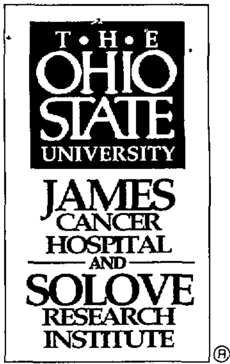

Arthur G. James Cancer Hospital and
Richard J. Solove Research Institute
Division of Radiation Oncology

300 West 10th Avenue
Columbus, OH 43210

Phone: (614) 293-8415
FAX: (614) 293-4044
Patient Scheduling: (614) 293-3241
Web Site Address:
http://www-radonc.med.ohio-state.edu

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June 2, 2006

Penny Lanzisera
Acting Chief
Medical Branch
U. S. N. R. C. Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Ms. Lanzisera:

I am enclosing my final report of the medical event incident in United Hospital Center, Clarksburg, West Virginia. A copy is also being faxed. Kindly do not hesitate to contact me if you require any further information or recommendations.

Sincerely yours,

Subir Nag, M.D.
Chief of Brachytherapy
Member, ACMUI

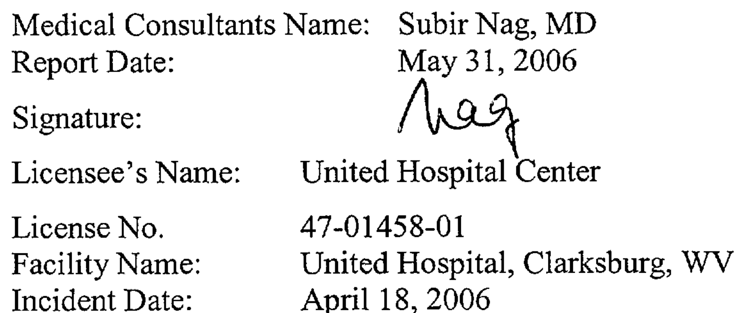
SN/ks

A Comprehensive Cancer Center Designated by the National Cancer Institute

Medical Consultant Report

Medical Consultants Name: Subir Nag, MD
Report Date: May 31, 2006

Signature:



Licensee's Name: United Hospital Center

License No. 47-01458-01
Facility Name: United Hospital, Clarksburg, WV
Incident Date: April 18, 2006

Prescribing Physician's Name: Michael A. Stewart, MD, United Hospital Center, Clarksburg, WV

Referring Physician's Name: Vicki Baker, MD, West Virginia University Hospital.

Individuals contacted during investigation: Michael A. Stewart, MD, Radiation Oncologist and James Isreal, Physicist.

Records reviewed:
Report of medical event dated May 2, 2006 and Written directive and treatment plans from United Hospital.

Estimated Dose to Individual or Target Organ: 1041 cGy
Probable Error Associated with Estimation: <1%
Prescribed Dose (Medical Administration Only): 500 cGy
Method Used to Calculate Dose: Treatment Planning Computer

Description of Incident: As detailed on the medical event report from United Hospital, the magnification factor of the x-ray had not been entered into the computer. The default magnification of the treatment planning system was 1.0 which resulted in the treatment time to be more than double of what it should have been. This happened on two patients. Normally the dosimetrist watches the data entry. The usual dosimetrist was on leave. The second dosimetrist was not as familiar and did not catch the error.

Assessment of probable deterministic effects of the radiation exposure on the individual: No significant adverse effect since the subsequent doses were reduced so that the total biological dose and the patient treatment were not compromised.

Current medical condition of the exposed individual: No adverse effect.

Was individual or individual's physician informed of Department of Energy Long-term medical study program? Not applicable since the subsequent doses were reduced so that the total biological dose and the patient treatment were not compromised.

Based on your review do you agree with the licensee's written report in the following areas:

a. Why the event occurred: Yes
b. Effect on the patient: Yes
c. C. Licenseee's immediate action on discovery: yes
d. Improvements needed to prevent recurrence: Yes.

I would like to add an additional recommendation to minimize the risk of a similar event happening in the future. An atlas of preplans should be made of common treatments being performed in the department. For example, in the present scenario, a standard plan could be made up for an intracavitary ring and tandem treatment and the treatment total time and individual dwell times be printed out for a standard dose (for example 10 Gy). When a new treatment plan is made, it would be compared with the standard treatment plan (scaling the dose as appropriate). For example, if the standard treatment plan is for 10 Gy and the prescribed dose is 5 Gy, the total treatment time should be approximately half of the standard treatment time. This reduces the risk of errors.

Areas where you do not agree with the licensee's evaluation: None

Did the licensee notify the referring physician: Yes.

Did the licensee notify the patient: Yes

Provide an opinion of the licensee's plan for exposed individual follow-up: Not applicable since the subsequent doses were reduced so that the total biological dose and the patient treatment were not compromised.

MEDICAL CONSULTANT REPORT (SHORT FORM)

(If site visit is not necessary)

Medical Consultants Name: Subir Nag, MD
Report Date: May 31, 2006
Signature:

Licensee's Name: United Hospital Center

License No. 47-01458-01
Facility Name: United Hospital, Clarksburg, WV
Incident Date: April 18, 2006
Estimated Dose to Individual or Target Organ: 1041 cGy
Probable Error Associated with Estimation: <1%
Prescribed Dose (Medical Administration Only): 500 cGy
Method Used to Calculate Dose: Treatment Planning Computer

Description of Incident: The magnification factor of the x-ray had not been entered into the computer which resulted in the treatment time to be more than double of what it should have been. This happened on two patients.

Why Site Visit is Not Required: I have interviewed the physician and physicist on the telephone. The root cause was because the regular physicist was not available and the covering physicist was not familiar. After the error was discovered, the subsequent treatment doses of the patient were reduced. Hence, the total dose and the patient treatment were not compromised. The licensee acted in the proper manner, reported the incident on discovery, and has already taken steps to prevent recurrence. Hence, I do not feel an on-site evaluation will be required for this medical event.

Assessment of probable deterministic effects of the radiation exposure on the individual: No significant adverse effect since the subsequent doses were reduced so that the total biological dose and the patient treatment were not compromised.