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RADIATION ONCOLOGY CENTER

Reportable Event  
10 CFR 35.33

030-01501

6 May 1994

Mr. John Jones  
Nuclear Regulatory Commission  
Region III 801 Warrensville Rd.  
Lisle Illinois 60532-4351

Dear Mr. Jones,

As per our discussion of Monday, April 25, 1994, we am submitting this report concerning a Co-60 Teletherapy Misadministration at the Jewish Hospital in St. Louis under the Washington University Medical Center License (number 24-00063-10). The following are the details concerning the event.

**Background Information:** The treatment unit is an Eldorado 76 teletherapy unit. The patient was being treated for metastatic cancer to the brain. On April 21, 1994, the patient was given a prescription (written directive) calling for 3000 cGy whole brain irradiation to be delivered in 300 cGy fractions. The technique called for right and left lateral beams. One fraction was delivered according to this prescription. On April 22, 1994, based on new diagnostic information, the treating physician gave a verbal order to make a slight change in the beam delivery technique in order to include the patient's right orbit. The new technique called for angulation (15 degrees) of the teletherapy unit's treatment head in lieu of straight lateral beams. Specifically, the technique change called for an RAO (right anterior oblique) and an opposed LPO (left posterior oblique). It was mathematically determined that the treatment head angle be offset (from a lateral angle) by ~ 15 degrees to avoid treating the left eye (which had been blocked for the lateral beam segment).

The Eldorado 76 Cobalt teletherapy unit is a stand mounted unit and thus does not have a gantry that rotates about a fixed isocenter; instead, the treatment head can be rotated. Therefore, a treatment head angle of 195 degrees was prescribed for both oblique beams. A normal lateral beam would call for the patient to lie on their side with the gantry pointing down at an angle of 180 degrees and the patient rotated, while the machine stays fixed, in order to achieve parallel-opposed beams.

**Treatment:** After receiving one fraction according to the original prescription (lateral opposed beams to whole brain), the patient was to begin being treated with the new beam arrangement calling for slightly oblique beams. On 4/22/1994 at 11:00 A.M., the treating technologist, Ms. Karen Monroe, set up the patient for the LPO (left posterior oblique) beam by lying the patient on her right side and angling the gantry to 195 degrees. This caused the beam to enter the patients' left side with the beam edge posterior to the left eye. The angulation caused the beam to diverge as to encompass the right eye as desired. This field was setup with the assistance of the Radiation Oncology Resident assigned to the case, Gopal Desai Rao, M.D. and a senior radiation therapist, William Umfleet, B.S. This field was delivered accurately.

Ms. Monroe then rotated the patient so that the patient's right side was facing the slightly angled beam. She then incorrectly rotated the beam to 165 degrees and delivered a treatment that was essentially a RPO (right posterior oblique) which placed the beam edge posterior to the right eye.

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The beam most likely exited to encompass the left eye. Discovery of the event occurred after the treatment was completed via a conversation with the treatment therapist, the Radiation Oncology Resident, and Dr. Daniel Low, the Medical Physicist on site at time of treatment. The discussion centered around a *Polaroid* photograph, which is taken for future setup instruction. The photograph clearly indicates the incorrect gantry angulation.

Later in the day (4/22/1994), a written change was made to the written directive. The new prescription reads 300 cGy Whole Brain Irradiation to be delivered with one 300 cGy fraction (requiring lateral beams), and 2700 cGy Whole Brain & Right Eye Irradiation to be delivered in 300 cGy fractions (requiring oblique beams). The prescription was written by Robert Myerson, M.D., who is named as a license user.

**Consequences:** We feel the patient did receive adequate treatment to the whole brain for this fraction on 4/22/1994. The right orbit was treated as intended from the LPO beam. The dose delivered to the left eye was approximately 120 cGy for this fraction. I was alerted about the error after the treatment, and after discussion with the treating physician, the RSO, Dr. John Eichling, and the Chief Radiation Oncology Physicist, Dr. James Purdy, we concluded that this event constituted a *misadministration*, as an incorrect treatment site, the left eye, was treated. At 2:30 P.M., the referring Physician, Dr. Fracasso was informed. Drs. Myerson and Fracasso discussed the impact of the event and came to the opinion that there is no negative impact on the treatment and the morbidity to the patient is nil. At 3:35 P.M., I called the NRC Operations Center and reported the Misadministration to a Mr. Greg Scarfo. At 4:15 P.M., the patient was informed of the event. The patient received an explanation of the event. The patient was informed that the error should not lead to any morbidity effects and that the outcome of her treatment is also unaffected. At 4:25 P.M., I received a call from Mr. Thomas Young of the Region III office. I explained the event to both Mr. Scarfo and Mr. Young. On Monday, 4/25/1994, I received a call from Mr. John Jones of the Region III office. I explained the event in further detail to him. On Tuesday, 4/26/1994, I received a call from Ms. Evelyn Mattson of the Region III office. She informed me that she will perform an inspection on May 2 and 3, 1994, concerning the event. She also informed me that Dr. Daniel Flynn will serve as a clinical consultant.

**Investigation:** After interviews with Ms. Monroe, Drs. Desai and Low, it was determined that the verbal instructions were clear, but should have been documented in greater written detail before treatment. Therefore, as there was no change to the written directive indicating the change to site of treatment (to include the right orbit) and technique change (new field arrangement), we have also filed a *Recordable Event*.

An isodose plan for the dose distribution of the fraction delivered on 4/22/1994 was performed, which confirmed the calculated dose delivered to the left eye. An isodose plan for the dose distribution accounting for all the fractions to be delivered was also done.

**Immediate Action:** In order to proceed with the patient's remaining fractions, the patient was simulated before the next fraction. The simulation called for further fine tuning of the fields to fulfill the prescription. New fields were designed and new calculations were performed. The treating radiation therapist was reminded of the policies set forth in our QMP program, and clarified on the treatment fields to be used for the remainder of the treatment. In addition, a supervisory radiation therapist accompanied Ms. Monroe for the next fraction to ensure proper delivery.

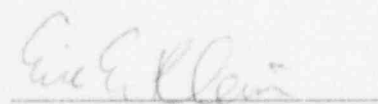
The Misadministration was reported to the Washington University Radiation Safety Committee on May 4, 1994. A letter was sent to the patient today regarding the misadministration (see enclosed letter).

**Long term Action:**

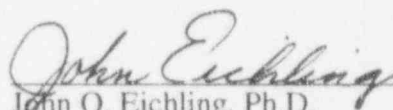
- A. We have discussed a policy change to ensure that all treatment designs calling for gantry angles other than normal angles (oblique) will have either, a simulation before treatment begins, or have all fields set up in the room confirmed by a physician before treatment begins.
- B. The staff (physicians, residents, physicists, technologists, etc.) were reminded about the key points in our Quality Management Program, namely;
  - 1. That an authorized physician must sign and date a prescription that clearly describes the total prescribed dose, dose per fraction, and treatment site. This includes changes to the prescription.
  - 2. The treating therapist shall review the prescription before each treatment to verify the specific details (treatment information) are in accordance with the prescription.
  - 3. A meeting was held on April 29, 1994 with all the therapists to discuss these points. At this meeting a formal memo was passed out to the technologists concerning clinical setups.
- C. A new treatment form is being developed to further clarify written directives and treatment instructions.

Respectfully submitted:

Reviewed by:



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Jewish Hospital  
Washington University  
School of Medicine



John O. Eichling, Ph.D.  
Radiation Safety Officer  
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Radiation Safety Committee, WUSM  
Quality Assurance Committee, Barnes - Jewish