October 17, 2022

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 October 4, 2022 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

John M. Falluca, MD

(iii) Brief description of the event

The written directive of a Y-90 TheraSpheres® treatment done on October 3, 2022 stated that the dose would be delivered to the "Left liver lobe: Highly perfused regions in segments 5 and 8". This was a typographical error, and the written directive should have stated the "Left liver lobe: Highly perfused regions in segment 4". The treatment was delivered to the intended region, "Left liver lobe: Highly perfused regions in segment 4".

(iv) Why the event occurred

The origin of the typographical error was the report of the ^{99m}Tc macro-aggregated albumin (^{99m}Tc-MAA) perfusion scan, where the perfused segment 4 was labeled as segment 5 and 8. It is important to note that the ^{99m}Tc-MAA perfusion volume, which was the highly perfused regions in segment 4, was used to establish the treatment volume in the treatment planning. Thus, the correct treatment volume was used despite the labeling error, and the treatment plan and subsequent written directive did specify the correct activity of Y-90 TheraSpheres® required to deliver the intended dose to the intended treatment volume.

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

All of the physicians involved, including the referring physician, the treating interventional radiology physician, the Authorized User, and the nuclear medicine physician reviewed the case and indicated that no harm to the patient resulted, because the correct Y-90 TheraSpheres® activity was appropriately administered to the correct treatment region.

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

The Y-90 TheraSpheres® treatment protocol will be changed in three ways. The treating interventional radiologist will now specify the intended treatment in writing. The treatment plan review procedure will add a formal review of the written directive by the treating interventional radiologist physician. Additionally, the treatment quality control procedure will include a verbal verification of the treatment site by the treating interventional radiologist prior to administering the dose.

(vii) Certification that the licensee notified the individual

The referring physician was informed of the details of this potential medical event on the same day of the treatment. As discussed in section (v) above, there was no harm and the treatment was appropriately delivered, thus the referring physician determined that notifying the patient of the typographic error would have no real purpose and would unnecessarily alarm the patient.

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