The Hospital Center at Orange

Orange Memorial Hospital Unit
New Jersey Orthopaedic Hospital Unit
(201) 266-2140

Department of Radiology
188 South Essex Avenue / Orange, New Jersey 07051

Joseph F. Carabetta, M.D.
Stephen P. Toder, M.D.
Michael O'Neal, M.D.

Ann M. Moore, M.D., Director

October 14, 1992

CERTIFIED MAIL-R.R.R. P 507 819 148

USNRC
Region I
475 Allendale Road
King of Prussia, Pa. 19405-1415

Re: License #29-03038-02

Dear Sir:

In response to your communication dated September 22, 1992, Docket #030-00347, we are providing the following information:

With respect to the roof of the Cobalt installation after the incident on January 31, 1991, "In Services" were held with maintenance to prevent a recurrence. Documentation for this and the other steps taken have already been filed with the NRC. During Ms. Cahill's inspection on August 25,1992, ladders were placed against the wall of the building to support scaffolding for work on the wall adjacent to the atrium. The workers were aware of the roof restrictions and no workers went onto the roof. The levels on the atrium are low and a review of the situation determined that the workers could not have been exposed to more than 10mR for the entire period (see enclosed addendum). However, another in service was held with maintenance and the workers involved in the incident, to stress the importance of the situation on the roof. In addition, the fence on the roof has high radiation signs posted.

In answer to the violations listed we will respond to them in the order in which they are presented in your letter.

A. The Prime-Alert system which had been in place prior to our renovations was found to be inoperable when it was replaced after the installation of the new Cobalt unit. A new one was ordered and has been installed at this time. However, during the interim period when Ms.Cahill arrived, a monitor with a preset level which provided a flashing indicator was in place in the room. Unfortunately the technologist had not switched the unit on when Ms. Cahill entered the room. Both technologists have been given "In Services" on the importance of having the radiation detection device "ON" when in the Cobalt room. The new Prime-Alert system is "ON" permanently, and its operation tested daily.

B. A beam condition light has been ordered and will be installed over the entrance to the room as soon as it arrives.

C. Monthly checks of the Cobalt unit will now include a timer linearity check over the range of use. This will be done by checking the timer against a stop watch.

cont'd.

October 14, 1992

D. Monthly checks of the Cobalt unit will now include checks of timer constancy, the accuracy of the optical distance indicator and the alignment of lasers. Notations indicating the operability of the electrical and mechanical stops, beam indicator lights and viewing system will also be made.

E. The radiation safety officer will now countersign all records of the leak and wipe tests.

All of the above corrective actions, with the exception of the installation of the beam indicator lights have now been taken, and records will be maintained. We expect to install the beam indicator light before the end of October, 1992.

We hope the steps we have taken meet with your approval.

Yours sincerely,

Arthur T. Dunn,

Ian P. Sinclair, Ph.D

Mary Natrella, M.D.

pc/

Enclosure

The Hospital Center at Orange
Orange Memorial Hospital Unit
New Jersey Orthopaedic Hospital Unit
186 South Essex Avenue / Orange, New Jersey 07051

MEMORANDUM

To: Dr. M. Natrella, E.S.O.

From: Bill McAndrew, Asst. Mgr. Radiology

Re: Possible exposure to roof repair personnel

On January 31, 1991, a roofer went onto the roof above the radiation therapy treatment room to continue roof leak temporary repair without notifying the therapy personnel. Although this gentleman was initially instructed to coordinate these repairs with the therapy technicians, he assumed that no treatment was being done due to equipment problems as was the case during the two preceding days.

Dr. Ian Sinclair and I discussed the possible extent of this individual's exposure and concluded that he received a probable exposure of 10 to 20 mR, and a liberal estimate of 50mR, but definitely under 100 mR for the time spent working in that area. This is based on his having been on the roof directly above the treatment area for a period of 2.5 hours, during which total patient treating (source open) time would not have exceeded 30 minutes, the gantry angle for all patients treated did not exceed 90 degrees with the majority of the treatments at 0 degree angle. The most recent survey (1/26/89) was referenced to show that a 90 degree gantry angle yields 30 mR/hr directly above the source. Therefore as a worst case scenario:

30.0 mR/hr x 0.5 hr. = 15 mR

This exposure is well within N.R.P.D. for non-occupational personnel and requires no reporting to the N.R.C..

As a preventive measure, Mr. Thomas will check that the "Radiation Area" posting is intact for entry to the roof.

Please contact me if you require any further information.

