Department of Veterans Affairs

Memorandum

Date: January 28, 2021

From: Director, VHA National Health Physics Program (NHPP) (11SPEC12)

Subj: Radiation Safety Program Inspection - Inspection Report 523-20-I01

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

1. Kim Wiebeck, BSRT (R)(T) and Joseph S. Bravenec, M.S., NHPP inspectors, performed an announced reactive inspection of your facility's radiation safety program, beginning on August 11, 2020, with continuing review through January 26, 2021. The focus of the inspection was a medical event that occurred on August 5, 2020. The inspectors visited your facility on August 31 and September 1, 2020, as part of the inspection.

2. Attached to this memorandum is the inspection report. No violations were identified. A response to this report is not necessary.

3. In accordance with U.S. Nuclear Regulatory Commission Management Directive 8.10, Directive Handbook Section III.B., you should make a copy of this inspection report available to the referring physician.

4. Thank you for the courtesy and cooperation extended during the inspection. Please contact Ms. Wiebeck, at 850-293-9759, if you have any questions about the inspection.

Edwin M. Leidholdt 398105

Digitally signed by Edwin M. Leidholdt 398105
Date: 2021.01.28 10:58:35 -08'00'

Edwin M. Leidholdt Jr., Ph.D., FACR

Attachment

cc: Network Director, VISN 1 (10N1)
Director, VHA National Nuclear Medicine and Radiation Safety Service (11DIAG1)
Acting Director, VHA National Radiology Program (11DIAG1)

Attachment

RADIATION SAFETY PROGRAM INSPECTION
VHA National Health Physics Program (NHPP) Inspection Report Number 523-20-I01
VA Boston Healthcare System, Boston, Massachusetts
August 11, 2020 – January 26, 2021

1. Introduction

NHPP initiated a reactive inspection at the above facility, on August 11, 2020, in response to notification of a medical event at the facility involving a Y-90 microsphere therapy procedure. Kim Wiebeck and Joseph S. Bravenec, MS, NHPP Managers, conducted the inspection. They performed a site visit to the VA medical center (VAMC) in West Roxbury, MA, on August 31 and September 1, 2020, as part of the inspection. They were accompanied by Edwin M. Leidholdt, Jr., Ph.D., NHPP Director, during the site visit. Ms. Wiebeck presented preliminary findings at a meeting with healthcare system executive leadership and other key staff on September 1, 2020. She stated that the inspection would remain open pending further review and consultation with a VA physician consultant group. Review of the event continued remotely, primarily via email, for several months. The inspection was closed on January 26, 2021. A final briefing with key facility staff will be conducted after signing of the report.

2. Scope of Inspection

The inspection followed a pre-approved inspection plan. All items on the inspection plan were completed. The inspection consisted a review of radiation safety practices and selected records specific to the Y-90 microsphere therapy program; review of written directives and administration records for all Y-90 procedures performed since the last NHPP routine facility inspection on September 27, 2017; review of Y-90 procedure mapping images versus post implant bremsstrahlung images for approximately 30 percent of these procedures; and interviews with facility staff involved in the medical event. The inspectors toured the Interventional Radiology (IR) suite utilized for Y-90 microsphere procedures and completed spot-check radiation measurements in the Nuclear Medicine Service sealed source storage room, which is used for storage of Y-90 microspheres prior to patient procedures and radioactive waste after the procedures.

3. History of Facility's Y-90 Microsphere Therapy Program

The facility was approved for use of TheraSphere® Y-90 microspheres in May 2015, in accordance with the US Nuclear Regulatory Commission (NRC) licensing guidance document entitled "Microsphere Brachytherapy Sources and Devices," dated June 2012. The first three patient treatments, with oversight by BTG proctors, were performed on July 24, September 8, and November 17, 2015. Eight TheraSphere® patient treatments were completed in 2016. In January 2017, Y-90 SIR-Spheres® use was added to the permit, with a commitment to utilize the NRC Y-90 microsphere licensing guidance document dated February 2016. A treatment team, consisting of the Chief Nuclear Medicine Technologist, Authorized User (AU) Nuclear Medicine Physician, and an IR physician, has performed a total of 58 TheraSphere® and 6 SIR-Spheres® procedures through August 2020. (The same AU and IR physician performed

all 64 procedures.) In accordance with 10 CFR 35.41, the facility developed, implemented and maintained the "Boston VA Healthcare System Microsphere Therapy Manual".

