Yale New Haven Hospital
1826
20 York Street, New Haven, CT 06504

Radiological Physics - WWW 204

Licensee No.: 06-00819-03
Docket No.: 030-01244

December 22, 1992

Keith Brown, Ph.D.
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406

Report of Therapy Misadministration

Dear Mr. Brown:

A therapeutic brachytherapy misadministration occurred at Yale-New Haven Hospital (YNHH) on November 30, 1992. The misadministration was identified on December 2, 1992, when a staff dosimetrist noted a missing source while performing an inventory of the sources after the completion of treatment. The dosimetrist promptly reported the discrepancy at 2:30 PM to the Radiation Safety Officer (RSO). The source was found and recovered which will be detailed in a subsequent report to the NRC. The RSO reported the source loss incident to Rudy Karsch of the NRC's Operation's Center on December 2, 1992 at 6:10 PM after recovery of the source. The RSO discussed the possibility of a misadministration with Jenny Johansen of NRC Region I the next morning. This report is being provided in compliance with the requirements of 10 CFR 35.33 (a)(2), regarding records and reports of misadministrations.

The patient was referred to Dr. Kenneth B. Roberts of the Therapeutic Radiology Department for combined external beam radiation therapy (EBRT) and intracavitary brachytherapy by Dr. Joseph Chambers of the Gynecological Oncology Department after receiving 2 cycles of chemotherapy. The EBRT delivered a total of 3,960 cGy (rad) to the pelvis in 22 fractions and a total of 4,300 cGy to the paraortic region in 30 fractions. The patient was then scheduled to receive 2 Fletcher-Suit Delclos (FSD) tandem and ovoid intracavitary radiation treatments followed by a pelvic wall boost (See Attachments 1 & 2). The patient received the first FSD on November 16, 1992, which delivered 2,440 cGy to the right point A and 2,280 cGy to the left point A. The first FSD treatment was completed without complication.

Point A is defined as a point 2 cm lateral to the cervical canal of the uterus and 2 cm above the external cervical os. The EBRT Pelvis field includes the right and left point A. The paraortic and pelvic wall boost fields do not include point A.

ENCLOSURE (2)

The second FSD treatment was initiated on November 30, 1992 at 12:00 PM. The 28 hour placement (See Attachments 3,4,5 & 6) was intended to deliver 1,568 cGy to the right point A and 1,848 cGy to the left point A. The treatment consisted of the placement of one 35 mCi and one 24 mCi Cs-137 source in the tandem and a 35 mCi Cs-137 source in each ovoid. A therapeutic radiology resident placed the sources into the patient and the placement was observed by a dosimetrist. The resident and the dosimetrist did not perceive a source falling from the applicators during the procedure. After investigation, we assume the most likely scenario is that one of the sources intended for the ovoids was misplaced by the resident physician and fell into the bed instead of going into the ovoid as planned. The resident did not notice the missing source during the removal on December 1, 1992 at 4:00 PM. Using a GM detector, he performed a removal survey which was negative and returned the removed sources to the Radium Room.

The next day at 2:00 PM a dosimetrist went to the Radium Room to clean the sources and applicators and to return the sources to the active inventory. The dosimetrist did not notice the missing source until after the other source had been removed from the ovoid applicator. Therefore, it is uncertain which ovoid of the apparatus was loaded during the treatment. We have assumed the left ovoid source was missing as a worst case estimate.

Assuming the left ovoid was not loaded, the second FSD treatment delivered 1,439 cGy to the right point A and 1,235 cGy to the left point A (See Attachments 7 & 8). This resulted in a treatment error of -8.2% to the right point A and -33.2% treatment error to the left point A for the second FSD treatment. Adding the previously delivered doses from the first FSD placement and the external beam treatments, results in an error of -1.6% to the right point A and -7.6% to the right point A for the combined treatments. Please refer to Attachment 9 for a summary of the prescribed and delivered doses.

The misplaced source contained 35 mCi of Cesium-137 as of December 2, 1992. It is believed that the source fell into a linen bedpad which is routinely placed under gynecological brachytherapy patients to prevent blood and other bodily fluids from contaminating the bed sheets. The patient and the nurse believe the linen bed pad was changed soon after source application and was removed from the room. The bedpad was placed in a linen hamper in the hallway outside the patient's room.