William McAndrew, R.T.

cc. Dr. Ann Moore
Dr. Thomas Borok
Dr. Ian Sinclair
George Thomas

The Hospital Center at Orange

186 South Essex Avenue / Orange, New Jersey 07051

Date 1/26/89

RADIATION SURVEY
COBALT 50 UNIT

Gantry Angle 90°		120°	
Head Angle 0°		0°	
Location	mR/hr	Location	mR/hr
A window	0.5		0.6
A' door	0.4		0.3
B	2.0		1.0
C	0.8		0.6
D	0.6		16.0
E	1.5		2.0
E'	2.0		1.5
F	< 0.1		< 0.1
G	< 0.1		< 0.1
H	0.2		0.1
Above	30.0		110.0

Gantry Angle 135°		150°	
Head Angle 0°		0°	
Location	mR/hr	Location	mR/hr
A window	0.5		0.8
A' door	0.3		0.3
B	0.8		0.5
C	0.5		0.2
D	12.0		5.0
E	1.2		0.6
E'	1.2		1.0
F	< 0.1		< 0.1
G	< 0.1		< 0.1
H	0.2		0.2
Above	240.0		290.0

The
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188 South Essex Avenue / Orange, New Jersey 07051

Date 1/26/89

RADIATION SURVEY
COBALT 60 UNIT

Gantry Angle 0°
Head Angle 0°

Location	mR/hr
A window	0.6
A' door	0.3
	0.3
C	0.1
D	.0
E	0.4
E'	0.1
F	< 0.1
G	< 0.1
H	< 0.1
Above	5.5

30° Tow. Waiting Room

Location	mR/hr
	0.3
	0.2
	0.6
	0.2
	6.0
	0.8
	0.8
	< 0.1
	< 0.1
	< 0.1
	5.0

Gantry Angle 45°
Head Angle 0°

Location	mR/hr
A window	0.2
A' door	0.2
B	1.0
C	0.3
D	10.0
E	1.8
E'	1.5
F	< 0.1
G	< 0.1
H	0.2
Above	12.0

60° Tow. Waiting Room

Location	mR/hr
	0.5
	0.3
	1.8
	0.5
	12.0
	1.8
	1.8
	< 0.1
	< 0.2
	0.2
	22.0

The Hospital Center at Orange

188 South Essex Avenue / Orange, New Jersey 07051 Date 1/26/89

RADIATION SURVEY
COBALT 60 UNIT

Gantry Angle 180°		210°	
Head Angle 0°		0°	
Location	mR/hr	Location	mR/hr
A window	1.0		1.8
A' door	0.2		0.2
B	0.2		< 0.1
C	0.1		< 0.1
D	1.4		0.2
E	0.2		0.2
F'	0.2		0.2
	< 0.1		< 0.1
	< 0.1		< 0.1
	0.2		0.2
Above	55.0		300.0

Gantry Angle 225°		240°	
Head Angle 0°		0°	
Location	mR/hr	Location	mR/hr
A window	2.5		3.0
A' door	0.2		0.2
B	0.3		0.1
C	0.3		< 0.1
D	0.1		< 0.1
D'	0.1		< 0.1
E	0.1		< 0.1
E'	0.1		< 0.1
F	< 0.1		< 0.1
G	0.3		0.5
H	0.2		0.2
Above	210.0		180.0

The Hospital Center at Orange

180 South Essex Avenue / Orange, New Jersey 07051 Date 1/26/89

RADIATION SURVEY
COBALT 60 UNIT

Gantry Angle 270°		300°	
Head Angle 0°		0°	
Location	mr/hr	Location	mr/hr
A window	3.0		1.8
A' door	0.1		0.3
B	0.1		0.1
C	< 0.1		< 0.1
D	< 0.1		< 0.1
E	< 0.1		< 0.1
E'	< 0.1		< 0.1
F	< 0.1		< 0.1
G	< 0.1		< 0.1
H	0.3		0.5
Above	33.0		21.0

Gantry Angle 315°		330°	
Head Angle 0°		0°	
Location	mr/hr	Location	mr/hr
A window	1.5		1.4
A' door	0.3		0.3
B	0.1		0.1
C	< 0.1		< 0.1
D	< 0.1		< 0.1
E	< 0.1		< 0.1
E'	< 0.1		< 0.1
F	< 0.1		< 0.1
G	1.0		0.5
H	0.2		0.2
Above	18.0		5.0

The
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188 South Essex Avenue / Orange, New Jersey 07051 Date 1/26/89

