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Saint Alphonsus Health System

3/9/2016
Saint Alphonsus Regional Medical Center-Boise
1055 N. Curtis Rd.
Boise, ID 83706

U.S. NRC Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511

RE: Notification of Medical Event License Number # 11-27306-01.

To Whom it May Concern:

Per NRC requirement noted in 10 CFR Subpart M, Section 30.3045 (a)(1) and 30.3045(d), this report is being submitted to provide details of a medical event that occurred on February 26, 2016. This event was previously reported by phone as required in 10 CFR, Subpart M, Section 30.345(c) on February 26, 2016 at 1836 EST to NRC Operations Center reference #271369

(i) Saint Alphonsus Health System-Boise

(ii) Dr. John Knochel prescribing Authorized User.

(iii) Patient was to receive 3.1 GBq of Y90 Theraspheres for treatment of right liver lobe hepatocellular carcinoma. Assay dose of 3.2 GBq was prepared via manufacture protocol and brought to the Interventional Radiology suite and placed into the delivery apparatus. Manufacturer representative was on-site and provided further instruction on apparatus setup of infusion lines. Surefire catheter was deployed in the same location of the initial pre-treatment planning procedure. After angiography confirmed this position, the Theraspheres product was delivered and the entire delivery apparatus was removed from the patient and placed in the appropriate waste jar. After the infusion, and per protocol, post implantation measurements were taken both of the patient and infusion set. It was discovered that the patient's readings were significantly lower than expected along with higher readings than expected within the infusion line. Per protocol the patient was imaged post Y90 implantation of which demonstrated activity noted in the target location. The radiologist's interpretation of that exam notes activity within target area with no activity seen in the chest or abdomen, outside the intended target area. Review of final calculations indicates that the patient received .491GBq which was approximately 15% of the written directive. Imaging of the infusion lines within the waste jar demonstrate activity of the Y90 Theraspheres retained within the infusion lines.

(iv) After review with the Surefire catheter representative, it appears the Surefire apparatus may not have been fully extended which would have potentially provided an occlusion and prevented all of the Theraspheres from passing through the device. We are continuing to investigate the cause.

(v) The patient was contacted 3 days post procedure to follow up to determine any symptomatic episodes. The patient stated that the patient has not felt any effects from the procedure. The patient was also seen two weeks post procedure for review of any symptoms from the procedure. The patient to date has not reported any unusual symptoms.

(vi) We have ordered a different, and newer Surefire product to use instead of the Surefire product that has been used for previous Y90 cases. We have discontinued the use the Surfire product at issue for this procedure.

(vii) The patient was notified immediately post procedure by Dr. Knochel that it appeared that the patient received less than the total intended dosage of the Y90 Theraspehere. The patient has been followed within clinic as set forth in (v) above. The patient will continue to be followed as medically appropriate.

Sincerely,

Eric Colaianni

Eric M. Colaianni CNMT, RSO, SAHS-Boise-License number 11-27306-.01,