U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-00359/87-001

Docket No. 030-00359

License No. 29-07566-02 Priority 3 Category G3

Licensee: St. Peter's Medical Center
Department of Radiation Therapy
254 Easton Avenue
New Brunswick, New Jersey 08903

Facility Name: St Peter's Medical Center

Inspection At: New Brunswick, New Jersey

Inspection Conducted: April 28, 1987

Inspectors: John E. Glenn for 7/7/87
Jenny M. Johansen, MS date
Senior Health Physicist

Approved by: John E. Glenn 7/7/87
John E. Glenn, Ph.D., Chief date
Nuclear Materials Safety Section B

Inspection Summary:
Inspection conducted April 28, 1987 (Report No. 030-00359/87-01

Areas Inspected: Special unannounced inspection to review the circumstances surrounding a reported therapeutic misadministration with a cobalt-60 teletherapy unit, including notification of incident, background/review of circumstances, policy and procedures, conclusions/corrective actions, and information obtain subsequent to the inspection.

Results: No violations were identified.

Details

1. Persons Contacted

* Richard Moed, Vice President, Support Services
* Alexander Haas, M.D., Director, Radiation Oncology
* Paul Zec, Radiology Administrator
* Daniel Alessandro, Chief Medical Physicist, Radiation Safety Officer
* Robert Tokarz, Radiation Safety Officer
Leo Meisberger, Medical Physicist
Denise Rolleri, Supervising Radiation Therapy Technologist
Radiation Therapy Technologist A (Tech A)
Radiation Therapy Technologist B (Tech B)

* Present at Exit Interview

2. Notification Of Incident

The licensee's medical physicist notified Region I at 2:00 p.m. on April 24, 1987, that a patient received a dose of 600 rads to the lumbar spine area, rather than to the thoracic spine area as prescribed. The dose was given in 200 rad treatments on April 20, 21, and 22, 1987. A second technologist discovered the misadministration upon reading the physician's prescription in the patient's chart. The patient had been previously treated with 3000 rads to the lumbar spine area and still retained the tatoo marks made for the treatment fields at that time. The technologist mistakenly used these tatoos to set up the treatment; rather than the correct tatoos for the thoracic area, when she did not open the patient's gown far enough to show the entire spine. The patient's referring physician and radiotherapist had been notified and had evaluated the dose as having no detrimental clinical effect on the patient due to the patient's disease state. The patient will be given the full course of treatment to the thoracic spine area.

3. Background/Review of Circumstances

The inspector interviewed the Director of Radiation Oncology (physician), the Chief Medical Physicist (physicist), the Supervising Technologist (Suprv. Tech) and the two technologists (Tech A and Tech B) involved with the treatment or supervising the treatment of the patient.

From these interviews the inspector obtained the following information:

Prior to April 9, 1987 the patient had been given palliative treatment to three fields in the lumbar spine, sacrum and sacrum-hip areas. These three fields were tattooed on the patient's back in accordance with the licensee's tattoo policy and were present when the patient set up was simulated, and the patient was tatooed for the thoracic spine field (See Attachments 1, 2, and 3) on April 9, 1987. The licensee's "Policy on Recording Treatment" (See Attachment 4) required that polaroid pictures be

taken of the treatment fields (See Attachment 1) and placed in the patient's chart. However, on April 9, 1987, contrary to the Recording Treatment Policy, the picture taken by Tech A, who simulated and tatooed the patient, did not include all of the three previous fields as well as the new thoracic field (See Attachment 5.)

On April 9, 10, 13, 14 and 15 the patient was treated as an in-patient and gowned with the garment opening in the front. Tech A performed the alignment of the light field on the tattoo markings for the thoracic field. Tech B assisted with the treatment of the patient, but was not present in the therapy room when Tech A pulled the patient's gown up to expose the thoracic tatooes and covered the tattoos of the three previous fields with a blanket. The patient was released from the hospital on April 15 and returned for treatment on April 16 as an outpatient, gowned in a garment that opened in the back. The patient's bra helped Tech B setup on the thoracic field by alignment of the light field with the tattoos. The patient's clothing covered the previous tattoos of the sacral-hip, sacrum and part of the lumber spine. This was the first time that Tech B had set-up the patient. The patient was re-admitted to the hospital and returned to the oncology department gowned in an in-patient garment (opened in the front) on April 20, 21, and 22, 1987. Tech B set up the patient and mistook the lumber spine field as the thoracic spine field when she saw the top of the previous sacrum field and did not raise the patient's gown for enough up to see the tattooed thoracic treatment area. Tech A was on vacation on April 20th. Dressed as an in-patient, the patient was not wearing a bra to help identify the thoracic tattooed area. On April 20th, Tech B saw that the light field exceeded the tattooed field, checked the polaroid picture, but attributed this misalignment to skin shifting and treated the patient based on the light field. On April 21st, Tech B set up the patient and had Tech A double check the light field against the tattoos and the patient's picture. Both Techs dismissed the misalignment to shifts in the patient's skin. Again on April 22nd, the misalignment was noted. On this date the Techs checked the simulator films against the picture and tattoos. The misalignment was again dismissed as skin shifting. According to the Supervising Tech, all technologists had been orally instructed to notify a physician, a physicist, or the Supervising Tech if discrepancies are noted in the tattooed field versus light field. The Techs failed to notify any of these individuals on April 20, 21 and 22, 1987.

