1305 W 18th Street
PO Box 5039
Sioux Falls, SD 57117-5039

Ph: (605) 333-1000
sanfordhealth.org

SANFORD HEALTH

August 14, 2015

U.S. Nuclear Regulatory Commission, Region IV
Division of Nuclear Materials Safety
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

Re: Written Report for event report number 51287

Re: Medical Event Report No. 51287
Sanford Medical Center, dba Sanford USD Medical Center
License No: 40-12378-01; Docket No. 030-03249

(i) Licensee: Sanford Medical Center, dba Sanford USD Medical Center

(ii) Prescribing Physician: Dr. Shannon Peck

(iii) Brief Description of the Event

At approximately 1100 (CT) on August 4, 2015 the Nuclear Medicine Radiation Safety Manager (NMRSM) notified the Radiation Safety Officer (RSO) for Sanford Medical Center, that she suspected a medical event had occurred involving a SIR-Spheres (Y-90 microspheres) injection on July 31, 2015. She discovered this during a routine written directive audit the morning of August 4, 2015. After the RSO and the NMRSM discussed the apparent circumstances of the event and performed a preliminary investigation of associated documents, at 1150 (CT), the RSO and the NMRSM declared that a medical event had occurred and began appropriate notification and documentation activities.

The direct cause of this medical event is the use of an incorrect number for prescribed activity in technician calculations. In the written directive, the prescribing physician had prescribed an activity based on a 20% reduction in calculated activity due to lung shunt volume (1.36 GBq reduced to 1.09 GBq). Both pre-reduction and post-reduction numbers appear on the written directive form. The nuclear medicine technician performed calculations for a drawn volume based on the activity without a 20% reduction. The technician then drew a volume with an activity of 1.48 GBq, 8.8% higher than the incorrectly used pre-reduction value, but within the procedurally allowable 10% range of what he believed to be the prescribed activity. The drawn amount, therefore, was 35.8% higher in

activity than the prescribed value. The final decay-corrected result after delivery was that the patient received a dose 26% greater than that prescribed (1.09 GBq prescribed, 1.37 GBq delivered). The RSO met with the Vice President of Heart and Vascular, who has responsibilities over nuclear medicine, and explained the NRC Y-90 microspheres guidance, the medical event, and medical event reporting requirements of 10CFR35.3045. The NMRSO and RSO met with the prescribing physician and discussed the medical event with him. He was made aware of the reporting requirements in 10CFR35.3045, specifically part (e). At approximately 1700 (CT) on August 4, 2015 the Vice President of Heart and Vascular and the RSO contacted the patient's oncologist, as well. He approved of notification of the dosage error to the patient by the prescribing physician. At 1709 (CT) the Vice President of Heart and Vascular and the Radiation Safety Officer called the NRC Operations Center at (301)-816-5100 to report that licensee Sanford Medical Center (dba Sanford USD Medical Center), license number 40-12378-01, was reporting a medical event as defined by 10CFR35.3045. We were given an Event Report Number of 51287. The prescribing physician notified the patient of the dosage error at 0825 on August 5, 2015.

(iv) Why the Event Occurred:

With regards to this event, it was determined that three main factors contributed to this event:

1) The prescribed activity in the written directive for SIR-Sphere procedures is not always in the same area on the written directive sheet, especially for procedures involving an activity reduction due to lung shunt calculations.
2) The dose verification procedure used by the technologists with regards to this event was not completely independent and only one set of calculations was performed. Instead of independently verifying the activity used in calculations, one technician went through his calculations with the other technician and possibly caused confirmation bias.
3) During the procedural "time-out" (or final confirmation of correct patient, procedure, and activity) the prescribing physician was not shown the written directive sheet.

In addition to a multi-cause analysis of the event, a review of all SIR-Spheres administrations by the licensee was performed. No additional medical events were found.

(v) Effect Upon the Individual Who Received the Administration

Based upon lung shunt activity used in pre-delivery calculations and assuming the activity was only present in lungs or liver, it is estimated that the patient involved in this medical event received a possible difference in effective dose equivalent of 0.68 Sv with respect to the effective dose equivalent the patient would have received from the dose prescribed in the written directive. As stated above, the patient received an administered activity 26% greater than prescribed. Under criteria (a)(1) and a(1)(i) of 10CFR35.3045, this constitutes a medical event. The subject of this medical event has not exhibited adverse side-effects

attributable to the additional activity administered, and the prescribing physician does not expect the individual to do so.

(vi) Actions to Prevent Recurrence

As a result of the analysis, review, and the investigation of this medical event, the following three actions described below will or have been completed prior to further SIR-Spheres injections:

1) A new written directive form has been made to clarify the prescribed dose.
2) Dual dose verification procedures for SIR-Spheres administrations have been revised to improve dose verification procedures by including separate and independent technologist calculations regarding the drawn dose. Procedures include an independent verification of the written directive dose as used in calculations.
3) SIR-Spheres procedures have been revised to create a process in which the written directive is shown to the administering physician during the procedural "time-out".
4) Technician training with regards to changes in procedures and independent dual dose verification without confirmation bias will be completed prior to the next SIR-Spheres administration.

(vii) Notification of Individual Who Received the Administration

The prescribing physician notified the patient of the dosage error at 0825 on August 5, 2015. The Vice President of Heart and Vascular also was present when the physician notified the individual and can attest to this occurrence.

A copy of this report annotated with the name of the individual who is the subject of the event and his/her medical record number will be provided to the prescribing physician, and the oncologist of the individual who received the administration within 4 days of this issuance.

Sincerely,

Steven Moeckly, MS DABR
Radiation Safety Officer, Sanford Medical Center (Sioux Falls)