July 26, 2023

Henry Ford Hospital
Radiation Safety Office
2799 West Grand Blvd.
Detroit, Michigan 48202-2689
(734) 657-4133 Mobile (Preferred)
(313) 916-8456 Fax

Regional Administrator
U.S. Nuclear Regulatory Commission
Region III
2243 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Dear Sir or Madam:

This is the written report as required by 10CFR 35.3045(d) documenting a potential medical event that was reported on July 12, 2023 by Henry Ford Hospital (License 21-04109-16; Docket: 030-02043). The information required for this report follows:

(i) Licensee's name

Henry Ford Hospital

(ii) Name of prescribing physician

Mohamed Elshaikh, M.D.

(iii) Brief description of the event

The patient was undergoing a procedure called 'Intravascular Brachytherapy'. This procedure is performed in an interventional cardiology suite with fluoroscopic guidance with the intent to use radiation to prevent restenosis at a site where prior treatment (e.g. stent placement) has been unable to prevent scar tissue growth and/or restenosis. In this case, on July 11th, 2023, the patient underwent the required cardiac intervention by Dr. Mir Basir to ensure the left circumflex artery was open enough to attempt the brachytherapy procedure. Then Dr. Basir positioned the catheter with preloaded indicator of source train (IST). After removing these dummy sources, the transfer device with the Sr/Y-90

radioactive source was connected to the catheter by the Radiation Oncologist. After a time out was performed to confirm all treatment parameters, the source was pushed out of the device towards the treatment position via hydraulic pressure from a water loaded syringe. After approximately 10 seconds, (the typical time it takes for the source to reach the intended position), the Radiation Oncologist asked the Interventional Cardiologist to confirm that the source had arrived in the correct treatment position. The Interventional Cardiologist did confirm that the source had arrived in the treatment position. At this point the timer was started by the Medical Physicist present to treat the patient to the prescribed dose of 23Gy to a depth of 2mm in the circumflex artery of the heart. After the time was completed, the source was then retracted back to the device, all required surveys and documentations were completed. At approximately 4:30pm on July 11th, 2023, the Interventional Cardiologist was reviewing the images saved to the PACS system and reported that he could not verify the location of the source on the images and thus the patient had not received the prescribed brachytherapy to the circumflex.

(iv) Why the event occurred

This event occurred because there was some uncertainty at the time of source delivery as to whether or not the source had actually arrived at the treatment site. This uncertainty was partly related to the quality of the images being used to verify correct placement of the source, the visual complexity of the fluoroscopic images (due to the presence of brachytherapy equipment, interventional equipment and pre-existing medical devices).

(v) The effect, if any, on the individual(s) who received the administration:

In the opinion of prescribing physician, the radioactive source did not reach the most distal location which would have been the treatment area, the circumflex. The source provided the prescribed radiation to another part of the vasculature proximal to the treatment location (with a wider circumference). The prescribed dose is provided to a depth of 2mm from the catheter surface. This dose is used to prevent scar growth but is not enough dose to provide harm to the wider vasculature or the patient.

(vi) What actions, if any, have been taken or are planned to prevent recurrence

The following actions will be taken:

1. Our policy will now require that, Immediately after the brachytherapy source reaches the treatment site:
    a. Verbal confirmation from both the Interventional Cardiologist and the Radiation Oncologist that the source has reached the intended treatment site.

2. After the source arrives in the treatment position, the Interventional Cardiologist must acquire an image showing that the source reached the intended position for proper documentation.
    a. Prior to delivery/insertion of the brachytherapy source into the patient, the Interventional Cardiologist will press/engage the “Cine” pedal during delivery/insertion of the source until the source reaches the treatment site. Importantly, utilizing the cine pedal will improve the image quality of the acquired fluoroscopic image, as well as automatically save the images on the interventional suite console.
3. Our training frequency will be twice a year; with the requirement that team members (Interventional Cardiologists, Radiation Oncologists, Medical Physicists) who participate in this procedure must complete this training.
    a. This training will include a vendor training component on how to properly use the treatment equipment (catheters, transfer device, etc.)
    b. This training will include key 10 CFR 35 information including requirements for the written directive, reporting requirements, etc.

(vii) Certification that the licensee notified the individual

The Interventional Cardiologist notified the patient at the end of the day on July 11th, 2023 that the patient did not receive the brachytherapy to the intended region of the circumflex. The Interventional Cardiologist is the referring physician in this case, and thus has been notified per 10CFR35.3045(d)(2)(e).

If you should have any questions regarding this request, please feel free to contact Alan Jackson via phone at (734) 657-4133 or via e-mail at alanj@rad.hfh.edu.

Sincerely,

Alan Jackson, MS, CHP
Radiation Safety Officer