On April 22nd the patient was released from the hospital and returned for treatment on April 23, 1987 gowned in an out-patient garment (opening in the back). During setup of the patient, who now had her bra on for reference, the Techs discovered that the treatments on April 20, 21, and 22, 1987, were given to the previously tatooed lumbar spine area rather than the newly tattooed thoracic spine field. The techs immediately notified the oncology physician, the Supervising Tech, and physicist.

The physicist, upon notification that a misadministration had occurred, talked with the technologists involved, determined that the radiation onology physician and referring physician were notified, and adjusted the patient's chart to show the dose on April 20, 21 and 22, 1987 was administered to the lumbar-spine, rather than to the thoracic spine as prescribed. The physicist notified the NRC On April 24, 1987 of the therapy misadministration.

No violations were identified.

4. Organization, Policy and Procedures

The Radiation Therapy Department is staffed by 3 radiation oncology physicians, 2 medical physicists and 7 radiation therapy technologists. The department uses a simulator to set-up all therapy treatments prior to use of either a Varian Clinic 18 linear accelerator or a cobalt-60 teletherapy unit to deliver radiation treatment doses. The supervising technologist stated that the licensee treats on the average, 30 to 40 patients per day on the cobalt-60 unit.

The inspector reviewed the licensee's policies on "Recording Treatment" and "Tattooing" (See Attachment Nos. 3 and 4).

A licensee representative stated that it appeared from the picture in the patients chart (Attachment No. 5) that the licensee's internal policy on "Recording Treatment" was not carried out, as the picture did not show all the previous tattoos on the patient.

The physician stated that medical records involved with the patient's treatment on the cobalt-60 unit were reviewed each Wednesday during chart rounds. The oncology physicians, therapy technologists and medical physicists attend these meetings. He further stated that review of this patient's record during chart rounds would not have indicated that a misadministration had occurred, as the technologists recorded the dose a having been delivered to "Field 4, PA T-spine" or "T-spine", as indicated on Attachment Nos. 6 and 7, respectively.

The physicist indicated that the medical physicist reviews the patient's chart once per week to check on the treatment times recorded and that another physicist has to independently verify the treatment plan. Medical physics procedures require two medical physicists to check and sign off on the calculations of treatment dose.

The supervising technologist reviewed with the inspector the step-by-step procedure for identification and treatment of an out patient. These procedures are summarized as follows:

a) The patient identifies himself to the technologist.

b) The technologist pulls the patient's treatment chart and instructs patient to go to dressing room, take off the necessary street clothes (i.e., those that cover the treatment area), don a hospital gown, and wait until called.

c) Patient is called to the teletherapy room to be setup for treatment. The patient's treatment chart is carried into the room by the technologist.

d) The patient is set up by the technologist with the light field checked against (1) the tattoo marks, (2) the dimensions of the the treatment field prescribed in the patient's chart by the physician, and (3) the picture taken of the field in the initial simulator setup.

e) If the light field and the tattoos are correctly aligned as indicated by the prescription and picture in the chart, the technologist exits the treatment room and delivers the radiation dose to the treatment area, recording the dose in the patient's chart. If the light field does not match the tattoo marks on the patient, the technologist is to inform the supervising technologist, the radiation oncologist, or the medical physicist.

The inspector reviewed the statements, representations and procedures as submitted for issuance of a license in accordance with 10 CFR 30 and 35 and determined that the licensee's internal policy on "Tattooing" and "Recording Treatment" were not documents that were required by the NRC for the issuance of the teletherapy license.

The licensee's other internal procedures as reviewed by the physician the physicist and the Suprv Tech were also not subject to NRC regulations or license conditions.

