Washington University in St. Louis
Environmental Health & Safety Radiation Safety Division

January 16, 2019

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, STE 210
Lisle, Illinois 60532-4352

Attention: Geoffrey Warren, Senior Health Physicist
US Nuclear Regulatory Commission, Region III

Subject: Written Report for a Suspected Medical Event (Event Number 53814)
In Accordance with 10 CFR 35.3045(d)

This correspondence is written in relation to the report of a suspected medical event submitted via phone call to the US NRC Operations Center on 4-Jan-2019 at 12:15 pm Eastern Time. The initial report described a dose to a different segment of the target organ than intended. Medical event number 53814 was assigned.

The information required by 10 CFR 35.3045(d) is provided as follows:

Licensee's Name: Washington University in St. Louis

Name of Prescribing Physician: Hyun Kim, MD

Brief Description of the Event:

A Written Directive was documented for a prescription/plan to treat patient A.C. with Yttrium-90 microspheres (Nordion Theraspheres). The prescribed activity was 1.06 GBq. The target tissue was segments 6 and 7 of the patient liver, using an intra-arterial route of administration.

Institutional procedures were closely followed in order to provide high confidence that the Y-90 microsphere administration was in accordance with the treatment plan, and consistent with the regulations described in 10 CFR 35.41. In line with this, the correct placement of the catheter was verified and recorded via fluoroscopic imaging immediately prior to infusion. The Y-90 microspheres were administered as planned, with 96% of the prescribed dosage delivered on 3-Jan-2019.

SPECT-CT images acquired post-administration (on the same day as the treatment) initially appeared to indicate that the Y-90 microspheres were deposited in segments 5 and 8 of the patient liver, instead of segments 6 and 7 as described in the written directive. Based on this initial information, the suspected medical event was reported to the US NRC Operations Center as described above. A reactive inspection was conducted on 10-Jan-2019 for this suspected medical event.

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After the reactive inspection concluded, further review of the case was conducted by a team of clinicians. After taking the limitations in the imaging software into account, the reviewing team of clinicians have evaluated that the Y-90 microspheres were administered to the correct patient, with the correct dosage and correct route of administration, and in agreement with the Written Directive. Upon reaching this determination, the suspected medical event was retracted on 14-Jan-2019 at 12:56 pm Eastern Time.

Why the Event Occurred:

The suspected medical event was reported, and eventually retracted due to two factors:

1) Initial interpretation of 10 CFR 35.3045(c) was for the reporting requirement to be carried out within the next calendar day after *occurrence* (not *discovery*) of the medical event. Based on this interpretation, the suspected medical event was reported within one day of occurrence. However, based on clarification received during the reactive inspection, the licensee is allowed to pursue appropriate *discovery* before reporting a medical event. In hindsight, the suspected medical event was reported prematurely.
2) Initial evaluation of post-administration SPECT-CT imaging was performed using a software program that incorrectly registered the CT and the SPECT images. This incorrect registration resulted in the distorted location of the Y-90 microsphere activity. Further review of the case by a team of clinicians, using the correct software program which appropriately registered the CT and SPECT images, established that the Y-90 microspheres were deposited in the location described in the written directive – segments 6 and 7 of the patient liver.

Both factors would have been mitigated if a more extensive process of *discovery* was pursued and completed prior to reporting the suspected medical event. For corrective action, Washington University in St. Louis will conduct a more extensive process of *discovery*, including review and identification of a medical event by an appropriate committee, before determination of a reportable medical event.

The effect, if any, on the individual who received the administration:

The individual who received the administration was treated according to the Written Directive. Only the effects related to the treatment are expected.

What actions, if any, have been taken or are planned to prevent recurrence:

For future suspected medical events, a multi-disciplinary team will be convened to conduct a review and determination of whether the suspected medical event satisfies the conditions outlined in 10 CFR 35.3045. If the multi-disciplinary team establishes the *discovery of a medical event*, the steps outlined in 10 CFR 35.3045 shall be followed.

Certification that the licensee notified the individual:

Patient A.C. was notified of the suspected medical event by the treating Interventional Radiologist in coordination with the Authorized User on 4-Jan-2019, one day after administration of the Y-90 microspheres. Patient A.C. was notified of the retraction of the suspected medical event by the treating Interventional Radiologist in coordination with the Authorized User on 10-Jan-2019.

Thank you for reviewing this correspondence and for your continued guidance. Please feel to contact me on my desk phone at (314) 295 6473 or via email at maxwell.amurao@wustl.edu for additional information or questions.

Sincerely,

mla

Maxwell Amurao
Radiation Safety Officer

Cc: Barry A. Siegel, M.D., Radiation Safety Committee Chairman
Bruce D. Backus, P.E., Environmental Health & Safety
Christopher W. Goddard, Associate General Counsel