Assuming the source was in direct contact with the patient's skin and not moved for 15 minutes after the application was performed and using a surface exposure rate of 513 Roentgen/min for a 1 Curie Cesium-137 source from Appendix B, Table 6, NCRP Report No. 40, and a conversion factor of 0.96 Rad/Roentgen, we calculate a worst case exposure to the patient's skin of 258 cGy.

The patient was seen in the clinic by Dr. Roberts on December 3, 1992. The patient was informed at that time of the misadministration. A careful exam of the patient's skin was also conducted and no evidence of skin erythema was noted. Dr. Roberts reviewed the incident with the referring physician, Dr. J. Chambers and also asked other staff therapeutic radiologists to review the case. They concluded that no additional treatments were necessary to make up for the missing source. Dr. Roberts informed the patient of this and informed her that she could get a second opinion if desired.

After the incident, a boost dose of an additional 540 cGy to the pelvic wall was administered as scheduled after the FSD treatment by EBRT. This additional treatment was delivered in 3 fractions between December 7 and 9, 1992. This boost dose does not significantly alter dose received by the right or left point A.

On December 21, 1992, the patient was seen again by Dr. Roberts in the clinic. The patient had reported a tender spot on the back of her leg. Upon exam a 2.5 cm by 0.5 cm area of hyperpigmentation was observed on the dorsal surface of the upper leg just below the right buttock. There was no evidence of ulceration during the exam. This spot is consistent with the actual source dimensions and also with the assumed scenario. The estimated skin dosimetry would also be consistent with this observation. Dr. Roberts scheduled the patient for a follow up exam in two weeks and will keep the area under observation.

In order to prevent a recurrence of this incident, the following steps have been taken:

1. Residents will be reinstructed to visually confirm that sources are present in the applicators during the patient loading process and to visually track the sources into the FSD or other afterloading device.

2. Dosimetrists will be instructed to visually observe the patient loading process to confirm the applicators are correctly loaded and placed into the patient.

3. A linen hamper will be placed in each brachytherapy room so linen will not be allowed out of the room until it is surveyed during the unloading process.

4. Soiled linen which cannot be left in the room will be surveyed by nursing personnel before being placed into the normal linen hampers for washing.

5. Residents will be instructed to visually reconfirm correct source placement upon removal and to inventory afterloaded sources promptly after removal.

If there are any further questions concerning this incident please contact Michael J. Bohan, Radiation Safety Officer at (203) 785-2950.

Sincerely,

Michael J. Bohan

Michael J. Bohan
Health Physicist/RSO

cc: Patient
All Staff Dosimetrists
All Staff Residents
Stephen Bencivengo, Associate Administrator, Therapeutic Radiology
Joseph Chambers, M.D., Gynecological Oncologist
Carolyn Dicker, Chief Dosimetrist
Robert Lange, Ph.D., Chairman, Radiation Safety Committee
Ravinder Nath, Ph.D., Director, Radiological Physics
Kenneth Roberts, M.D., Therapeutic Radiologist
Norman Roth, Assistant Vice President, Administration
Stuart Warner, Asst. Counsel, Medicolegal Affairs

Attachments (9)

CLINIC

UNIT NO Attachment

NAME

ADDRES 1

BIRTH D

(If handwritten, record name, unit no., and birth date)

YALE-NEW HAVEN HOSPITAL
AMBULATORY SERVICES

HISTORY AND
PROGRESS NOTES

9/2/92
cont.

Rectal exam reveals good tone, no rectal masses, a normal RV septum and a brown heme negative stool.

Impression & Plan: 39 y/o female with node positive clinical stage IB SCC od the cervix, s/p chemotherapy. We will proceed with EBRT to a total dose of 3960-4500 cGy. After reviewing her pathology, we will decide if a paraortic chimney field is indicated. After her EBRT has been completed, we will then proceed with 2 FSD ICRT's. We have discussed the anticipated benefits and side effects of this treatment course with the patient and she has agreed to proceed. Her simulation will be on Wed., 9/16/92 at 1:00 p.m. We have ordered a KUB and cross-table lateral films of the abdomen and pelvis to assist in locating her transposed ovaries and involved lymph node regions which were clipped at the time of laparotomy.