No violations were identified.

5. Conclusions/Corrective Actions

Licenses representatives stated that the misadministration occurred due to human error. It could have been prevented if established procedures had been rigorously followed.

Licensee representatives stated that part of their corrective actions involved immediate disciplinary action against Tech A and Tech B. Internal policies are being reviewed to evaluate possible changes to assure that misadministrations do not occur in the future. The physicist stated that

a training session had been scheduled with all the technologists to review the incident and the licensee's internal policies. In addition, the technologists involved would have special training sessions and would be placed on probation. All the work of the two technologists would be reviewed by the supervising technologist and radiation oncology physicians.

6. Exit Interview

The inspector reviewed the scope and findings of the inspection with the individuals indicated in Section 1. The inspector indicated that there were no violations of NRC"s rules, regulations or license conditions. The licensee's representatives stated that a written report about the misadministration would be sent within the 15 day requirement as specified in 10 CFR 35.33.

7. Information Obtained Subsequent to the Inspection

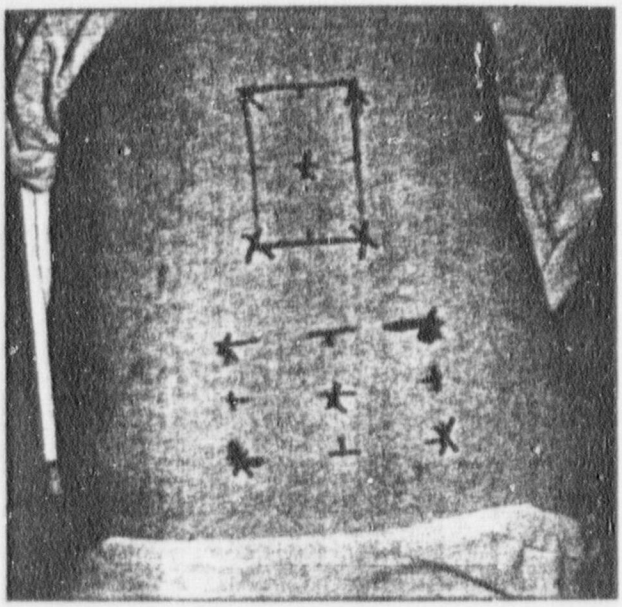
The licensee's 15 day report on the misadministration was received on May 13, 1987. (See Attachment 8) In this report the licensee stated that the patient died on April 30, 1987, due to progression of the patient's diease. The referring physician and oncologist determined the misadministration did not contribute to the patient's demise.

