St. Vincent
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November 8, 2017

Mr. Geoffrey Warren
Senior Health Physicist
Nuclear Materials License Branch
United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Ste. 210
Lisle, IL 60532-4351

Re: ***Report and notification of Medical Event: EN# 53040***

Dear Mr. Warren:

As required under 10 CFR 35.3045, this correspondence is provided as written notification within fifteen (15) days after discovery of a Medical Event as defined in 10 CFR 35.3045 (a) (1) (iii).

(i) Licensee name:

St. Vincent Hospital & Health Care Center
2001 West 86th Street
Indianapolis, IN 46240-0970

USNRC Materials License Number: 13-00133-02

(ii) Name of Prescribing Physician:

Brandon Martinez, M.D.

(iii) A brief description of the event:

On Friday, October 27, 2017, at or around 1415 hours, a 61 y.o. male was being treated for metastatic uveal melanoma, liver only metastatic disease. The Written Directive (WD) prescribed activity was 60 mCi of Y-90 microspheres [Sir-Spheres ™] with vascular access to right hepatic artery. The assay time of 1415 was documented and calculated assayed dose of 54.7 mCi was recorded. The typical procedural start and routine was noted. The microcatheter was placed in the proper hepatic artery and the hepatic arterial anatomy was interrogated. The dose was requested from physics department and was brought to Intra-vascular imaging suite. The dose draw was discussed with Diagnostic Physics Services (DPS) and the administration kit was connected per manufacturer protocol and standards. The dose infusion was initiated. The dose had a very large number of microspheres as a result of the large activity ordered and the prolonged decay. Once connected the dose administration was initiated and first aliquot was infused.

The flush line was then opened and flush was initiated with 50/50 contrast. At this point the AU, Brandon Martinez, M.D., noted the microspheres were not infusing appropriately. The AU made attempts to trouble-shoot the infusion process by the utilization of smaller syringes and manipulation of the connections and catheters present. The AU recognized the dose vial had lost its seal and was in danger of overflowing. Once the AU identified the infusion process was not going to be successful, the AU stopped the case and contained the material in a closable plastic (HDPE) container with the help of the physics department. The case was immediately discussed and documented. The calculated patient dose delivered at 1528 ET was calculated to be 11.5 mCi (-80.83% of prescribed dosage as noted on the WD). The failed dose administration appeared to be result of the micro catheter clogging.

The Radiation Safety Officer (RSO) notified the USNRC Operations Center by telephone at 13:39 ET on October 28, 2017, and spoke with Mr. Vince Klco of the USNRC in Rockville, MD to report the Medical Event. A Medical Event Notification Number was assigned: EN 53040.

Mr. Wroblewski was later contacted on Monday, October 30, by Mr. Geoffrey Warren, Senior Health Physicist, Nuclear Materials Inspection Branch, Region III, via telephone to discuss the Medical Event in more detail and again on Thursday, November 02, 2017 by Mr. Zahid Sulaiman of the USNRC, Region III. Mr. Sulaiman has scheduled on site interviews to occur on November 9, 2017, to be conducted by Mr. Sulaiman to include St. Vincent Hospital Staff and Associates who were involved in the Y-90 procedure of October 27, 2017, (e.g., AU, Health Physicist, NMT, & RSO).

(iv) Why the event occurred:

We believe the Medical Event occurred as a result of the combination of two factors that lead to the clogging of the micro-catheter.

1) The patient's treatment was delayed by one day (roughly 26 hours) due to the medical instability of the patient of the patient on the day of the initial scheduled procedure, October 26, 2017. This delay caused the activity to decay by approximately 25%. This required a 25% increase in the number of microspheres to be delivered;
2) The relatively high prescribed activity. The prescribed dose on the written directive was 60 mCi which is at the high end of the range for this treatment. The prescribed dosage also allowed for an increase in the number of microspheres.

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

No biological or physical adverse effects are expected as a result of this Medical Event. The patient will be scheduled for follow-up treatment within the next 2-3 weeks.

(vi) Actions that have taken place or are planned to prevent recurrence:

In response to the Medical Event of October 27, 2017, should a similar situation (e.g., large patient dose with a larger quantity of microspheres present) occur in the future, the AU believes the best strategy moving forward is to adjust the infusion technique by utilizing smaller aliquots of material and/or a slower infusion rate and allow for a less concentrated material to be infused.

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian):

Brandon Martinez, M.D., stated he had spoken with the patient and the family, each of whom was notified immediately of the incident and arrangements were made for re-treatment at that time. The referring physician has also been informed of this incident as well.

If you have any questions, please feel free to contact Dr. Feldman or me at 317-338-7030 or 317-338-2381, respectively.

Sincerely,

A Joel Feldman, M.D. FACS
Regional President
St. Vincent Indianapolis
Peyton Manning Children's Hospital
at St. Vincent Hospital
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Edward E. Wroblewski, M.A.,DABSNM
Radiation Safety Officer
St. Vincent Indianapolis Hospital
2001 W. 86th St
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cc: Risk Management
Brandon Martinez, M.D. (CORVASC)
NRC file