RJ Smith

Robert J. Smith, M.D. for
Kenneth B. Roberts, M.D.

cm
cc:Drs. J. Chambers, Bartlett (CHCP), Kische

D:9/2/92
T:9/3/92

BINDING LINE

OA (REV 9-82)

YALE - NEW HAVEN HOSPITAL

RADIATION THERAPY

NAME: Attachment
ADDRESS:
BIRTH DATE:
PHONE:
REL. OR FRIEND:
ADDRESS:
FAMILY DOCTOR:
ADDRESS:

UNIT NO. W Haven, CT 06530 THERAPY No. 92-698
STATUS:
REFERRING PHYSICIAN: Dr. Joseph Chambers
ADDRESS: 336 FMB
PHONE: 5-5778
ATTENDING RADIATION THERAPIST: Dr. Kenneth Roberts
RESIDENT: Dr. Robert Smith

2

DIAGNOSIS: Cervical carcinoma

HISTOLOGY: Squamous cell carcinoma

STAGE IB

T N M

DATE: 9/2/92*

HISTORY, PHYSICAL EXAMINATION, TREATMENT POLICY

The patient was treated with laser therapy to the cervix in 1986 for dysplastic changes. A subsequent PAP smear in March 1992, showed class III cells. A biopsy in May 1992 showed invasive squamous cell carcinoma with lymph vascular space invasion. A CT scan showed no lymphadenopathy. On May 27, 1992, the patient had staging lymph node dissection with frozen section showing metastatic SCC to lymph nodes including low paracaval nodes. A planned hysterectomy was aborted and the patient went on to receive 2 cycles of chemotherapy and was subsequently referred for primary radiation therapy.

cm

Kenneth B. Roberts, M.D. M.D.

SUMMARY OF RADIATION THERAPY

REGION TREATED	RADIATION ENERGY	DOSE MAX. SURF.	DOSE MAX. TUMOR	DOSE MIN. TUMOR	TOTAL TIME (DAYS)	TREATMENT PERIOD
1. Pelvis	10 Mv			3960	30/22 fr	9/24/92 — 10/23/92
2. Paraortic region	10 Mv			4500	42/30 fr	9/24/92 — 11/4/92
3.						
4.						

CLINICAL COURSE AND DISPOSITION OF PATIENT

Radiotherapy was well tolerated for the most part. Towards the end of the treatment course, the patient developed some perianal and perineal irritation. These areas became associated with some excoriations and one ulcerative lesion over the right labia, not clearly within the treatment fields. Once the pelvic fields reached the dose of 3960, the skin healed over the subsequent week to week and one half while treatments continued to the paraortic fields. The radiation therapy technique utilized AP/PA treatment fields with placement of a compensator in the paraortic region such that the pelvis was treated at 180 cGy/fraction while the paraortics were treated at 150 cGy/fraction. The rationale for this technique was to hopefully minimize the acute toxicity as well as diminish the risk of any late small bowel complications. The patient will subsequently receive 2 tandem and ovoid intracavitary radiation treatments to then be followed by pelvic sidewall boost.

cm

Kenneth B. Roberts, M.D. M.D.

CARBON COPY TO: Chambers, Barrett, Kische

D:11/12/92;T:11/13/92

952 (Rev. 4/84)

-- PROGRAM ISODOS - THERAPLAN V05 --- COPYRIGHT (c) 1990 Theratronics
Linear source calculation on 30-NOV-92

Patient Name:
Distribution Title:

Calculation plane orientation
Origin: X Y Z
0.0 0.0 0.0
Original(AP) plane

Rotation angles:
Horizontal: 0.0
Vertical: 0.0
Normal: 0.0

Film magnification:
AP: 1.50; LATeral: 1.55

Total source activity: 49.4
Time of implant: 1.00 Hours

Attachment 3

Linear source calculation on ----

SOURCE #	TYPE	FILT (mm)	ACTIVITY	UNITS	LENGTHS TOTAL	LENGTHS ACTIVE	SOURCE END POINT COORDINATES X	Y	Z	X	Y	Z
1	Cs-137 (2cm)	0.17	13.89	mgm.	2.00	1.40	0.02	-0.06	1.95	-0.02	-0.03	-0.01
2	Cs-137 (2cm)	0.17	9.68	mgm.	2.00	1.40	0.00	-0.02	-0.01	-0.02	-0.03	-1.96
3	Cs-137 (2cm)	0.17	12.90	mgm.	2.00	1.40	2.03	1.30	-1.73	1.93	-0.55	-2.30
4	Cs-137 (2cm)	0.17	12.90	mgm.	2.00	1.40	-1.93	1.19	-2.06	-2.04	-0.68	-2.62

