MANSFIELD GENERAL
YOUR HEALTH CARE CENTER IN NORTH CENTRAL OHIO

Dtm 10CFR 35.33

December 29, 1997

Mr. John Madera
Chief, Material Licensing Section
NRC Region III
801 Warrenville Rd.
Lisle, Illinois 60532-4351

License Number: 34-02007-02 - 03000407

Dear Mr. Madera:

This is to report the misadministration of radiation treatment and to evaluate the cause of the misadministration and the measures to prevent misadministration in the future.

Misadministration to report:

A patient had treatment prescribed on November 3, 1997 by Radiation Oncologist, Dr. Kyee Koh, M.D., using 6MeV linear accelerator X-ray beam for anterior and posterior ports at 180 cGy per fraction and total 20 fractions. After 3600 cGy in 20 fractions, treatment was coned down to the anal area for an additional 900 cGy in five fractions by using the Cobalt 60 beam. The 25th fraction was given on December 9, 1997. After examination of the patient, Dr. Koh decided to give an additional five fractions to the same anal area plus five fractions to the new coned down area of the left groin by using the Cobalt 60 beam. Dr. Koh gave this directive orally to the therapist to do five more fractions to the anal area and five fractions to the new coned down area of the left groin. The therapist apparently did not understand or hear the oral directive for the anal area. The verbal revision of the written directive to the anal area was not clearly documented. Documentation of the verbal order should be recorded on the chart by the therapist. Dr. Koh made a written revision to his original written directive to the anal area by using an arrow to indicate the fraction changing from 5 to 10 within 24 hours. This entry was not signed and dated by Dr. Koh. The progress note as part of the chart was signed and dated on December 10,1997. Dr. Koh did make a written directive to the new coned down area of the left groin. It was signed and dated on December 10, 1997.
On December 16, 1997, the last day of treatment for the final five fractions,Dr. Koh found the additional five fractions to the anal area was not given.

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The total prescribed dose to the anal area was 1800 cGy. The actual delivered dose to the anal area was 900 cGy. The misadministration is -50% underdose to the treatment of the anal area and there was no harm to the patient.

Action to take:

On December 16, 1997, immediately after the incident, NRC region III office was notified by the Radiation Safety Officer, Dr. David Chin, Ph.D. and some information was faxed. NRC Washington Office, Mr. Bob Stranski was notified by the therapist-in-charge, Mrs. Angela Scott, R.T.(T.). On December 17, 1997, Dr. Koh informed patient that he did not receive five treatments to the anal area as planned. On December 18, 1997, Dr. Koh contacted the patient's referring physician, Dr. Michael Stanek, D.O. and discussed the misadministration with him. Dr Stanek and Dr Koh decided that no treatment was necessary to compensate for the lost five fractions to the anal area.

Evaluation of the misadministration and the root cause:

Dr. Koh used an arrow to indicate a change of original written directive from 5 to 10 fractions. It was not signed or initialed and dated. He documented his change of the original written directive in the patient's progress note which was made a part of the patient's chart. This has been the method which Dr. Koh used to change the number of fractions to the original written directive. In addition, he also made verbal revision to his original written directive to the therapist before the treatment was given to the anal area and verbal directive to therapist before the treatment was given to the left groin. These verbal revisions of the original directive to the anal area and verbal directive to the left groin were not clearly documented in the chart.

On December 12, 1997, Dr. Chin checked the calculation which was done on December 10, 1997. He also initialed the dose calculation chart but did not detect the problem because the calculation check was for the left groin and a stopping mark was put on the chart to indicate the completeness of the treatment of the anal area. He checked the chart on December 13, 1997 to ensure the dose delivered to the left groin area was correct. He then reviewed the chart on December 16 for chart completion

after Dr. Koh found the mistake.

On December 10, 1997 the primary therapist asked Dr. Koh to set the left groin, Dr. Koh asked her whether she had finished the treatment of the anal area. After she set up the left groin, she did the calculation for the left groin. At that time, she had the verbal directive given by Dr. Koh. She completed the chart after she finished the treatment of the patient. But she did not document the verbal directives to the left groin and the anal area in the chart and have Dr. Koh sign and date them.

On December 10, 1997 a calculation to the left groin was done by the primary therapist and the calculation did not get rechecked until December 12, 1997. The calculation was rechecked and there was no mistake. If the prescription is less than ten fractions, the second treatment should not be given until the calculation was checked.

The therapists who treated the patient for the remaining treatments did not detect the error.

The root cause of this misadministration is due to the QMP procedure not providing clear guidelines for therapists, physicist, and the authorized user for written revision to the original directive.

Measures to prevent future misadministration:

Upon the evaluation, the following measures have been taken and will be enforced and a QMP meeting was called to make sure all therapists understood.

