IE-07

PUBLIC

December 7, 1994

Memorial Hospital
ATTN: George E. Soper, Ph.D.
Senior Vice President
615 North Michigan Street
South Bend, IN 46601

Dear Dr. Soper:

SUBJECT: NRC MEDICAL CONSULTANT REPORT

Enclosed is the NRC Medical Consultant Report regarding the medical misadministration that occurred on September 15, 1994. The report is forwarded to you for information purposes only.

No response is required by this letter.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter and the enclosure will be placed in the NRC Public Document Room.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by B. J. Holt

B. J. Holt, Chief
Nuclear Materials Inspection
Section 1

License No. 13-18881-01
Docket No. 030-17335
EA No. 94-217

Enclosure: As stated

bcc w/enclosure:
D. Serig, NMSS
S. Merchant, NMSS
PUBLIC (IE 07)

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OFFICE	DRSS/RIII		DRSS/RIII		DRSS/RIII					
NAME	RGattone:bt		JCameron		BJHolt					
DATE	12/6 /94		12/6/94		12/6/94					

To; Ms. B. J. Holt ph 708-829-9836
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From: M.L. Griem, M.D, Med. Consultant & former Member ACMUI
Professor, Univ. of Chicago
FAX 312-702-2629
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Re: License 13-18881-01 PNO -III-94-77

Dates: Sept. 29, 94 1 page FAX from NRC region III
Oct. 5, 94 Full package received by mail
Oct. 7, 94 first contact with RSO, FAX data requested
Oct. 14, 94 Contact with Dr. King,
Fax data re-requested
Oct. 20, 1994 (case review)

Signed: M Griem 11/15

Persons contacted: David Hornback, M.D. Radiation Safety
Officer (MH)
Karl King, M.D. Radiatior Oncologist
Phone - 219-284-7461

Summary:

Two cesium 137 brachytherapy sources were used in a temporary implant in an ovoid applicator for vaginal therapy of a patient with poorly differentiated endometrial cancer. This was combined with external beam radiation therapy from a linear accelerator. The dose for the brachytherapy was somewhat lower than planned however this was compensated for in the subsequent treatment plan. The treatment appears to be within the standard of care for this disease.

Event description and dose estimate:

The patient had surgery for the removal of a tumor of the uterus on 7/20/74. Following an initial course of external beam radiation therapy starting on 8/29/94 for this pelvic tumor, at a dose of 20 Gy the patient was then treated with the intracavitary cesium brachytherapy to add additional localized treatment to the apex of the vagina using two colpostats containing Cs-137 sealed

sources. The planned dose was higher by 31% than the final dose of 41.65 Gy to the vaginal mucosa for the Cs-137 brachytherapy. A correction was made in the additional external beam radiation therapy to compensate for change brachytherapy dose as outlined in the letter to the referring physician dated Oct. 13, 1994.

Medical Evaluation:

The resultant plan is an acceptable plan and within the standard of care for this combined treatment using surgery and radiation therapy. The critical normal tissue at risk is the small bowel which as the result of the pelvic surgery is "plastered" against the apex of the vagina where the brachytherapy sources were placed. This dose might be 65 Gy based on the isodose curves as recalculated and which were supplied to me on Oct. 13, 1994. Some additional few treatments were given following the brachytherapy before a shield was placed in the mid-line to shield the apex of the vagina from additional radiation. The final plan may in fact reduce the risk of complications related to the small bowel. This combined treatment as completed on Oct. 13, 1994 should result in tumor control in the fields of therapy. The dose to the bone marrow should not change significantly. Standard follow-up is planned.

Analysis of this event.

With brachytherapy the dose distributions may vary as much as 30% depending on where one evaluates the dose in the target volume. it may not be easily to achieve the current 20% variation recommendation in every brachytherapy case particularly when one considers the steep dose gradients very near some sources and that some minor movement of a source will cause a considerable change in dose.

The licensee took appropriate action in the subsequent external beam treatment and compensated for the brachytherapy dose delivered. He has informed the referring physician of the final treatment as stated in the letter of Oct. 13, 1994. I don't know whether the patient was informed however in this case the final treatment is within he standard of care for this disease.

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