U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-18133/94001(DRSS)

Docket No. 030-18133

License No. 21-05432-04 Category G Priority 2

Licensee: Marquette General Hospital
420 West Marquette Street
Marquette, MI 499855

Inspection Conducted: November 29, 1993

Inspector: John A. Grobe for 3-9-94
David W. Nelson Date
Radiation Specialist

Approved By: John A. Grobe 3-9-94
John A. Grobe, Chief Date
Nuclear Materials Inspection
Section 2

Inspection Summary

Inspection on November 29, 1993 (Report No. 030-18133/94001(DRSS)
Areas Inspected: This was a special, announced, limited scope safety inspection to review the circumstances surrounding the misadministration of a brachytherapy dose. The inspection included interviews with involved parties, a review of the pertinent medical records and an on-site visit to the brachytherapy storage vault. The report also includes the findings of a medical consultant hired by the NRC to evaluate the medical consequences of the misadministration.
Results: The licensee's QMP program failed to prevent the misadministration of a brachytherapy dose on November 17-19, 1993. No violations were identified.

DETAILS

1. Persons Contacted

* Richard Moreland, RSO, Physicist
* Dr Davidson, Medical Oncologist
* Linda Olson, Director, Cancer Center
* Sharon Ahaffer, Assistant Administrator

* Indicates those persons present at the exit interview on November 29, 1993.

2. Licensed Program

The licensee operates a large nuclear medicine and radiation oncology program. Brachytherapies are performed routinely, two to three patients a month.

3. Purpose of Inspection

A special inspection was conducted to investigate the circumstances surrounding the November 17-19, 1993, misadministration of a Brachytherapy dose at Marquette General Hospital.

4. Summary of Incident

On November 17, 1993, a patient at the Marquette General Hospital had a gynecologic insertion consisting of a uterine tandem and vaginal ovoids. The tandem (catheter) was loaded with 30, 20, and 20 milligram equivalent Cesium-137 seeds, and the colpostats were loaded with 30 milligram equivalent of Cesium-137. Upon removal of the intracavitary sources on November 19, 1993, it was noticed that the plastic tube (catheter) containing the uterine sources was too short to reside in the uterine cavity. According to the initial radiographs the three tandem sources actually had resided in the vaginal vault not the uterine cavity. A review of the dosimetry calculations on November 19, for the actual insertion, indicated that a misadministration had occurred.

On November 19, 1993 the Radiation Safety Officer (RSO) at Marquette General Hospital notified the NRC by telephone that a misadministration of a brachytherapy therapy dose had occurred at Marquette General Hospital on November 17-19, 1993. On November 29, 1993 a NRC inspector was dispatched to the hospital to investigate the misadministration.

On November 26, 1993 a letter was sent by the Marquette General Hospital to the NRC Region III office to explain the circumstances surrounding the misadministration and its consequences. On or about the first of December 1993, the information collected by the inspector, during the

November 29, 1993 inspection, was forwarded to Dr. Stitt, a medical consultant contracted by the NRC to review the incident. On February 1, 1994 the medical consultant's report was faxed to the NRC Region III office.

5. Medical Consultants Report

On November 24, 1993 a letter was sent to Judith Stitt M.D. requesting that she serve as a medical consultant with respect to the misadministration that had occurred at Marquette General Hospital on November 17-19, 1993. Material (simulation x-rays and the Theraplan isodoses) collected during the November 29, 1993 were sent to her on or about December 1, 1993. On February 1, 1994, a package containing Dr Stitt's report was delivered to the NRC's region III office.

Dr Stitt's report indicated that there had been underdosing to the endometrium, cervix and paracervical tissues and the middle and lower vagina had been irradiated inadvertently. The doses to the middle and lower vagina, however, were not expected to cause any acute or late sequelae since those tissues were known to be extraordinarily tolerant of radiation. In addition, the dose to the bladder and rectum had not been altered significantly because of the placement of the sources in the tandem.

