please reply to this message to acknowledge receipt?

Please do not hesitate to call if you have any questions.

v/r Mark

Mark W. Edwards

Mark W. Edwards
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North Little Rock, Arkansas
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800-815-1016 (NHPP Safety Hotline)