RADIATION SURVEY
COBALT 60 UNIT

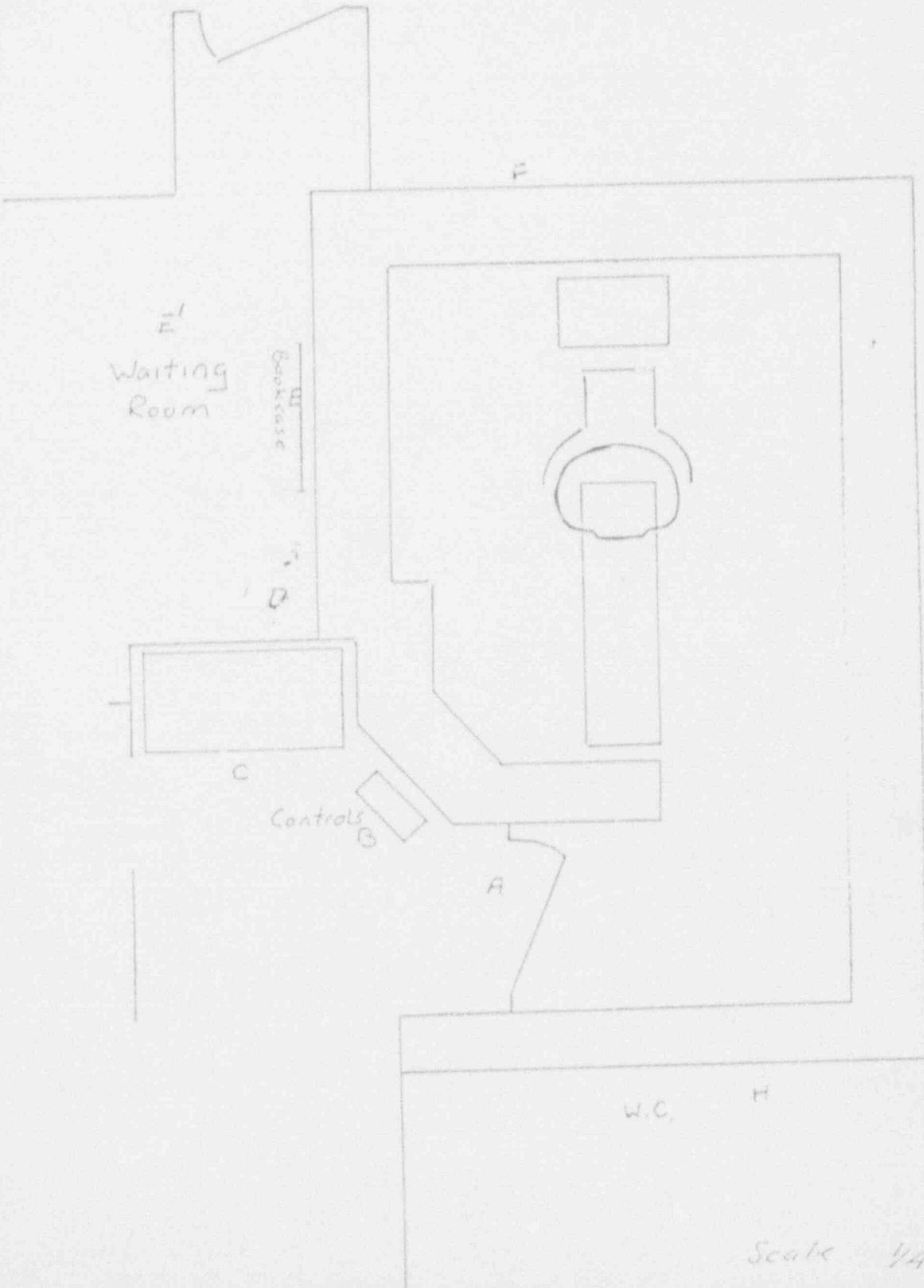
Gantry Angle	45°		315°	
Head Angle	45° tow. floor		45° tow. Floor	
Location	mr/hr		Location	mr/hr
A window	1.0			0.5
A' door	0.3			0.1
B	0.1			0.1
C	0.1			0.1
D	1.0			0.8
E	0.1			0.1
E'	< 0.1			0.1
F	< 0.1			< 0.1
G	0.3			< 0.1
H	0.5			< 0.1
Above	6.0			6.0

Gantry Angle			
Head Angle			
Location	mr/hr	Location	mr/hr
A window			
A' door			
B			
C			
D			
D'			
E			
E'			
F			
G			
H			
Above			

RADIATION SURVEY

COBALT 60 UNIT

Nov 2nd 1983



Scale 1/4" = 1'

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

SEP 22 1992

Docket No. 030-00347 License No. 29-03038-02

The Hospital Center at Orange
ATTN: Arthur Dunn, President
188 Essex Avenue
Orange, New Jersey 07051

