THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

OFFICE OF RADIATION SAFETY MC-3930
Tel: (203) 679-2250

September 17, 1996

US Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19400

License Number: 06-13022-05

Dear Ms. Bhalla:

Please find enclosed a revised version of the University of Connecticut Health Center's Quality Management Program for Cobalt Teletherapy. These revisions were made as corrective actions following the misadministration reported to NRC on August 7, 1996. Many of the revisions are due directly to your meeting with myself and other Oncology staff members conducted during your visit on August 14, 1996. All involved have considered this event in great detail and are of the opinion that actions taken will reduce the likelihood of a recurrence.

The revisions to the Quality Management Program (QMP) are indicated in bold cap letters. The effective date of implementation of the revised QMP was September 5, 1996, after many of the primary staff members received detailed QMP training by me on its contents. QMP Training Sessions were held on August 28, August 29, September 4, September 5, September 12 and included physicists, dosimetrists, therapists and authorized users. A correspondence was sent to the Chairman and Chief of Radiation Oncology with QMP Training requirements for involvement with Cobalt Teletherapy (see attachment). In addition, a list of those approved for Cobalt Teletherapy was posted at the control console (list as of 9/12/96 attached). The major revisions in the QMP include:

- **A definition of the treatment plan**
- **Specifics concerning authorized user approval of treatment plans and where, for Cobalt Teletherapy , signatures and dates are required.**
- **A requirement for therapists to review, initial and date the physics calculations to ensure verification signatures are present as required by the QMP**

- **Inclusion of the dose per port on the Written Directive**
- **Requirements for the dosimetrist/physicist to actively seek out a verification of physics calculations prior to the first treatment if doing less than or equal to 3 fractions**

If you require further information concerning our revisions to the Teletherapy QMP, please contact me at 860-679-2250.

Sincerely,

Kenneth W. Price,
Radiation Safety Officer

KWP:lf

Attachments

THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

OFFICE OF RADIATION SAFETY MC-3930
Tel: (203) 679-2250

Septembe 5,1996

TO: Dr. Andrew Salner
Chairman and Chief of
Radiation Oncology

FROM: Kenneth W. Price, Director
Radiation Safety Office

SUBJECT: Cobalt Teletherapy Quality Management Program Training

I have attached a listing of those individuals who, to date, have attended a Quality Management Program training seminar. These individuals are permitted to work in their specific areas of responsibility for Teletherapy. Any individual not on the list must attend QMP training prior to any involvement with the Teletherapy Unit. Any individual requiring such training should feel free to contact me at any time to arrange for a session. This list will be posted above the Teletherapy console and revised as needed.

I would, at this time, like to express my thanks to you and your staff for their cooperation and interest concerning our efforts in this area. If you have any concerns or comments please feel free to call me.

KWP:lf

Attachment

cc: Paul Davern
Robert Dowsett
Julius Kocsondy
Sarah Locher
Deborah McMahon
Leonard Paplauskas
William Pickett
Raymond Ryan
Tina Taft

AUTHORIZED USERS/QUALIFIED USERS
COBALT TELETHERAPY 9/12/96

The following individuals have completed **Cobalt Teletherapy Quality Management Program Training** and are authorized as users of the Cobalt Teletherapy Unit. Any individual not on this list may not be involved in Cobalt Teletherapy until such training is received.

AUTHORIZED USERS

Robert Dowsett, M.D.
Andrew Salner, M.D.
Jacqueline Lyon, M.D.
Judith Buckley, M.D.

PHYSICISTS

Arthur Pinkerton
Sarah Locher
Janet Gortney

DOSIMETRISTS

Ellen Kurdzo
Dannette Guay
Maureen Vagnini

THERAPISTS

Valerie Lavake
Margaret Lane
Betsy Leary
Theresa Dionne
Tina Deckers

Kenneth W. Price
Radiation Safety Officer
Office X2250
Pager 587-2769

Quality Management Program Policy For
^{60}co Teletherapy Unit
University Of Connecticut Health Center
License # 06-13022-05

Revised 8/27/96
Implementation September 5, 1996

The information which follows describes the University of Connecticut Health Center's Quality Management Policy as required by 10 CFR 35.32 for teletherapy. The implementation of THE ORIGINAL POLICY begAn with patients beginning treatment after January 27, 1992. All staff will be informed of this policy through a special seminar, and this information will be included in annual training sessions given to users of the teletherapy unit.

