NRC MEDICAL CONSULTANT'S REPORT

DATED APRIL 23, 1996

MEDICAL CONSULTATION REPORT NRC Reg.III FINAL REPORT 4/10/96 pgl
Lic.#21-01333-01; PRO-III-96-010 Wm Beaumont Hosp. Rev. ML Griem

TO: Cynthia D. Pederson, Director
Division of Nuclear Safety, NRC Region III
801 Warrenville Road
Lisle IL 60532-4351

FAX 708-515-1259

Mr. Robert Hays Phone 708-829-9819

Mr. John D. Jones - Phone 708-829-9832

Mr. Thomas F. Young Phone 708-829-9835

FROM: Melvin L. Griem, MD - Consultant NRC
Former member ACMUI
Univ. of Chicago
FX 312-702-0610
Ph 312-702-6883

RE: MEDICAL INSPECTION REPORT PNO-III-96-010
WILLIAM BEAUMONT HOSPITAL - BRACHYTHERAPY EVENT 2/24/96

Signature: Mel L Griem Date: 4/23/96

Patient Identification: Female patient with cancer of cervix

NRC Contact Mr. Robert Hays 2/29/96 (Est Skin dose 0.587 Gy)

Individuals Contacted:
Cheryl Culver Schultz, M.S. Radiation Safety Officer
3/1/96 FAX dated 3/1/96
New data 3/21/96 by phone

Dr. Peter Chen, MD Authorized User and Prescribing Physician. 3/14/96 (several more contacts the last being 4/4/96)

Records Reviewed:
NRC Documents: FAX dated 3/7/96
Review of incident: reported by C. Culver Schultz
FAX dated 3/1/96
Dosimetry: Dated Feb. 22, 1996

SUMMARY:
After external beam radiation therapy, 2 low dose rate (LDR) brachytherapy implants were planned for this female patient with carcinoma of the cervix Stage IIB. The final result was the use of an LDR implant followed by an intracavitary series of treatments directed to the lesion with the high dose rate (HDR) unit for intravaginal brachytherapy. The lesion responded in a very satisfactory fashion. During the first brachytherapy procedure the patient moved, dislodged the implant and exposing the skin of the thigh to an estimated maximum dose of 26 rads or 0.26 Gy.

Detailed report:

A brachytherapy interstitial implant where the sources were from a remote LDR afterloader were used to treat a female patient with advanced carcinom. of the cervix. The stage of the disease is described as a Stage IIB carcinoma of the cervix or as outlined over the phone by the authorized user and finally confirmed as Stage IIB. The "B" in the staging indicates extension of the tumor laterally toward the pelvic wall in the paracervical region where the uterine artery and the ureter are situated. The lesion is described as bulky with extensive cervical involvement. An implant was designed to treat this extensive disease using 26 remote afterloading LDR needles to give a planned dose of 3250 cGy in a treatment duration of 65 hours. The procedure was monitored continuously by TV. The loading of the implant was tailored to encompass the tumor bearing area. Details of the procedure are carefully described in her report of Cheryl Culver Schultz the RSO dated 3/1/96. On the morning of 2/24/96 the sources were retracted to allow the husband to visit the patient and at 7:10 AM the sources were again in treatment position. At 7:20 Am the source alarm sounded. The staff was called, sources were retracted and the connection of the afterloader and the applicator was checked. Treatment was restarted at 9:12 AM.
At 10:05 the treatment was interrupted, the practical nurse unclamped the Foley catheter and checked the perineum. Treat was restarted following this check. At 10:36 AM the whole implant device was found between the patient's legs. The sutures holding the implant were broken. The estimated dose to the skin of the legs was between 26 and 22.1 cGy. This patient had external beam radiation therapy in addition to the above LDR brachytherapy The LDR brachytherapy dose to the tumor was essentially as planned.

Subsequently a second implant using a similar LDR interstitial technique was attempted on March 4, 1996. This template procedure was unsuccessful. The implant was difficult, CT Simulation suggested that the needles may have been near the bowel, and the patient was in considerable distress.

The handling of this treatment dilemma:
Radical surgery of the tumor site was not possible. At the time of this review either additional external beam radiation therapy focused on the paracervical region will be done or some type of brachytherapy procedure would be considered using intracavitary methods.
ON 3/20 a high dose rate (HDL) intracavitary procedure was planned. The use of a Fletcher -Suit type of applicator was also being considered. Four or five HDR procedures were carried out on this patient using intravaginal brachytherapy. The response on 4/4/96 the last HDR procedure was excellent.

The patient's legs were observed over the past 4 weeks. No erythema or other skin changes were observed, the site of the unplanned skin exposure. No other organs are at risk.

Description of the Event and reliability of th data:
The description of the event is carefully documented in the William Beaumont Hospital report in part A by the radiation safety officer Cheryl Culver Schultz. I can only add that a discussion with The Authorized User, Dr. Peter Chen, MD confirms the report. After the initial follow-up on 3/18/96 and 3/19 several other discussions have been held the most recent being 4/4/96. The analysis by Cheryl Culver Schultz is as stated in the above report is superb.

My opinion:

1. a. Dose to target (tumor) area in patient:
   The tumor dose was achieved by the two brachytherapy procedures, the LDR interstitial and the HDR intracavitary..
   The dosimetery is excellent.

   b. The skin dose is as stated or less than calculated based on the biological response and the lack of reaction on 4/4/96.

2. Side Effects in the patient.
   Essentially none. No need to notify the DOE Long-Term Medical Study Program. No late effects will be seen. No bone marrow at risk. No stochastic or non-stachastic effects will be seen.

3. Possible Staff exposure
   No risk of exposure.

4. Accuracy of medical information.
   This is again one of the best reports I have seen in my experience on the ACMUI and as a consultant.

5. The QA program is in place.

6. I am not convinced that this is a true misadministration.

7. I think the outcome for this patient will be very favorable based on the obserations of tumor respo. se made on 4/4/96.

4/96- 5 modified final Report.
original sent by FAX 4/10/96
changes represent spell check Lic # correction in header.
& minor change to make summary clearer.
MB.