1. A new charting system has been developed (copy attached). A new documentation method will be used to control the flow of the charts which need to have revisions to the original written directive. All the written directives or revisions of the original written directive will be printed in the prescription summary and they will be signed and dated by Radiation Oncologist.

2. The verbal prescription or order is only to be used for emergency situations. If an emergency situation has occurred, the verbal prescription or order must be documented on the chart within 24 hours. For the normal practice of radiation therapy the verbal prescription will

not be accepted. Therapists have been directed to have the Radiation Oncologist sign and date the verbal prescription immediately after the verbal prescription is received.

3. The calculation check must be completed by physicist or authorized user according to QMP. A check list to direct therapists to give the physicist the chart to check, and if the check does not occur by the physicist or authorized user prior to the time limit stated in the check list, no treatment should be given under any circumstance (copy of check list included).

This report was prepared and written by David Chin, Ph.D. , Radiation Safety Officer, MedCentral Health System. If you have any questions, please contact David Chin, Ph. D. (R.S.O.) at (419) 526-8883.

Sincerely,

James Meyer, President
MedCentral Health System

Enclosure: As stated
CC: Debbie Piskura, Reviewer

MedCentral Health System/Mansfield Hospital

Department policy: Dose prescribed >10 fractions, dose calculation check should be done before 3 fractions or 10% of total fractions.
<=10 fractions and >3 fraction , dose calculations should be done before 2nd treatments.
<=3 fractions, dose calculation should be done before treatment. If Physicist or Angela not available, ask Dr. Koh to check and initiated.

Patient Name:_____Primary Therapist:_____
Date of Service from :_____to:_____ ( )New Page/____Pages before this page
After this treatment:_____Treatment ID NO:_____

New/Modified Chart Review	Rx #	CHK	Weekly CHK	Weekly Chart Check
New/Modified Patient Chart Review For FLD NO _____ 1. Patient Identification YES/ NO 2. Consent Signed/Witnessed YES/ NO 1 & 2 for New Patient Chart Only 3. Prescription Completed YES/NO If Oral, Oral prescription d mented in chart YES/ NO d have Dr. complete immediately. If Modified, check last prescription. 4. TX Planning Check prescription. Any question, ask Dr. / Physicist immediately 5. Parameters on simulation worksheet and setup parameters are checked. If IFD difference(absolute) >= 1cm, notify Angela immediately 6. MU/Time Calculation Step #3 on _____. If >5%, Have physicist check immediately. Have physicist check according to policy stated below.	1		Give to DC	DC initial here_____
	2		Date:___ /___	1. Check calculation
	3		Give to DC	2. Tx planning implementation
	4		Initial_____	3. Simwork check
	5		Date_____	5. TX record completed
	6			6. Documentation checked
	7		_	
	8		Give to DC	
	9		Initial_____	
	10		Date_____	5. TX record completed
	11			6. Documentation checked
	12			
	13		Give to DC	
	14		Initial_____	
Daily- Tx Record and Documentation	15		Date_____	5. TX record completed
Modified Patient Chart Review For FLD NO _____ 1. Prescription Completed YES/NO If Oral, Oral prescription documented on chart YES/ NO and have Dr. complete immediately. If Modified, check last prescription. 2. TX Planning Check prescription. Any question, ask Dr. / Physicist immediately 3. Parameters on simulation worksheet and setup parameters are checked. If IFD difference(absolute) >= 1cm, notify Angela immediately 4. MU/Time Calculation Step #3 on _____. If >5%, Have physicist check immediately. Have physicist check according to policy stated below.	16			6. Documentation checked
	17			
	18		Give to DC	
	19		Initial_____	
	20		Date_____	5. TX record completed
	21			6. Documentation checked
	22			
	23		Give to DC	
	24		Initial_____	
	25		Date_____	5. TX record completed
	26			6. Documentation checked
	27			
	28		Give to DC	

MEDCENTRAL HEALTH SYSTEM
MANSFIELD HOSPITAL
Treatment Prescription Summary

Patient name:_____ Patient ID:_____

Intention of Treatment:_____ NO of Sites:_____

Treatment Site				
Dose Plan				
Plan ID				
Plan Reviewed date				
Patient Position				
Technique				
Dose per Fraction in cGy				
To Which point or Depth				
Fraction per Week				
Date of Start				
Total Fractions				
Total Dose in cGy				
Reference Point				
Dose at Reference Point				
Maximum Dose (PTV)				
Minimum Dose (PTV)				
Organ at Risk				
Dose to Oragn at Risk				
Treatment After this Prescription				

Plan ID:_____ Beam Parameter Summary

FLD NO						
FLD Name						
Energy						
FLD WT						
Wedge						
Wedge %						
FLD Dose						
% IDL		Total Dose in cGy for These Fields per Fraction=				

Radiation Oncologist:_____ Date:_____

Form Prescription summary