DEPARTMENT OF RADIOLOGY
Henry Ford Hospital & Health Network

Radiation Safety Office

Henry Ford Hospital
2799 West Grand Blvd.
Detroit, Michigan 48202-2689
(313) 916-7042 Office
(313) 916-8456 Fax

February 13, 2017

Cynthia D. Pederson, 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 February 1, 2017 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; Munther Ajlouni MD
(iii) Brief description of the event;

The written directive of a Y-90 TheraSpheres® treatment done on January 31, 2017 specified that the dose to the left lobe of the liver be 60 Gy (6,000 rad). No treatment was intended for the right lobe. Bremsstrahlung imaging following the Y-90 microspheres treatment demonstrated Y-90 microspheres throughout both lobes of the liver. As a consequence the right lobe of the liver was treated to a dose of 36.6 Gy. The dose to the left lobe was 48.6 Gy which was 81% of the intended dose.

(iv) Why the event occurred;

The precise reason for this event remains unknown. It is important to understand that the only viable treatment location was a narrow window just distal to vasculature that supplies the right lobe of the liver. The activity in the right lobe could have been infused by reflux (backflow) or if the orientation of the catheter flipped during injection (which is

considered unlikely). These treatment challenges were recognized by the interventional radiologist Scott Schwartz, MD. Dr. Schwartz checked the proper position of the catheter in multiple ways. Once he identified a treatment position, he verified catheter positioning and distribution with a contrast agent. This was assessed at both a high pressure and low pressure mimicking Therasphere delivery conditions. After another confirmation of positioning immediately prior to treatment, the catheter is connected to the TheraSpheres® treatment apparatus. After this final connection, Dr. Schwartz again checked the physical position of the catheter under fluoroscopy to ensure the catheter tip remained in the correct position. Nonetheless, movement of the catheter remains a possibility and could have been caused by unnoticed patient movement. Angiographically undetected reflux is another possibility because the flow dynamics of the TheraSpheres® product probably differs from both the contrast agent and ^{99m}Tc albumin aggregated (99mTc-MAA) used for the treatment planning.

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

All of the physicians involved, including Interventional Radiology, Nuclear Medicine, and Radiation Oncology indicated that no harm resulted to the patient because of this deviation and no change to the patient's medical plans are expected. Additionally, this case was discussed at morbidity and mortality conference. There was unanimous consensus that in retrospect, no change in technique would have been advised and nothing would have been done differently. The right lobe of the liver was treated for hepatocellular carcinoma with TheraSpheres® on 12/7/2016 to a dose of 141.6 Gy and thus was already a treatment target. Additionally, the right lobe is already essentially nonfunctional due to more remote treatments on a background of cirrhosis, and additional acute effects are not expected.

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

The only corrective action we can identify is not viable. That is to exclude patients with challenging anatomy. Given the rarity of this situation; the low safety significance of this event; and the potential benefits to patients affected by the deviation; limiting this treatment is unethical.

(vii) Certification that the licensee notified the individual;

The referring physician (Scott Schwartz, MD) was informed of the details of this medical event on the same day of the treatment and he notified the patient about the treatment deviation the day following the treatment.

If you should have any questions regarding this request, please feel free to contact Alan Jackson via phone at (313) 916-2739 or via e-mail at alanj@rad.hfh.edu.

Sincerely,

Alan Jackson, MS, CHP
Radiation Safety Officer

cc: Radiation Safety Committee
Edward Harvey, USNRC
S. Schwartz, MD
M. Ajlouni, MD
I. Dalal, MD
C. Martin, VP Radiology

Filename: HFH NRC Medical Event Report re 01-31-2017 TheraSpheres treatment.docx