oint dose calculations for patient LEDBETTER,PAULA

#	X	Y	Z	DOSE RATE	TOTAL LABEL DOSE	% CONTRIBUTION FROM SOURCE # 1	2	3	4
	-0.02	-1.91	-0.86	54.67	54.7 Cal Bla	29	36	17	16
2	-0.03	1.87	0.25	56.41	56.4 CAL RECT	44	26	15	13
3	-0.07	3.51	-1.45	24.81	24.8 REAL REC	22	23	27	26
4	0.00	-2.77	-3.72	20.68	20.7 REAL BLA	16	23	27	31
5	-2.09	0.00	0.03	56.01	56.0 RT.PT.A	36	24	8	30
6	1.91	-0.03	0.05	65.99	66.0 LT.PT.A	35	23	33	7
7	-5.92	-0.03	0.02	10.80	10.8 RT.B	26	18	12	42
8	5.89	0.00	0.05	11.16	11.2 LT.PT.B	25	17	44	12

NOTE: Dose calculation is cut off at 20000. If such a dose is reported, higher doses may be present.

28 hr

Attachment 4

YALE-NEW HAVEN HOSPITAL
CURIETHERAPY

(If handwritten, record name, unit no., and birth date)

Therapy No. 92-698

Ref. by: Chambers I

Clinical Diagnosis: Stage B scc of cervix Stage: IB

Pathological Diagnosis: scc @ perivesical nodes (1/4), @ pelvic nodes (2/4) cervical (1/3)

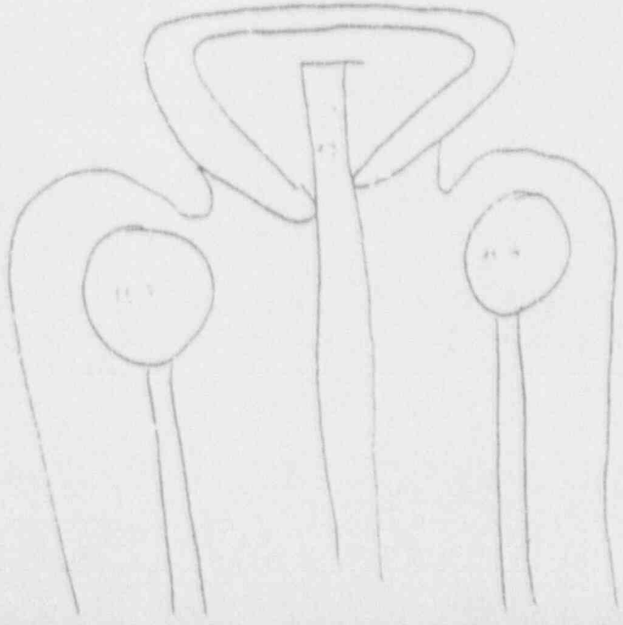
Date: 11/30/92

History and Description of Lesions (Including Previous Treatments):

39 yo well until '88 Bx → dysplasia. In ca vag D/C 7/92 class III PAP, Bx 5/92 scc & vascular invasion. Intended as ~~terminal~~ neoadjuvant Hyst, but pt found to have (+) nodes. Now s/p 2 cycles chemo, 3960 cGy pelvis, FSD #1 11/16/92 4700 cGy para-aortics.

On Exam today scar to 7.0 cm, retroflexed uterus, cervix was visually & mass. No masses or nodules on palpation. RVS (-). FSD #2 placed today & duplicated

Treatment Plan and Diagrams:



51.4 mg Ra Eq ^{137}Cs

28 hr placement for a total of 1439 mg hr.