4. Chronology of Medical Event

Patient History – The patient involved has hepatocellular carcinoma in the right lobe of his liver. Prior to transferring to the Boston VAMC, the patient had undergone three transarterial chemoembolization (TACE) procedures at the Miami VAMC in 2014. In late 2014, the Boston VAMC IR physician performed extensive initial mapping of the patient's hepatic arterial system via MRI. The IR physician performed three additional TACE procedures on the patient in 2015. The patient underwent his first Y-90 TheraSphere® treatment of 120 Gy to the right lobe of the liver on June 28, 2017. A second TheraSphere® treatment of 210 Gy to the right lobe of the liver was delivered on February 9, 2018. Due to recurrence in the right lobe of the liver, planning for a third TheraSphere® treatment began on July 16, 2020, with a MAA mapping study and a liver volume CT scan on July 17, 2020. At the time of this procedure, the right lobe of the liver was shrunken and primarily contained necrotic tissue. The AU reviewed the treatment plan, for a 225 Gy radiation lobectomy dose for the right lobe, with a non-VA physician consultant on July 28, 2020.

The third TheraSphere® treatment of the patient was performed on August 5, 2020. A catheter was placed through the femoral artery into what was identified as the right hepatic artery. Conventional angiographic images were compared to the mapping angiography images of July 16, 2020. The images appeared to match the prior catheter placement and it was concluded that the catheter was correctly placed into the right hepatic artery. At approximately 1:00 pm (EDT) 2.29 GBq (61.9 mCi) of Y-90 microspheres (TheraSphere®) was infused to deliver 211 Gy to the right lobe of the liver. With a six percent difference between prescribed dose and administered dose, the treatment was considered successful and not a medical event. Post-implant bremsstrahlung SPECT/CT imaging was performed at approximately 4:30 pm (EDT) on the day of the procedure. It was discovered that the Y-90 microspheres had been delivered to a 530 cc segment of the left lobe of the liver. The permittee determined that this segment of the left lobe would receive a dose of 160 Gy. At approximately 6:30 pm (EDT), the AU and Radiation Safety Officer (RSO) concurred that a medical event had occurred. The AU sent by email an initial report to the RSO at 8:34 pm (EDT). Retrospective review of images from the procedure led the facility to conclude that that the catheter had been mistakenly placed in the middle hepatic artery, which supplies blood to Segment 4 of the left liver lobe.

5. Facility's Actions in Response to the Medical Event

In accordance with 10 CFR 35.3045(e), the patient and referring physician were notified by the AU on the evening of August 5, 2020, that the microspheres had been delivered to an unintended location. Treatment of the patient with Vitamin E and Pentoxyfilline

(following a consult with radiation oncology) was promptly initiated to reduce damage to the liver.

The RSO notified NHPP of the medical event by telephone at 10:30 am EDT on August 6, 2020. At 11:08 am (EDT), August 6, 2020, the AU forwarded a copy of her initial report to NHPP. These notifications complied with the notification requirement of 10 CFR 35.3045(c).

As was mentioned above, the patient was notified of the treatment error on the day of the treatment. Furthermore, the Chief of Staff, Chief of Radiology, and Risk Management notified the patient in accordance with VHA Directive 1004.08, Disclosure of Adverse Events to Patients, on August 6, 2020.

The facility sent an August 14, 2020, memorandum to NHPP as the 15-day written report required by 10 CFR 35.3045(d). This memorandum, signed by the Medical Facility Director, addressed all items specified in the regulation. NHPP subsequently submitted the report to NRC on August 17, 2020, in accordance with 10 CFR 35.3045.

6. Effects on the Patient

As a result of this error, normal liver tissue in Segment 4 of the left lobe was exposed to a dose of Y-90 microspheres while recurrent tumor in the right lobe of the liver remained untreated. The AU and IR physician continued to review patient status to determine if and when an additional Y-90 procedure should be performed to complete the planned radiation lobectomy dose to the shrunken, necrotic right lobe. As of October 1, 2020, no adverse effects to the patient from the medical event had been noted. A two-month follow-up liver function test showed acceptable liver function despite the event. In early November 2020, the patient had a successful microwave ablation of residual hepatomas in the right hepatic lobe. A December 2020 MRI showed complete ablation of tumor and follow-up laboratory test results remain stable.