1. Prior to the administration of any teletherapy dose, a "University of Connecticut Health Center Radiation Oncology Prescription" (written directive) will be required. Written directives will be retained for a period of at least three years after the treatment. A example copy of this written directive is attached and will be signed and dated by the authorized user.

   a. THE WRITTEN DIRECTIVE WILL INCLUDE, AT A MINIMUM THE FOLLOWING INFORMATION

      DATE
      AUTHORIZED USER SIGNATURE
      DESCRIPTION OF TREATMENT
      TECHNIQUE
      REGION
      PORT
      MODE
      DEPTH
      DAILY DOSE/FRACTION
      FRACTIONS PER WEEK
      DOSE FOR THE COURSE
      TOTAL DOSE
      DOSE PER PORT

   b. Revisions to the initial dose course will be indicated on the written directive and will be initialed and dated by the authorized user prior to the administration of the revised dose or fraction.
      A COMPLETE ENTRY LINE WILL BE ENTERED ON THE WRITTEN DIRECTIVE FOR PATIENTS TEMPORARILY TRANSFERRED FOR TELETHERAPY FRACTIONS, AND WILL BE DATED AND INITIATED BY AN AUTHORIZED USER.

THIS ENTRY WILL BE MADE ON A LINE IN THE SECTION OF THE WRITTEN DIRECTIVE ABOVE THE "COMMENTS" SECTION. AT A MINIMUM THIS ENTRY WILL INCLUDE THE NUMBER OF FRACTIONS, DOSE PER FRACTION, DOSE PER PORT, SIGNATURE/INITIAL OF THE AUTHORIZED USER AND DATE.

c. Oral revisions to a written directive are discouraged. However, an oral revision to a written directive is acceptable if, because of the patient's condition, a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user within 48 hours of an oral revision.

d. Oral directives are discouraged. If, because of the emergent nature of the patient's condition, the preparation of a written directive would jeopardize the patient's health, an oral directive is permitted provided that:

- information provided in the oral directive is entered into the patient record immediately
- THE ORAL DIRECTIVE ENTERED INTO THE RECORD IS REVIEWED, INITIALED/SIGNED AND DATED BY AN AUTHORIZED USER, within 24 hours

2. Patient identity is verified by at least two means. Patient identity will be verified by

a. Patient's name

b. Using a photograph of the patient which is placed in the patient's chart.

Other methods may be used for patient identification.

3. The authorized user shall approve the treatment plan, and establish that it provides sufficient information and direction to meet the objective of the treatment. The treatment plan will be initialed and dated by the authorized user indicating such approval PRIOR TO THE FIRST TREATMENT.

FOR THE PURPOSES OF THE QM PROGRAM, AUTHORIZED USER APPROVAL OF THE TREATMENT PLAN WILL BE INDICATED BY AN INITIAL/SIGNATURE AND DATE ON

- THE CALCULATION SHEET IF NO ISODOSE CURVES ARE USED
  OR,
- FOR COMPLEX TREATMENTS, THE ISODOSE CURVES USED FOR TREATMENT PLANNING.

4. The information concerning the treatment plan and the delivered doses will be provided on the computer output "rectangular mu calculations rocs ver **4.0.1" (OR UPDATES)**, the "University of Connecticut Health Center Radiation Oncology Treatment Summary", and the "John Dempsey Hospital Radiation Oncology Daily Treatment Record". These three forms are attached. Minor revisions in these forms may occur, but such revisions will not omit any information which is required to satisfy the QM requirements as stated in 10 CFR 35.32. The "qualified user", under the supervision of an authorized user, will verify before each treatment that:

   a. the treatment site agrees with the written directive

   b. the dose per fraction agrees with the written directive

   c. the patient's identity is verified by checking the patient's name and photograph, or other acceptable means

   d. these verification steps will be indicated by an initial and date in the daily treatment record for each fraction.

   THE FOLLOWING ONE TIME VERIFICATIONS ARE REQUIRED AND WILL INSURE:

   E. THAT THE PHYSICS CALCULATIONS HAVE BEEN VERIFIED PRIOR TO THE FIRST TREATMENT IF THREE OR FEWER FRACTIONS ARE PLANNED , OR WITHIN THREE WORKING DAYS AFTER THE ADMINISTRATION OF THE FIRST FRACTION FOR THERAPIES INVOLVING MORE THAN THREE FRACTIONS. INITIAL AND DATE THIS CHECK.

   F. THE AUTHORIZED USER HAS INITIALED AND DATED THE TREATMENT PLAN PRIOR TO THE FIRST TREATMENT. INITIAL AND DATE THIS CHECK.

5. A policy is established requiring a "qualified user" to seek guidance, and to not perform the treatment if any questions or doubt exists concerning the written directive, the dose fraction, or the treatment plan.

6. All "qualified users" will after each teletherapy fraction enter the treatment time, dose administered, and cumulative dose delivered. This

information will be entered into the "Daily Treatment Record" (attached). Each such record will be initialed and dated by the "qualified user".

