

RADIATION ONCOLOGY

University of Wisconsin School of Medicine

Department of Human Oncology, Timothy J Kinsella MD, *Chairman*
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January 26, 1994

John A. Grobe
Section Chief
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Rd.
Glen Ellyn, IL 60137

Dear Mr. Grobe:

Attached is the Medical Consultant Report on the Marquette General Hospital, Marquette, Michigan, regarding a misadministration of therapy incident. Records were reviewed; the incident has been described; the medical consequence of the exposure have been addressed; and I do agree with the written report submitted by the licensee. If you have any questions, please feel free to contact me (608/263-8500).

Sincerely,



Judith Anne Stitt, M.D.
Associate Professor of Human Oncology AND
Clinical Director, Section of Radiation Oncology

JAS/dtp

Enclosures

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Timothy J Kinsella, MD, *Director* Yvonne Pola, MS, *Administrator* Judith A Stitt, MD, *Clinical Director*

Radiation Oncology 263-8500

D R Barton MD, D A Buchler MD, P M Hanari MD, T J Kinsella MD, P A Mahler MD PhD,
M P Mehta MD, M A Ritter MD PhD, R A Sicéves MD PhD, J A Stitt MD
B R Paliwal PhD, *Director*, T R Mackie PhD, N E Peters MS, B R Thomadsen PhD

FEB 08 1994

MEDICAL CONSULTANT REPORT

Medical Consultant Name: Judith Anne Stitt, M.D.

Report Date: 01 / 18 / 94

Signature: *J Stitt*

Licensee Name: Marquette General Hospital

License No. 21-05432-04

Patient's Identification No.: Not given

Incident Date: 11 / 19 / 93

Individual/Patient's Physician Name: Cheryl Davison, M.D.

Individuals Contacted During Investigation: Cheryl Davison, M.D., David Nelson, NRC
(Name and Title)

Records Reviewed: (General Description)

Isodose curves of the proposed and the actual gynecologic insertion.

Gynecologic insertions radiographs.

Narrative regarding therapy administration from Upper Michigan Cancer Center.

NRC documents.

Calculated Dose to Individual: _____

Prescribed Dose (Medical Misadministration Only): _____

Method Used to Calculate Dose: _____

Description of Incident:

On November 17, 1993 a patient at the Upper Michigan Cancer Center had a gynecologic insertion consisting of a uterine tandem and vaginal ovoids. The tandem was loaded with 30, 20, 20 mg. eq. of cesium-137, the colpostats were loaded with 30 mg. eq. of cesium-137. Upon removal of the intracavitary sources on November 19, 1993, it was noticed that the plastic tube containing the uterine sources was of insufficient length to reside in the uterine cavity. According to measurements and initial radiographs the three sources actually resided in the portion of the tandem situated in the vaginal vault.

Computerized isodose distributions of the proposed as well as the actual therapy were generated. The following table describes the doses that were planned versus the doses that were given according to the computerized treatment plan.

	<u>Planned Dose (cGy)</u>	<u>Given Dose (cGy)</u>
Point A Right	2777	1435
Point A Left	2434	1161
Sidewall Left	952	664
Sidewall Right	524	397
Bladder	1919	2036
Rectum	1682	2028
Lower Vagina	0	2700

My determination of dose to the vaginal surface is based on the theraplan isodose of 11/23/93 that demonstrates a 2700 cGy isodose line at 1 cm from the sources placed in the inferior position of the tandem. This distance of 1 cm would take into account the presence of the applicator handles and vaginal packing.

Medical Consequence of Exposure:

Because of improper placement of the cesium tubes in the tandem, there was an underdosing to the endometrium, cervix, and paracervical tissues. In addition, the middle and lower vagina were irradiated when no radiation dose had been planned to this area. The patient underwent a subsequent insertion to give additional dose to the cervix and paracervical regions so that an appropriate dose of irradiation from brachytherapy was achieved. The dose given to the middle and lower vagina, is of a level that would not be expected to cause any acute or late sequelae since these tissues are known to be extraordinarily tolerant of radiation. The dose to the bladder and rectum was not altered because of the placement of the sources inferior in the tandem rather than in the superior location.

Was individual or individual's physician informed of DOE Long-Term Medical Study Program?	Y	N
Would individual like to be included in the Program?	Y	N

COMPLETE FOR MEDICAL MISADMINISTRATION

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1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to MRC pursuant to 10 CFR 35.33 in the following areas:

- | | | | |
|--|------------------------------------|-------------------------|-----|
| a. Why the event occurred | <input checked="" type="radio"/> Y | <input type="radio"/> N | |
| b. Effect on the patient | <input checked="" type="radio"/> Y | <input type="radio"/> N | |
| c. Licensee's immediate actions upon discovery | <input checked="" type="radio"/> Y | <input type="radio"/> N | |
| d. Improvements needed to prevent recurrence | <input checked="" type="radio"/> Y | <input type="radio"/> N | |
| e. Licensee's plan for followup of patient | <input checked="" type="radio"/> Y | <input type="radio"/> N | N/A |

2. In areas where you do not agree with the licensee's evaluation, provide basis for your opinion:

3. If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with medical ethics?

Y N

If not, comment on why the reason was not valid.

I was informed by the Radiation Oncologist, Dr. Davison, that she informed the patient of this incident.