



December 26, 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 54445)  
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 13-Dec-2019 at approximately 7:30 pm Eastern Time. The initial report described a dose to a different segment of the target organ than intended. Medical event number 54445 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 Physicians: Lauren Henke, MD and Hyun Kim, MD

**Brief Description of the Event:**

A Written Directive was documented for a prescription/plan to treat patient W.S. with Yttrium-90 microspheres (Nordion Theraspheres) on 6-Dec-2019. The target tissue was segment 4 of the patient liver, using an intra-arterial route of administration. The prescribed activity to the anterior portion of segment 4 of the liver was 2.04 GBq. The prescribed activity to the posterior portion of segment 4 of the liver was 0.83 GBq.

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 the infusions.

The Y-90 microspheres were administered as planned, with 95.4% of the prescribed activity delivered to the anterior portion of segment 4, and 93.4% of the prescribed activity delivered to the posterior portion of segment 4.

Shunting to segment 2 was visualized at the time of mapping and embolization of the segment 2 branch was attempted at the day of the Y-90 microsphere delivery (immediately before Y-90 microsphere administration) to minimize the potential for the activity to be deposited in areas other than segment 4. Successful embolization as confirmed by dyna-ct.

SPECT-CT images acquired post-administration appeared to indicate that the Y-90 microspheres were deposited in the anterior and posterior portions of segment 4 of the patient liver as prescribed. However, the images also appeared to reflect that microspheres were deposited in segment 2. The process of investigation and discovery was completed on 13-Dec-2019, and the suspected medical event was reported by telephone to the US NRC Operations Center within a few hours.

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:

The administration was performed as planned, while carefully following the existing procedures. The same high level of adherence to the existing procedure is planned.

Certification that the licensee notified the individual:

The patient's referring physician (Hepatologist) was informed within 24 hours of discovery of the medical event on 13-Dec-2019, as per 10CFR35.3045(e). Repeated attempts were also made to reach the patient within 24 hours, but were unfortunately immediately unsuccessful. The patient was notified of the suspected medical event by the treating Interventional Radiologist in coordination with the Authorized User on 16-Dec-2019.

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

Sincerely,

Maxwell Amurao, PhD MBA  
Maxwell Amurao  
Radiation Safety Officer

Digitally signed by Maxwell Amurao, PhD MBA  
DN: cn=Maxwell Amurao, PhD MBA, o=Washington University in St. Louis, ou=Radiation Safety Division,  
email=maxwell.amurao@wustl.edu, c=US  
Date: 2019.12.27 17:03:12 -0500

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

**Warren, Geoffrey**

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**From:** Amurao, Max <maxwell.amurao@wustl.edu>  
**Sent:** Friday, December 27, 2019 5:09 PM  
**To:** Warren, Geoffrey; Amurao, Max  
**Subject:** [External\_Sender] Written report -- event number 54445  
**Attachments:** 2019 12-27 Suspected Medical Event 13-Dec-2019 Written Report - final signed.pdf

Good evening Mr. Warren -- The written report for event number 54445 is being submitted to you as an attachment to this email. This report is provided in accordance with 10CFR35.3045(d).

Please feel free to contact me for additional information or questions regarding this correspondence.

respectfully,

-max amurao, RSO for US NRC RML 24-00167-11