F 5851 (Rev. 4/88)

ISOTOPE: ^{137}Cs

APPLICATOR	LOCATION	TYPE OF SOURCE	NO. OF SOURCES	FILTRATION	DISTANCE AREA VOLUME	TOTAL ACTIVITY
FSD	Cervix	^{137}Cs	4			51.4 mg Ra-Eq

Attachment 5

TIME OF TREATMENTS:

APPLICATOR	DATE AND TIME OF APPLICATION	DATE AND TIME OF REMOVAL	TOTAL TIME	TOTAL MG-HR
FSD	11/30/92 12 noon	12/1/92 4pm	28 hr	1439

(BINDING LINE)

DOSAGE MEASUREMENT:

INSTRUMENT USED:

R/HR

CM.	BLADDER R	BLADDER M	BLADDER L	RECTUM R	RECTUM M	RECTUM L
3						
5						
7						
9						
11						
MAX. R/HR	20.7			24.6		
MAX. DOSE(R)	579.6			688.8		

CALCULATED DOSE:

~~1568~~ (R)(RAD)(REP) TO (R) pt A IN 28 HR.

~~1348~~ (R)(RAD)(REP) TO (R) pt A IN ~~28~~ HR.

~~308~~ (R)(RAD)(REP) TO (R) pt 3 IN 28 HR.

308 (L) pt 3 28

DISPOSITION OF PATIENT:

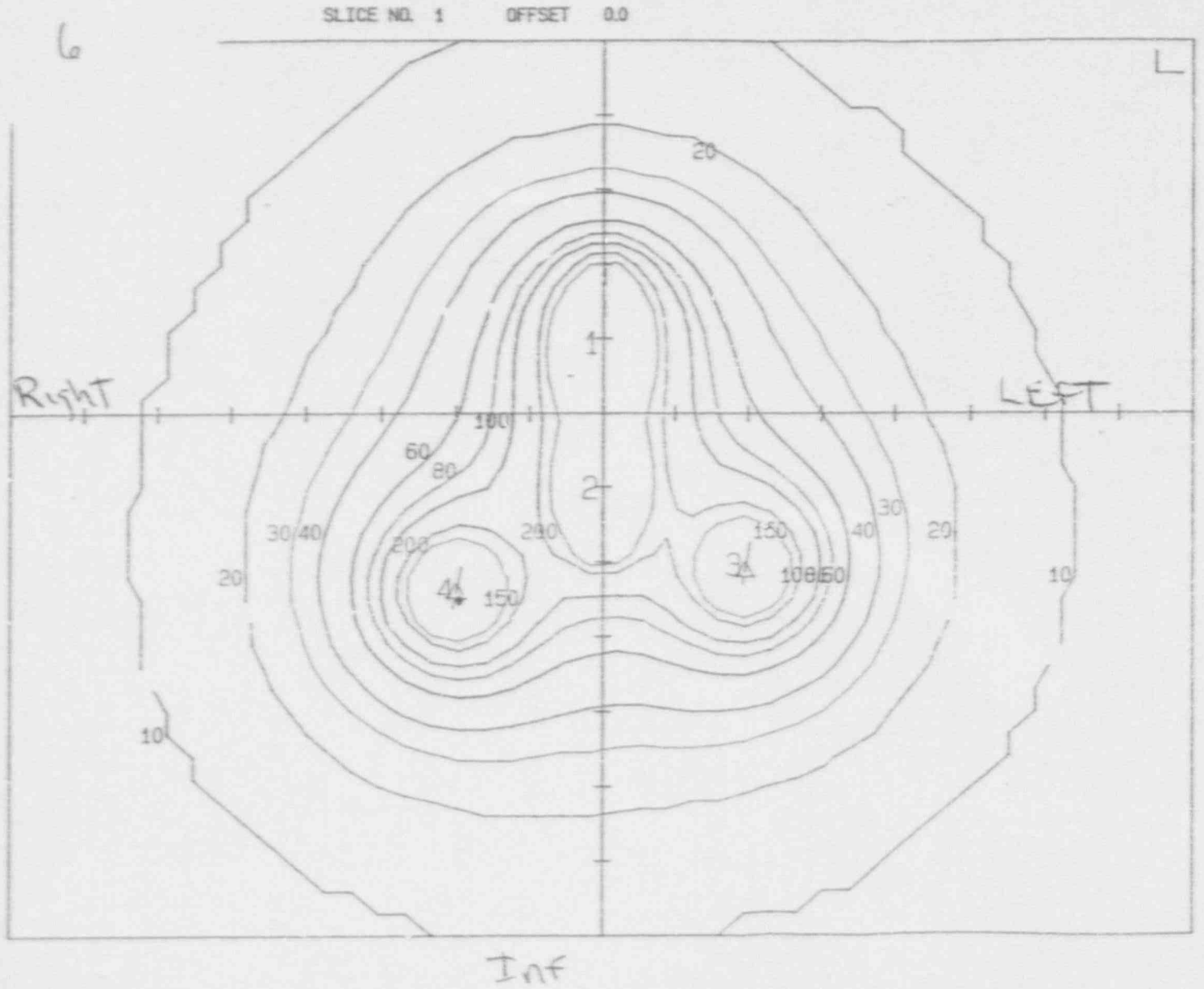
SIGNED _____ M.D.

