August 23, 2023

Henry Ford Hospital
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Ryan Craffey, Senior Health Physicist
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Mr. Craffey:

This is the written report as required by 10CFR 35.3045(d) documenting a medical event that was reported on August 8, 2023 by Henry Ford Hospital (License 21-04109-16; Docket: 030-02043). The Event Number was recorded as 56666. The information required for this report follows:

(i) Licensee's name

Henry Ford Hospital

(ii) Name of prescribing physician

Scott Schwartz, M.D.

(iii) Brief description of the event

The written directive for this Y-90 TheraSpheres® treatment prescribed the activity to be delivered as 0.98 GBq (26.4 mCi). Instead, 0.77 GBq (20.7 mCi) was delivered. Consequently, the patient received only 78.6% of the intended dose which exceed the 10 CFR § 35.3045 requirements because the dose delivered exceeds "0.5 Sv (50 rem) to an organ or tissue" and "The total dosage delivered differs from the prescribed dosage by 20 percent or more". Subsequent measurements determined that the missing activity almost entirely remained in the source vial.

(iv) Why the event occurred

It remains unclear why this amount of residual activity remained in the source vial. Our process requires multiple flushes of the source vial. The treatment was done fully in accordance with the procedure. We can only speculate as to why this undertreatment occurred. We intend to request the device manufacturer, Boston Scientific, to examine the treatment system components once sufficient radioactive decay has occurred. It is possible that they will identify the root cause using methods unavailable to us.

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

The therapy administration resulted in an approximate dose of 250 Gy to the treatment site, which was 78.6% of the written directive dose. David McVinnie, M.D., who is the referring physician and the treating interventional radiology physician, indicated that a therapeutic dose had still been delivered by the 250 Gy. The Authorized User, Scott Schwartz, M.D., replied with the following: “I believe (the) dose is sufficiently therapeutic”, “studies suggest good treatment response”. There is no plan to change the patient’s treatment course as a result of this event. Post-therapy follow-up and CT/MR imaging evaluations will occur as part of the normal treatment course for this patient.

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

Since we have not conclusively identified the cause of this medical event, we have not determined what changes, if any, need to be made. We have conducted approximately 1000 treatments without previously experiencing a medical event of this type. It is arguable that changing the process is not indicated given the low frequency of this issue which has a decidedly minor consequence in this instance.

One issue we intend to review is the methodology of surveying the contents of the source vial in the treatment room. Ideally, the survey method would be able to identify significant residual activity in the source vial prior to completion of the treatment. However, this case has shown us that when the source vial is in the TheraSphere™ delivery device treatment apparatus the residual activity is effectively shielded. Also, the patient elevates the radiation level in the vicinity of the treatment apparatus after dosing. Consequently, the current standard survey methods, which use the electronic dosimeter on the delivery device to indicate contents of vial, are unable to conclusively identify the presence of residual vial activity in the treatment room. Please note that the current methodology is done in the manufacturer specified matter and the residual measurement meets industry standards, so this situation is likely true for the vast majority of other TheraSphere™ users. We plan to trial the use of additional survey methods with

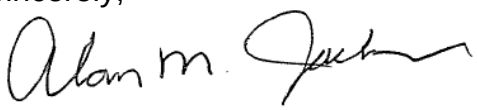
the goal of improving the measurements of residual vial activity in the treatment room.

(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 as the treatment. As discussed in section (v) above, the referring physician considered the treatment to be therapeutic. The referring physician notified the patient about the underdose but that he believes the treatment resulted in an “appropriate therapeutic/tumoricidal dose”.

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 M. Jackson, MS, CHP
Radiation Safety Officer