7. A weekly Oncology Chart Review will be performed by a "qualified user" to detect mistakes. These weekly chart reviews will be indicated in the "Daily Treatment Record" by an initial and date in the "Notes" or "Charge Code" column.

8. The dose calculations as provided on the computer generated "rectangular mu calculations rocs ver **4.0.1" (OR UPDATES),** will be verified and checked as indicated on this attached form. Such checks will be done, whenever possible, by an authorized user or qualified user who did not make the original calculations. The date and initials of the person performing the check will be entered at the bottom of the form. If the prescribed dose is to be administered in more than three fractions, dose calculations will be checked within three working days after administering the first fraction. If the prescribed dose is to be administered in three fractions or less, dose calculations will be checked prior to the first fraction.

- **THE QUALIFIED USER AND/OR AUTHORIZED USER PERFORMING THE INITIAL PHYSICS CALCULATIONS, WHEN THE TREATMENT INVOLVES THREE OR FEWER FRACTIONS, IS REQUIRED TO ACTIVELY SEARCH OUT AND OBTAIN A VERIFICATION PRIOR TO RELEASING THE INFORMATION FOR SUBSEQUENT TREATMENT. THIS VERIFICATION MAY BE DONE VIA FAX.**

The signature and/or initials on the "rectangular mu calculations rocs ver **4.0.1" (OR UPDATES)** output will be verification that

a. input to computer dose calculations has been checked and that correct data for the patient was used

b. arithmetic is correct

c. correct transfer of data from the written directive to the treatment plan has occurred

d. all other factors concerning the treatment have been checked.

9. **EMERGENCY TREATMENTS**

IN SITUATIONS WHERE EMERGENCY TREATMENT IS REQUIRED INVOLVING A SIMPLE TREATMENT AND AN AUTHORIZED USER AND/OR PHYSICIST IS NOT AVAILABLE, A QUALIFIED USER MAY PERFORM PHYSICS CALCULATIONS PROVIDED

A. AN AUTHORIZED USER PROVIDES AN ORAL DIRECTIVE FOR THE TREATMENT AND IT IS ENTERED ON THE WRITTEN DIRECTIVE.

B. A SECOND QUALIFIED USER OR AUTHORIZED USER VERIFIES THE CALCULATIONS PRIOR TO THE TREATMENT.

C. AN AUTHORIZED USER INITIALS AND DATES THE ORAL DIRECTIVE WITHIN 24 HOURS AND A PHYSICIST VERIFIES, INITIALS AND DATES THE CALCULATIONS WITHIN 24 HOURS.

10. Unit Quality Control Program

A description of the teletherapy quality control program was provided with the University of Connecticut Health Center's license application, Item 10.5, "Operating Procedures". Included are morning start up procedures, daily functional checks, as well as policy on monthly spot checks and full calibration requirements. Records of these aspects of the quality control program are reviewed by the Teletherapy Physicist and the Radiation Safety Officer. This quality control program has been in existence since the teletherapy license was issued, and no changes are anticipated.

11. Non-Routine Procedures

The output of the teletherapy unit will be determined for any treatment plan for which a full calibration was not done. Specifically, outputs will be determined and documented by the Teletherapy Physicist for special procedures involving

a. field sizes that fall outside the range of the most recent full calibration

b. transmission factors for beam modifying devices not measured during the most recent full calibration

Calibration data will be dated and signed by the Teletherapy Physicist, and kept on the file for review.

12. Acceptance Testing For New Computer Software

Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program. Acceptance testing will also be performed after full calibration measurements when the calibration was performed

a. before the first medical use of the teletherapy unit

b. after source replacement

c. when spot-check measurements indicate the output differed by more then 5% for the output obtained at the last full calibration, corrected for radioactive decay.

The Teletherapy Physicist will document such testing by initialing and dating the record, and keeping such tests on file for NRC review.

13. Periodic Review Policy

Periodic reviews of the teletherapy QM program will be performed by the Radiation Safety Officer or his designated alternate at intervals not to exceed one year. These reviews will be maintained for at least three years. If a designated alternate performs a review, the Radiation Safety Officer will countersign the review. The elements of the review policy are

a. The number of cases reviewed will be as suggested in 10 CFR 35.32 (b), (1), (i). The goal of the audit is review every case. However, at a minimum the following number of cases will be audited per year

Number Cases	Minimum Audits
> 100	20%
20-100	20
< 20	ALL

b. Each patient case reviewed will be documented using the attached "Quality Management Periodic Review" checklist. This checklist is designed to provide "yes" answers for compliant treatments. These reviews will be kept on file for NRC review.

c. All recordable events and misadministrations as detailed in 10 CFR 35.2 will be reviewed, and such reviews documented. Such reviews will include considerations of alternatives to avoid future incidents. The checklist is designed to detect such occurrences. The reporting requirements of 10 CFR 35.33 will be followed.

d. The Radiation Safety Committee will be provided a summary of the periodic reviews by the RSO. The committee will decide if corrective actions are adequate, on the adequacy of the review process and require changes as necessary.

