McLaren

BAY REGION

February 19, 2015

U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532

McLaren Medical Center – Bay Region
Nuclear Medicine
1900 Columbus Avenue
Bay City, MI 48708

NRC License # 21-18585-01

On February 6, 2015 a medical event occurred at Jeppesen Radiation Oncology which resulted in one fraction of the dose delivered to the treatment target differing from the prescribed dose by more than 50%.

1) Licensee's name: McLaren Medical Center – Bay Region

2) Name of the prescribing physician: Paul Kocheril MD

3) Brief Description of the event: A 50 year old patient with endometrioid adenocarcinoma was prescribed an Iridium-192 High Dose Rate (HDR) treatment of 22 Gy delivered in 4 fractions (5.5 Gy per fraction) using a vaginal cylinder. After the 2nd fraction, while removing the transfer tube catheter (Varian PN: AL07292001), it was discovered that the transfer tube was placed 15cm proximal from the treatment position. The transfer tube catheter is reusable and close-ended. Therefore the end of the catheter represents the distal treatment position. At this location all source dwell positions were outside of the patient's body.

4) Why the event occurred: The event occurred because the transfer tube catheter was not fully seated inside the cylinder. Although there was a policy to verify the position of the cylinder and the length of the transfer tube catheter, there was not a policy or procedure in place to definitively verify the catheter position prior to treatment.

5) The effect on the individual who received the administration: Using 3D point dose approximation and information obtained in CT images acquired that day, it was determined that less than 1cc of skin on the right medial thigh received the max dose of 2.6 Gy. At this skin dose there is a possibility that the patient could present erythema. Permanent damage is not

expected. As of the date on this letter, the patient was evaluated at 4 days, 6 days, and 11 days post treatment of the medical event. There has not been a skin reaction identified and the patient has tolerated the course of treatment well. Because the source positions were outside the body, the patient did not receive any dose to the treatment volume during the medical event. An additional fraction was added to the written directive to correct for the lost dose.

All historical records were reviewed for previous patients treated with this close-ended transfer tube catheter. There was no evidence found of mis-administrations or patient symptoms resulting from source dwell positions being out of position.

6) What actions have been taken or are planned to prevent reoccurrence: On February 9, 2015, and before any additional HDR treatments, a policy was developed to verify the position of the transfer tube catheter prior to treatment. The patient is, and was previously, imaged using CT before each fraction to verify the position of the applicator. However, the transfer tube catheter is not visible with X-Ray imaging. The new policy requires placement of a radio-opaque marker wire inside the catheter prior to imaging and sign off by the authorized user that the position of the catheter was verified. A check was added to a "time-out" sheet to verify that the authorized user has signed off on the catheter position prior to starting treatment. All nursing and support staff were trained of the new policy on February 9, 2015.

7) Certification that the licensee notified the individual: The individual was notified at 4pm on February 6, 2015 (day of medical event).

Sincerely,

Matthew Buczek, M.S.
Medical Physicist
Jeppesen Radiation Oncology Center
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JEPPESEN RADIATION ONCOLOGY CENTER

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A service of McLaren Bay Region and MidMichigan Medical Center – Midland

www.baymed.org

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Date: 2-19-15

The total number of pages, including the cover page is: 3
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PLEASE DELIVER THE FOLLOWING PAGES TO:

Name: Debbie Piskura or Ed Harvey Phone: 630-829-9867 Fax: 630-515-1259

Company: NRC Department: Division of Nuclear Materials Safety

FAX SENT FROM:

Name: Matthew Buczek Phone: 989-667-6670

Department: JEPPESEN RADIATION ONCOLOGY CENTER Fax: 989-667-6688

Additional Comments:
Debbie / Ed, Here is the written report for the medical event occuring at Jeppesen Radiation Oncology on 2-6-15. A copy will also be mailed to your office. Thank you, Matt Buczek

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