7. Findings and impressions

NHPP performed a focused reactive inspection in response to the medical event; this included a review of the facility's entire Y-90 microsphere therapy program.

a. The inspectors reviewed selected procedures and records and did not find any violations:

(1) Y-90 policies, procedures, procedure checklists, and written directive forms were reviewed and found to be in compliance with NRC guidance documents and 10 CFR 35.41.

(2) Staff training records specific to Y-90 training as well as 10 CFR 19.12 and 19.13 were reviewed and found to be sufficient.

(3) Personal dosimetry records for staff participating in microsphere therapy procedures as well as all individuals working with radioactive materials were reviewed by the inspectors; they concluded that all exposures were within the regulatory limits of 10 CFR 20 and demonstrated adherence to the ALARA principle. Interviewed staff were aware of their rights as radiation workers, understood proper use of personal radiation dosimeters, and had been issued annual notifications of exposure in accordance with 10 CFR 19.13.

The inspectors reviewed the written directives for all Y-90 microsphere therapies performed since the last routine NHPP inspection. The inspectors also reviewed and compared the pre-plan mapping image with the post-treatment bremsstrahlung images for approximately 30 percent of these previously performed procedures. The previous pre and post plan images reviewed demonstrated that the microspheres had been delivered to their intended locations. NHPP concluded that the medical event was an isolated occurrence rather than a programmatic issue.

b. The inspectors reviewed compliance with NRC regulations in 10 CFR 35.3045 regarding required actions by the permittee following discovery of a medical event, including notification of NHPP, notification of the patient, notification of the referring physician, and submission of a written report to NHPP. No violations of NRC regulations were identified regarding these regulatory requirements.

c. The inspectors, in discussions with permittee staff, determined the sequence of events before the medical event, and identified several unique circumstances:

(1) During initial mapping of the hepatic arterial supply in 2014, the IR physician noted that the patient had the following atypical anatomic deviations from normal anatomy:

i) The patient's right hepatic artery, which normally branches off the celiac artery, originated from the superior mesenteric artery (SMA). This occurs in approximately 10% of people.
ii) The patient's left gastric artery branched off the left hepatic artery. This occurs in approximately 15% of people.
iii) The patient's blood supply to Segment 4 of the left lobe was via the mid-hepatic artery which branched off the celiac artery. This occurs in approximately 40% of people.
iv) Segments 2 and 3 of the left lobe were supplied by an aberrant left hepatic artery that arises from the left gastric artery.

(2) Having performed three TACE and two previous Y-90 microsphere therapies to the patient's right lobe, the IR physician was very familiar with the patient's anatomic presentation. On the day of the Y-90 treatment, he did not believe he needed to include the celiac artery (which leads to the mid-hepatic artery, which supplies Segment 4 of the left lobe) during imaging of catheter placement. Additionally, the IR physician did not utilize 3-D imaging (cone beam CT) with the fluoroscopy imaging system during the

microsphere delivery procedure. Utilization of cone beam CT during the delivery procedure was not standard practice at the facility at the time of this treatment.

(3) On the date of the procedure, with assistance from an IR resident physician holding the catheter at the ostium, the IR Physician passed a guide wire through the catheter that appeared to traverse through what appeared to be the horizontally coursing aberrant right hepatic artery off the SMA. Subsequent multiple digital subtraction angiography (DSA) acquisitions with injection of contrast showed hepatic parenchymal enhancement and appeared to indicate that the microcatheter was positioned in the same location as in the prior mapping study. Having verified catheter position, the Y-90 microspheres were injected. Post-treatment bremsstrahlung SPECT imaging showed that the Y-90 microspheres had been delivered to a hypertrophied Segment 4 of the liver rather than the intended target of the right lobe of the liver.

(4) In retrospect, the IR physician noted, “As the right lobe has markedly shrunk with involution of the tumor following multiple successful embolization over the last 6 years, in addition to the combination of the multiple vascular variations, the middle hepatic artery (MHA) unusually has become enlarged and straightened in the interim with marked hypertrophy of the segment 4 that has extended and expanded all the way to the right abdomen mimicking his native right lobe (in the size, location and shape) along with transforming the MHA in its size, location and course into the appearance of his native right hepatic artery.” The middle hepatic artery was mistakenly recognized as the right hepatic artery at the time of the catheterization.

d. The inspectors, in discussions with permittee staff, investigated the potential causes of the event.

