BARBARA ANN
KARMANOS
CANCER CENTER
At the Detroit Medical Center

U.S. Nuclear Regulatory Commission
Region III
Material Licensing Section
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

June 12, 2017

RE: Written report of Medical Event of May 31, 2017

Licensee Name: Karmanos Cancer Center, License number 21-04127-06

Prescribing Physician: Harold Kim, M.D.

A brief description of the event:

On May 31 2017, our gamma knife model C failed during treatment delivery. Three out of 5 shots were successfully delivered to the single planned lesion. When attempting to dock for shot number 4 at 12:45 p.m., the couch immediately retracted from the treatment position due to a clutch malfunction. No further dose was delivered beyond the first 3 shots. The prescribed volume received a dose of 15.4 Gy versus the prescribed 20 Gy. Due to uncertainty regarding repair, i.e., the Elekta service person was not certain about the malfunction and could not estimate time of repair or assure the machine would be operational the next day, the fixation frame was removed from the patient's head at 4:00 p.m and the patient was released. A second service person arrived at 5:15 p.m. Repair was completed at 6:45 p.m.

Why the event occurred:

The event occurred due to the failure of the couch clutch to maintain the treatment position in which the collimator on the couch is docked with the sources assembly.

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

The risk of tumor progression of the partially treated metastatic lesion is higher with 77% of prescribed dose delivered.

What actions, if any, have been taken or are planned to prevent recurrence:

This malfunction was not evident during quality assurance testing that morning in which the couch was docked 3 times. It also did not occur at monthly QA testing or during May 19th 2017

routine preventive maintenance. At this time we do not know what preventive measures can be taken. We will ask the machine manufacturer Elekta for guidance.

Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not:

The patient was notified of the event on the day of treatment, May 31st, by the Authorized User and again On June 1st by the department executive director.

Harold Kim, M.D.
Clinical Director,
Karmanos Cancer Center Division of Radiation Oncology

Joseph T. Rakowski
Karmanos Cancer Center Radiation Safety Officer

Mara Jelich,
Executive Director, Radiation Oncology and Imaging
Karmanos Cancer Center

Warren, Geoffrey

From: Rakowski, Joseph <rakowski@karmanos.org>
Sent: Tuesday, June 13, 2017 7:07 AM
To: RidsRgn3MailCenter Resource
Cc: Warren, Geoffrey
Subject: [External_Sender] Medical Event Written Report
Attachments: image2017-06-13-075947.pdf

Dear Region III,

Please find attached the written report regarding the May 31, 2017 medical event at Karmanos Cancer Center as reported to the NRC Operations Center on June 1, 2017.

Joseph T. Rakowski
Radiation Safety Officer