Dear Mr. Dunn:

Subject: Routine Inspection No. 030-00347/92-001

On August 25, 1992, Ms. Mary Cahill of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to an an examination of your teletherapy program. The inspection was a review of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspectio consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Mr. Paul Mertz and other members of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that some of your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

The inspector identified weaknesses in your procedures for restricting access to the roof of the teletherapy facility. Specifically, on January 31, 1991 and on the day of the inspection, workers were on or near the roof of the facility without having obtained the permission of the teletherapy staff in accordance with your policy. Due to the potential for instantaneous high radiation dose rates, access to the roof should be restricted. On both occasions, the teletherapy unit was operating while workers were on or near the roof. While your staff's assessment indicated no excessive exposure received by the workers due to the the fact that the beam was directed downwards and the workers spent a short period of time on the roof, the potential for high exposures exists. In your response to this letter, please submit actions you have taken or plan to take to ensure that access to the roof and adjacent areas of your teletherapy facility is restricted and the implementation of your controls to restrict access is effective.

Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

M. Shanbaky

Mohamed M. Shanbaky, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Enclosures: Appendix A. Notice of Violation

cc:
Mary Natrella, M.D., RSO
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

APPENDIX A

NOTICE OF VIOLATION

The Hospital Center at Orange
Orange, New Jersey 07051

Docket No. 030-00347
License No. 29-03038-02

As a result of the inspection conducted on August 25, 1992, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1992), the following violations were identified:

A. 10 CFR 35.615(d) requires, in part, that a permanent radiation monitor capable of continuously monitoring beam status be installed in each teletherapy room, and if the permanent radiation monitor is inoperable, that any individual entering the teletherapy room use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source.

Contrary to the above, a permanent radiation monitor capable of continuously monitoring beam status was not installed in the teletherapy room, and individuals entering the teletherapy room did not use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that might result in an exposed or partially exposed source. Specifically, on August 25, 1992, a permanent radiation monitor was not installed in the teletherapy room and a temporary radiation monitor installed in the teletherapy room was not operable while patients were being treated, and a survey instrument or audible alarm personal dosimeter was not used.

This is a Severity Level IV violation. (Supplement VI)

B. 10 CFR 35.615(c) requires that each entrance to the teletherapy room be equipped with a beam condition indicator light.

Contrary to the above, as of August 25, 1992, each entrance to the teletherapy room was not equipped with a beam condition indicator light. Specifically, from January 1990 to August 1992, a beam condition light was not installed at the entrance to the teletherapy room.

This is a Severity Level IV violation. (Supplement VI)

C. 10 CFR 35.632(b) and 10 CFR 35.634(a) require, in part, that full calibrations and spot-checks, performed on each teletherapy unit at intervals not exceeding one year and once in each calendar month, respectively, include a determination of timer linearity over the range of use.

Contrary to the above, full calibrations and spot checks, performed on each teletherapy unit at intervals not exceeding one year and once in each calendar month, respectively, did not include a determination of timer linearity over the range of use. Specifically, a full calibration of a teletherapy unit performed in August 1992 and spot checks of another teletherapy unit performed from September 1991 to June 1992 did not include a determination of timer linearity over the range of use.

This is a Severity Level IV violation. (Supplement VI)

D. 10 CFR 35.634(f) requires, in part, that records of each spot check of the teletherapy unit include an assessment of timer constancy, the determined accuracy of each distance measuring or localization device, and notations indicating the operability of each electrical or mechanical stop, beam condition indicator light, and the viewing system.

Contrary to the above, records of each spot check of the teletherapy unit did not include an assessment of timer constancy, the determined accuracy of each distance measuring or localization device, and notations indicating the operability of each electrical or mechanical stop, beam indicator light, and the viewing system. Specifically, spot checks performed on the Picker Corp. Model 6223 (C8M/80) teletherapy unit from September 1991 to June 1992 did not include an assessment of timer constancy, the determined accuracy of each distance measuring or localization device, and notations indicating the operability of each electrical or mechanical stop, beam indicator light, and the viewing system.

This is a Severity Level V violation. (Supplement VI)

E. 10 CFR 35.59(d) requires, in part, that records of leak tests of sealed sources contain the signature of the Radiation Safety Officer.

Contrary to the above, as of August 25, 1992, records of leak tests of sealed sources did not contain the signature of the Radiation Safety Officer. Specifically, records of leak tests of the cobalt-60 sources performed in July 1991, January 1992, and June 1992 did not include the signature of the Radiation Safety Officer.

This is a Severity Level V violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, the Hospital Center at Orange is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.