(1) The facility conducted a system root cause analysis (RCA) of this medical event. “The RCA team determined that the time out was done appropriately. A cone beam CT was not performed prior to the Y-90 procedures as it was not the standard of practice for these procedures. It should be noted that based on interview with the providers involved in the event, the error was considered to be perceptual, due to an anatomical variant of the patient’s Left and Right hepatic arteries as the two arteries have similar courses on AP projection as normal variation.” “Treatment of the patient's evolving liver damage without 3-D imaging caused limited visualization of the right and left hepatic artery which resulted in a branch of the left hepatic artery to be inadvertently accessed instead of the right hepatic artery.” “Cone Beam CT is not a standard of practice for this procedure. After discussion among the IR attendings and nuclear medicine, they have discussed ways to include more radiographic imaging (cone beam CT) for every Y-90 mapping and Y-90 treatment, with the understanding that the benefits outweigh the risk of extra radiation from additional CT imaging.” NHPP concurs with the conclusions of the facility’s RCA.

(2) NHPP conducted a root cause analysis (RCA) utilizing the TapRoot® system. It was determined that the Y-90 procedure was a complex non-fault tolerant system that required knowledge-based decisions in which errors were not recoverable. A VA

physician consultant group, assembled at the request of NHPP to review the event, concluded that following facility policy and standards of practice the IR physician, based on clinical judgment, placed the catheter in a position that he believed would deliver the microspheres to the right lobe of the liver as intended. However, based on post-implant imaging, it appears that the catheter was incorrectly placed in the artery serving the Segment 4 of the left lobe of the liver instead of the artery serving the right lobe of the liver. Contributing factors to this human error include the patient's variant arterial anatomy as well as treatment-related distorted hepatic anatomy.

e. The inspectors reviewed the permittee's proposed actions to reduce the likelihood of a similar event. The permittee's actions to prevent wrong site errors include implementation of new IR procedures that utilize 3-D imaging visualization of the patient's anatomy during both the Y-90 mapping and Y-90 treatment procedures. The inspectors concluded that these actions sufficiently address the possible causes.

9. Persons Contacted During the Inspection

Vincent Ng, Healthcare System Director [2]
Michael E. Charness, M.D., Chief of Staff [1,2,3]
Heather Davidson, M.D., Deputy Chief of Staff [2]
Melissa Conway, M.P.H, Assistant Director [1,2]
Pamela Bellino, Patient Safety Manager [3]
Ali Guermazi, M.D., Chief of Radiology [2,3]
Rachel Powsner, M.D., Nuclear Medicine Physician and Authorized User [1,2,3]
Ducksoo Kim, M.D., Interventional Radiology Physician [3]
Chad A. Smith, Ph.D., Radiation Safety Officer [1,2,3]
George Brunson, RT(N), Chief Technologist, Nuclear Medicine and PET-CT [3]
Bashir Adeniyi, RT(CT) IR Radiologic Technologist [3]

1. Individual(s) participating in entrance meeting
2. Individual(s) participating in exit meeting
3. Individual(s) present or participating in inspection discussions

Song, Taehoon

From: Edwards, Mark W. <Mark.Edwards5@va.gov>
Sent: Tuesday, February 02, 2021 8:37 AM
To: Parker, Bryan
Cc: Leidholdt, Ed; Wiebeck, Kim C.; Bravenec III, Joseph S (HOU); Edwards, Mark W.
Subject: [External_Sender] VA Boston Medical Event Inspection Report.
Attachments: 2021 01 28 Boston Medical Event Insp Rpt.pdf

Good Morning, Mr. Parker,

On behalf of Dr. Leidholdt. Attached is the Boston medical event inspection report dated January 28, 2021.

Would you please reply to this message to acknowledge receipt?

Please do not hesitate to call Dr. Leidholdt, regardless of the date or time, if you have questions. He is mostly working at home and the quickest way to contact him is by cell phone: 916-833-8415.

Thank you…Mark.

Mark W. Edwards, USAF, Ret
VHA - National Health Physics Program (11SPEC12)
North Little Rock, AR 72114-1706
Office: 501-257-1515 Fax: 501-257-1570
NHPP After Hours Emergency Hotline: 800-815-1016