F 951 (REV. 11/59)

AP overlay

Attachment 6

Sup



TITLE TYPE UNIT SSD 100% WIDE LONG ENTRY COLLM STAT-STOP X Y Z WDG BAR WEIGHT TAR
1 IMP. Co-137 (2cm) ANGLES 0 0 0 0 0.0 0.0 0.0 TIME: 1.0 HOURS

Max:20000 (0000 %) at X= -2.0 Y= -2.5 100%= 100

AP OVERLAY

THERAPLAN V05

Scale = 1.50 : 1 10:06 30-NOV-92 PLANNER _____ APPROVED _____

--- PROGRAM ISODOS - THERAPLAN V05 --- COPYRIGHT (c) 1990 Theratronics
Linear source calculation on 03-DEC-92

Patient Name:
Distribution Title: _____

Calculation plane orientation
Origin: X Y Z
0.0 0.0 0.0
Original(AP) plane

Rotation angles:
Horizontal: 0.0
Vertical: 0.0
Normal: 0.0

Attachment 7

Film magnification:
AP: 1.50; LATeral: 1.55

Total source activity: 36.5
Time of implant: 1.00 Hours

Linear source calculation on ----

SOURCE #	TYPE	FILT (mm)	ACTIVITY	UNITS	LENGTHS TOTAL	LENGTHS ACTIVE	SOURCE END POINT COORDINATES X	Y	Z	X	Y	Z
1	Cs-137 (2cm)	0.17	13.89	mgm.	2.00	1.40	0.02	-0.06	1.95	-0.02	-0.03	-0.01
2	Cs-137 (2cm)	0.17	9.68	mgm.	2.00	1.40	0.00	-0.02	-0.01	-0.02	-0.03	-1.96
3	Cs-137 (2cm)	0.17	0.00	mgm.	2.00	1.40	2.03	1.30	-1.73	1.93	-0.55	-2.30
4	Cs-137 (2cm)	0.17	12.90	mgm.	2.00	1.40	-1.93	1.19	-2.06	-2.04	-0.68	-2.62