REGION I

REPORT NO. 030-00359/87-01

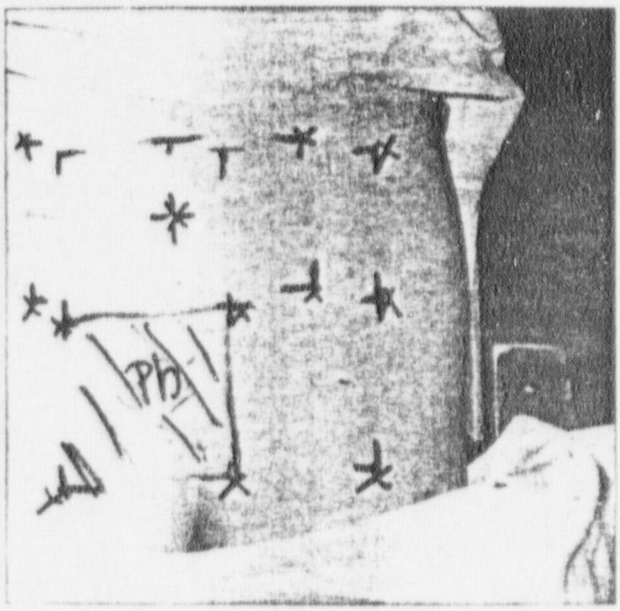
ATTACHMENT NO. 1

12-1-85



(1) PA L spine
10x7
80 SSD

(2) PA sacrum
8x14
80SSD



(2A, 3)
AP/PA Sacrum
17x16
80 SSD
2 Pb

old field inked
new field in black

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 2

300/day Lumbar D = 6 } → 3600
Sacral D = 4

WAS 12/11/85

DAILY RECORD OF TREATMENT Name: No.: Page: 1

Day or Treat. #	Date 1985	Tech. # and Letter	Portal of Entry or Site Treated	Time in Min.	Exposure in r/field (axis) (Single & Cumulative) Single	A	B	C	D	E	F	(Rads) (r) at Sites of interest Single and Cumulative 1*	2	3	4	5	6	Oper.	M.D.
1	12/11	1	PA L-Spine	3.01	276	276						200 / 200							
		2	PA Sacrum	2.57	240		240						200 / 200					1	ML
2	12/12	1	PA L-Spine	3.01	276	552						200 / 400							
		2	PA Sacrum	2.57	240		480						200 / 400					2	GL
3	12/13	1	PA L-Spine	3.01	276	828						200 / 600							
		2	PA Sacrum	2.57	240		720						200 / 600					3	ML 1/56
4	12/16	1	PA L-Spine	3.01	276	1104						200 / 800							
		2	PA Sacrum	2.57	240		960						200 / 800					6	GL
5	12/17	1	PA L-Spine	3.01	276	1380		2A	3			200 / 1000		2A3					
		2A	PA Sacrum	2.75	252		1212	252					134	134					
		3	AP Sacrum	1.36	124				124				66 / 1000	66 / 200				7	GL
6	12/18	1	PA L-Spine	3.01	276	1656						200 / 1200							
		2A	PA Sacrum	2.75	252		1464	504					134	134					
		3	AP Sacrum	1.36	124				248				66 / 1200	66 / 400				8	ML
7	12/19	1	PA L-Spine	3.01	276	1932						200 / 1400							
		2A	PA Sacrum	2.75	252		1716	756					134	134					
		3	AP Sacrum	1.36	124				372				66 / 1400	66 / 600				9	ML
8	12/20	1	PA L-Spine	3.01	276	2208						200 / 1600							
		2A	PA Sacrum	2.75	252		1968	1008					134	134					
		3	AP Sacrum	1.36	124	~~232~~			496				66 / 1600	66 / 800				10	GL
9	12/23	1	PA L-Spine	3.01	276	2484	~~2244~~					200 / 1800							
		2A	PA Sacrum	2.75	252		2220	~~1260~~					134	134					
		3	AP Sacrum	1.36	124				620				66 / [illegible]	66 / [illegible]				13	ML 1/57
10	12/26	1	PA L-Spine	3.01	276	2760						200 / 2000							
		2A	PA Sacrum	2.75	252		2472	1512					134	134					
		3	AP Sacrum	1.36	124				744				66 / 2000	66 / 1200				16	GL
11	12/27	1	PA L-Spine	3.01	276	3036						200 / 2200							
		2A	PA Sacrum	2.75	252		2724	1764					134	134					
		3	AP Sacrum	1.36	124								66 / 2200	66 / 1400				17	GL
12	12/30	1	PA L-Spine	3.01	276	3312						200 / 2400							
		2A	PA Sacrum	2.75	252		2976	2016					134	134					
		3	AP Sacrum	1.36	124				868				66 / 2400	66 / 1600				[illegible]	GL
13	12/31	1	PA L-Spine	3.01	276	3588						200 / 2600							
		2A	PA Sacrum	2.75	252		3228	2268					134	134					
		3	AP Sacrum	1.36	124				992				66 / 2600	66 / 18[illegible]				21	ML

SPMC X–8 (3/77) Non-Stock

Continue L-S spine to 3000 rad [illegible] sacral small (R) hip field to total 3000 rad

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 3

ST. PETER'S MEDICAL CENTER
254 Easton Avenue / New Brunswick, New Jersey 08903 / (201) 745-8600

DEPARTMENTAL TATTOOING POLICY

All patients in the Radiation Oncology Department will be tattooed. Those exceptions to this case are children and those patients who at the discretion of the physician need not be tattooed and this is to be entered by the technologist on the patient's treatment record.

April 15, 1987

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 4

ST. PETER'S MEDICAL CENTER
254 Easton Avenue / New Brunswick, New Jersey 08903 / (201) 745-8600