14. Corrective Actions Policy

Should the evaluation described in Section 13 identify an unintended deviation from the QMP, the Radiation Safety Officer shall

a. For events other than recordable events or misadministrations

1. discuss the event with authorized users and qualified persons involved with the case to determine what action, if any, may be taken to avoid a recurrence.

2. document these discussions.

3. revise the QMP if needed.

4. provide information pertinent to the cause of the event to all authorized users and qualified users, if appropriate.

b. For recordable events or misadministrations

1. report to NRC as required by regulation.

2. convene a meeting with all individuals involved with the case and determine the root cause(s) of the event.

3. revise the QMP, if appropriate, and or develop corrective actions.

4. bring the event to the attention of the Radiation Safety Committee for overview of corrective actions.

5. provide training to all users consisting of

- a review of the QMP
- a review of the incident and cause(s)
- Radiation Safety Committee mandated corrective actions.

c. Major modifications to the QMP will be submitted to the NRC within 30 days after the implementation of the modification.

QUALITY MANAGEMENT PERIODIC REVIEW
TELETHERAPY CHECKLIST

Patient Name:_____Dates:_____
RT#:_____
Physician:_____ AU__ Visit AU__ Super. AU__
Number of Fractions:_____Verification Date: _____

POLICY REVIEW	YES	NO
Written Directive (WD) ?	____	____
revisions, if any to WD, signed and dated ?	____	____
Two Forms Patient ID ? (name, photo)	____	____
AU signature/date on treatment plan?	____	____
Treatment site agrees with WD ?	____	____
Dose/fraction agrees with WD ?	____	____
Each treatment fraction, time, and cumulative dose entered in record and initialed/dated ?	____	____
Weekly chart check performed?	____	____
Dose calculations verified with initial and date, within time allowed ?	____	____
RECORDABLE EVENT ANALYSIS(a no is a record event)		
Radiation delivered with a WD?	____	____
All daily doses recorded?	____	____
All weekly administered doses <= 1.15 weekly prescribed doses	____	____
MISADMINISTRATION ANALYSIS(a no is a misadmin)		
All doses delivered to correct patient?	____	____
All doses delivered to correct site?	____	____
All doses as per WD and treatment plan?	____	____
<= 3 Fractions only calculated total administered dose <= 1.1 total prescribed dose?	____	____
> 3 Fractions only Weeks administered dose <= 1.3 prescribed?	____	____
Total administered dose <= 1.2 prescribed?	____	____

chklst Signature:_____Date:_____

John Dempsey Hospital
RADIATION ONCOLOGY DEPARTMENT

Region / Portal:		
Patient Position:		
Set-Up Details:		
Sim Tech / Rx Tech:		

DIAGRAMS:	DATE	NOTES

JOHN DEMPSEY HOSPITAL RADIATION ONCOLOGY DAILY TREATMENT RECORD

NAME: ______________________ PAGE NO: ______________

ATTENDING PHYSICIAN: ______________ THERAPY NO: ______________

REGION / PORT / MODE:

DESCRIPTION:

FIELD SIZE:

TREATMENT MODIFIERS:

COMMENTS

T.P. SEPS

CHARGE CODE	TECH	DATE	ELAPSED DAYS	FRACTION NO	M.U.	TIME	DAILY DOSE	NOTE	M.U.	TIME	DAILY DOSE	NOTE	M.U.	TIME	DAILY DOSE	NOTE	M.U.	TIME	DAILY DOSE	NOTE	DAILY DOSE	TOTAL DOSE	DAILY DOSE	TOTAL DOSE			NOTES	UTW	SEPS

University of Connecticut Health Center

RADIATION ONCOLOGY TREATMENT SUMMARY

NAME: THERAPY NO.: DATE:

ATTENDING PHYSICIAN:

TREATMENT AREA:

OF TREATMENT PORTS: # OF VISITS:

REGION	PORTS	AREA TREATED	MODE	TUMOR DOSE		DATES OF Rx		# OF VISITS	ELAPSED DAYS
					TOTAL	FROM	TO		

COMMENTS

University of Connecticut Health Center
RADIATION ONCOLOGY PRESCRIPTION

NAME:	RT #:	RT MD:	DATE:
DIAGNOSIS:			

DATE	DESCRIPTION	TECHNIQUE	REGION	PORT	MODE	DEPTH	DAILY DOSE	FX	DOSE THIS COURSE	TOTAL DOSE

COMMENTS

(Signature) M.D.