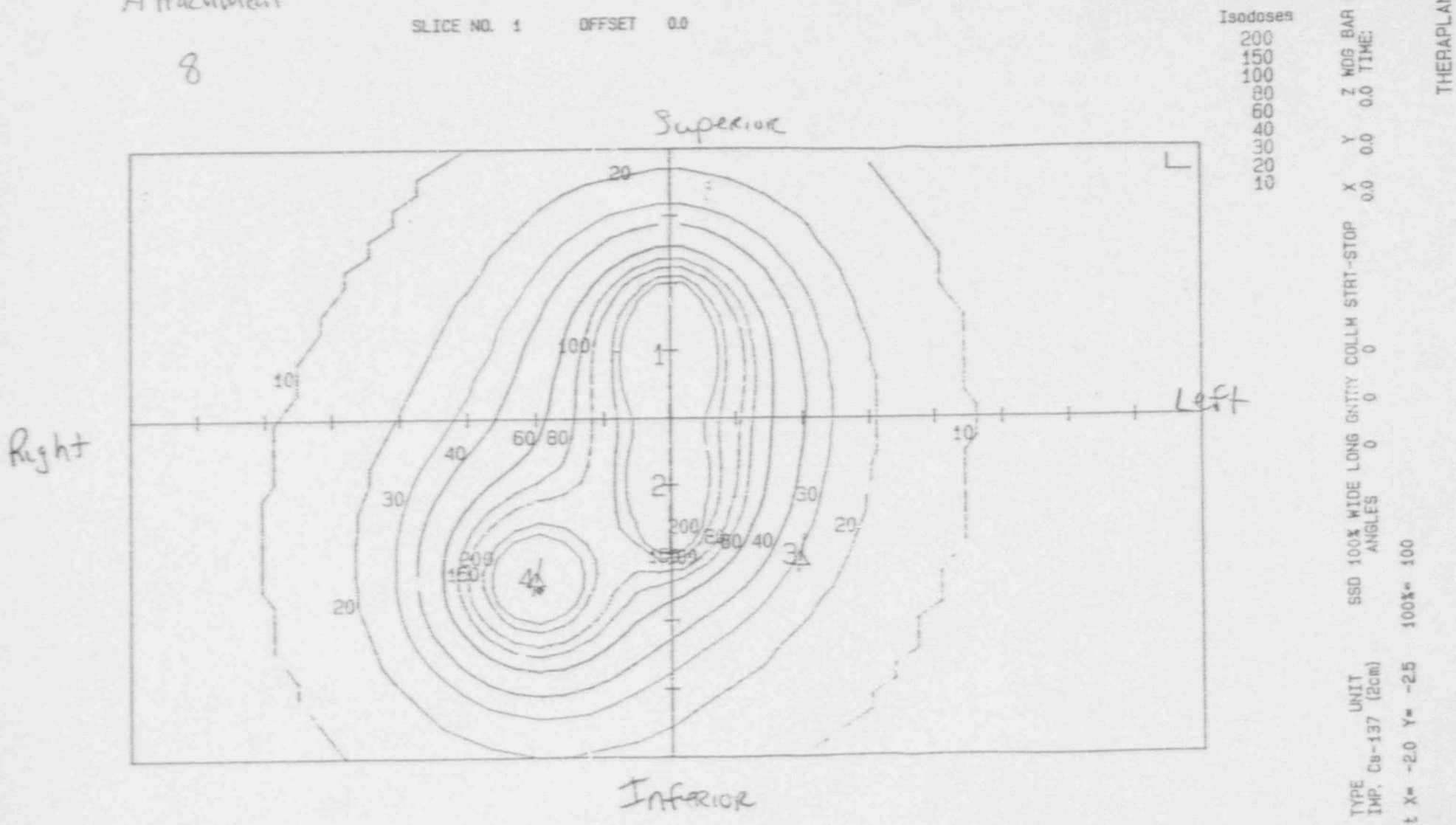
Point dose calculations for patient LEDBETTER,PAULA

#	X	Y	Z	DOSE RATE	TOTAL DOSE	LABEL	% CONTRIBUTION FROM SOURCE # 1	2	3	4
1	-0.02	-1.91	-0.86	45.27	45.3	calblad.	35	44	0	20
2	-0.03	1.87	0.25	47.72	47.7	CAL RECT	53	31	0	15
3	-0.07	3.51	-1.45	17.93	17.9	REAL REC	31	32	0	36
4	0.00	-2.77	-3.72	14.89	14.9	REAL BLA	23	32	0	43
5	-2.09	0.00	0.03	51.38	51.4	RT.PT.A	39	26	0	33
6	1.91	-0.03	0.05	44.09	44.1	LT.PT.A	53	35	0	10
7	-5.92	-0.03	0.02	9.42	9.4	RT.B	30	21	0	48
8	5.89	0.00	0.05	6.22	6.2	LT.PT.B	46	31	0	21

NOTE: Dose calculation is cut off at 20000. If such a dose is reported, higher doses may be present.

Attachment

8



Scale = 1:1 08:26 03-DEC-92 PLANNER _____ APPROVED _____

Attachment 9

Dosimetry Analysis
Missing Source - November 30, 1992

Right Point A				Left Point A			
	Rx Planned (Rads)	Rx Delivered (Rads)	% Error Cumul. Rx		Rx Planned (Rads)	Rx Delivered (Rads)	% Error Cumul. Rx
FSD #2	1568	1439	8.2% (1)	FSD #2	1848	1235	33.2% (1)
FSD #1	2440	2440	3.2% (2)	FSD #1	2280	2280	14.8% (2)
EBRT	3960	3960	1.6% (3)	EBRT	3960	3960	7.6% (3)
TOTAL:	7968	7839		TOTAL:	8088	7475	

Notes: (1) Percent error for FSD #2 alone
(2) Cumulative percent error for FSD #1 and FSD #2
(3) Cumulative percent error for EBRT, FSD #1 and FSD #2