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To: Parrel Wiedeman From: Joe Rakowski 313-745-1435
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 Phone: _____ Date: 6-30-09
 Re: Event CC: _____

Urgent For Review Please Comment Please Reply Please Recycle

•Comments:

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BARBARA ANN
KARMANOS
CANCER INSTITUTE

June 30, 2009

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

FROM: Karmanos Cancer Center

RE: Report of Gamma Knife Medical Event for License #21-04127-06
Sealed sources: General Electric Company AB Elekta Model 43047

On February 18, 2008, an administrative error medical event occurred at our Leksell Gamma Knife facility which resulted in the total dose delivered differing from the written directive by more than 20%, but which agreed with the therapy that was intended and planned by the radiation oncologist authorized user (AU) and the neurosurgeon. This was discovered during the 2008 annual quality management review that was completed on June 24, 2009.

1. Licensee's name: Karmanos Cancer Center.
2. Name of prescribing physician: Augustine Fregene, M.D. (deceased)
3. Brief description of the event:

On February 18, 2008, a stereotactic radiosurgery treatment plan was developed by the neurosurgeon, AU and authorized medical physicist (AMP) that satisfied the therapy intentions of the AU and neurosurgeon. Two of the three metastatic lesions that were discussed in advance at the neurosurgery tumor board meeting on February 13, 2008 by the neurosurgeon and AU were treated, the third being geometrically out of range of the gamma knife system. Specifically, the lesion locations selected at the tumor board meeting were right cerebellum, right occipital lobe and left temporal/parietal. The left temporal/parietal was out of range. The correct intended dose of 20 Gy to 50% isodose was planned and delivered on February 18. The AU and AMP specified both lesions on the Gamma Knife planning QA form which was signed by the AU, Neurosurgeon and AMP. The AU signed the plan and initialed every page including screenshots of the isodoses superimposed on the MRI images for both lesions. The plan included all of the information required in 10 CFR 35.40 (b)(3). Finally, the time out form was completed by the AU, neurosurgeon and AMP.

The administrative error medical event is the result of the AU not writing a directive for treatment of the right occipital lesion.

4. Why the event occurred:

Lack of attention to administrative tasks.

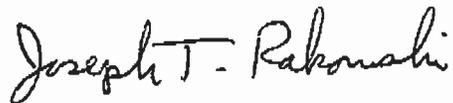
5. The effect on the individual who received the administration:

No detrimental effect. Treatment was delivered as planned according to doctor's orders.

6. What actions have been taken or are planned to prevent recurrence:

The gamma knife quality management review will be done on the day of treatment prior to delivery by a second physicist using the form/checklist attached. This process is already in effect.

Sincerely,



Joseph T. Rakowski, Ph.D.
Radiation Safety Officer
Karmanos Cancer Center

QUALITY MANAGEMENT REVIEW OF RADIATION ONCOLOGY TREATMENT
CHART
(Policy ROC 311 QMP)

PATIENT NAME _____ ROC ID _____

REVIEWER _____ DATE OF TREATMENT _____

Teletherapy (GK or STEREOTATIC RADIOSURGERY)

Treatment delivered as prescribed:	Y	N
Radioisotope	_____	_____
Treatment site	_____	_____
Total dose	_____	_____
Target coordinates per plan	_____	_____
Prescription signed & dated by AU	_____	_____
Plan signed & dated by AU	_____	_____
Dose delivered matches Rx	_____	_____

Note: AU = Authorized User