The medical consultant used the license's Theraplan isodoses to calculate the following planned and actual doses:

	Planned Dose (cGy)	Actual Dose (cGy)
Point A Right	2777	1435
Point A Left	2434	1161
Sidewall Left	932	664
Sidewall Right	524	397
Bladder	1919	2036
Rectum	1682	2028
Lower Vagina	0	2700

The vaginal dose was based on the Theraplan isodose lines generated November 23, 1993. The Theraplan indicated a 2700 cGy isodose line at 1 cm from the sources placed in the inferior position of the tandem.

Following the inspection the patient underwent another therapy to give additional dose to the cervix and paracervical regions so that an appropriate dose was achieved.

6 Incident Evaluation

10 CFR 35.2 defines a misadministration, in part, as the administration of a brachytherapy radiation dose when the calculated dose differs from the prescribed dose by more that 20 percent of the prescribed dose. Clearly the actual doses to the vagina and cervix meet the criteria for a misadministration.

Root cause analyses of the incident indicated that the licensee's QMP program had failed to ensure that brachytherapy sources were loaded into the correct length catheter and the licensee had lacked a method for ensuring that brachytherapy sources were positioned properly post insertion.

The licensee routinely used two lengths of plastic tubes (catheters) for brachtherapy, one for uterine applications and the other for vaginal applications. The physicist had pre-cut both catheters and taped them to the L-shield located in the brachytherapy source storage vault. Prior to the patient insertion the physicist had inadvertently loaded the prescribed (per the written directive) sources into the shorter length vaginal catheter. Subsequently that catheter was inserted into the tandem and the sources improperly positioned. Because the licensee's QMP did not require post insertion x-rays, the misadministration was not discovered until the oncologist had difficulty removing the shorter length catheter from the tandem.

The description of the event and the resultant doses to the patient were essentially as described in the telephone notification of November 20, 1993 and the letter dated November 26, 1993 letter. There were no deviations from either the licensee's procedures or QMP program noted during the inspection.

7. Conclusions

A misadministration had occurred, the licensee administered a brachytherapy radiation dose to the wrong treatment sites (10 CFR 35 Subpart A) and the licensee's QMP program was inadequate to prevent the misadministration.

The licensee indicated at the exit meeting that the physicist will, in the future, either use the same catheter for both the simulator and the insertion or tag an uncut catheter with the patient's name and use it for both the simulator and the insertion. At the exit meeting the licensee was undecided about which approach they would take and whether or not the change would be written into their QMP procedures. The proposed corrective actions appeared to be adequate.

No violations of NRC regulations were identified. The licensee complied with 10 CFR 35.33, i.e. the referring physician, patient and the NRC were all notified within the required time limitation.

8. Exit Meeting

At the conclusion of the on-site inspection on November 29, 1993, the NRC inspector met with hospital representatives, as described in Section 1 of the report, to summarize the event and discuss the findings.

Nelson

RADIATION ONCOLOGY

University of Wisconsin School of Medicine

Department of Human Oncology, Timothy J Kinsella MD, *Chairman*
Center for Health Sciences and the University of Wisconsin
Comprehensive Cancer Center, Paul P Carbone MD, *Director*

600 Highland Drive, Madison, Wisconsin 53792-0600 (608) 263 - 8500 FAX (608) 263 - 9167

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

FEB 8 1994

MEDICAL CONSULTANT REPORT

Medical Consultant Name: Judith Anne Stitt, M.D. Report Date: 01 / 18 / 94

Signature: Jstitt

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.

	Planned Dose (cGy)	Given Dose (cGy)
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

COMPLETE FOR MEDICAL MISADMINISTRATION

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

a. Why the event occurred	(Y)	N	
b. Effect on the patient	(Y)	N	
c. Licensee's immediate actions upon discovery	(Y)	N	
d. Improvements needed to prevent recurrence	(Y)	N	
e. Licensee's plan for followup of patient	(Y)	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.