POLICY ON RECORDING TREATMENT

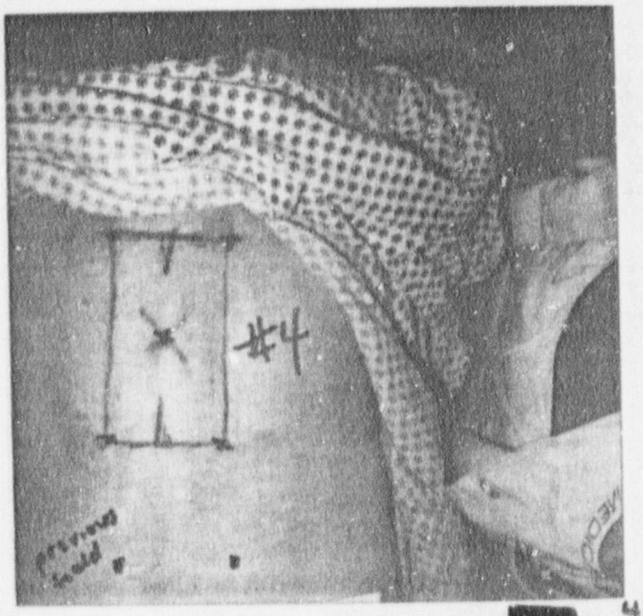
The Department of Radiation Oncology requires that the treatment record be maintained neatly and accurately each day by the Radiation Oncology Technologists. In the front of each calculation book assigned to the appropriate unit will be found a copy of a sample treatment record written up for that unit. It is the responsibility of the technologist to see that the patient's name is entered on the treatment record & photograph page. The technologist is to record the date the patient was simulated and the date he/she started treatment. The technologist is to enter the appropriate instructions and parameters for daily treatment on each patient. Polaroid pictures of the treatment fields are to be attached to the photograph page and the location of the tattoos indicated. Prior treatment field should be identified on the same polaroid. These polaroids are to be identified with the patient's initials and dated.

April/1987

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 5



[redacted]. 4/9/87

#4 PA T SPINE 12x7 @ 80 SSD

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 6

NAME		FIELD 4			FIELD			FIELD			FIELD 1			FIELD			FIELD		
	SITE	PA T-spine									PA L spine								
	FIELD SIZE	13 x 7		4/9/87							d: 6 cm								
DATE	DAY	TIME/MU	DAILY D.D.	TOTAL D.D.	TIME/MU	DAILY D.D.	TOTAL D.D.	TIME/MU	DAILY D.D.	TOTAL D.D.	TIME/MU	DAILY D.D.	TOTAL D.D.	TIME/MU	DAILY D.D.	TOTAL D.D.	TIME/MU	DAILY D.D.	TOTAL D.D.
	M																		
	T																		
	W																		
4/9	TH	1.94	255	255															
4/10	F	1.94	255	510															
4/13	M	1.94	255	765															
4/14	T	1.94	255	1020															
4/15	W	1.94	255	1275															
4/16	TH	1.94	255	1530															
	F		Holiday																
								Pt #					4/140						
4/20	M	1.94	255	~~1785~~	{?L spine			6494055			1.94	255	4395						
4/21	T	1.94	255	~~2040~~							1.94	255	4650						
4/22	W	1.94	255	~~2295~~	}						1.94	255	4925						
4/23	TH	1.94	255	~~2550~~	1785	RH													
4/24	F	1.94	255	~~2805~~	2040	RH													
4/27	M	1.94	255	2295															
4/28	T	1.94	255	2550															
	W																		
	TH																		
	F																		
	M																		
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	T																		
	W																		
	TH																		
	F																		

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 7

3000

CUMULATIVE DOSE DISTRIBUTION (cGy)

SIG.	A F	A E.D.	A DAILY	A TOTAL	B F	B E.D.	B DAILY	B TOTAL	C F	C E.D.	C DAILY	C TOTAL	D F	D E.D.	D DAILY	D TOTAL	E F	E E.D.	E DAILY	E TOTAL
	A T-Spine d→5cm				B				C Field #1 PA L-Spine d=6cm				D				E			
JJ	[illegible]		200	200																
SF	2	2	200	400																
JJ	3	5	200	600																
JJ	4	6	200	800																
JJ	5	7	200	1000	[illegible]															
JJ	6	8	200	1200																
		9	—	—																
												3000								
SF	7	12	200	~~1400~~	[illegible]						187	3187								
CB	8	13	200	~~1600~~							187	3374								
CB	9	14	200	~~1800~~							187	3561								
ML	10	15	200	~~2000~~	1400 [illegible]															
CB	11	16	200	~~2200~~	1600 [illegible]															
CB	12	19	200	1800																
ML	13	20	200	2000																
				3000																

TECHNOLOGISTS NOTES

[illegible]

INPATIENT
4/23 T-spine not treated
4/24 [illegible] T & L Spine [illegible]

4/24 – Pt billing corrected for 4/22, 4/21 & 4/22 on 4/24 by Arleen [illegible]

REGION I

REPORT NO. 030-00359/87-01

ATTACHMENT NO. 8