THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

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

August 21, 1996

U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406

License Number: 06-13022-05

To Whom It May Concern:

The University of Connecticut Health Center is submitting this report as required by 10 CFR 35.33 (a), (2), as a result of the Teletherapy misadministration reported to the NRC Operations Center on August 7, 1996 at approximately 4:00 pm.

Licensee's Name

The licensee's name is the University of Connecticut Health Center, 263 Farmington Avenue, Farmington, Connecticut.

Prescribing Physician's Name

The prescribing physician and authorized user's name is Robert J. Dowsett, M.D.

Brief Description of The Event

A patient was scheduled to receive the 21 st. treatment of 27 total dose fractions on a linear accelerator on August 7, 1996. The linear accelerator was not operational for this planned 21 st. treatment, and because the patient had missed a treatment the previous day, the authorized user was of the opinion that the individual should not miss another treatment. Therefore, the patient was scheduled for one treatment on the Teletherapy unit located adjacent to the linear accelerator. The patient was treated on the Teletherapy unit and for the 22 nd fraction received twice the intended radiation dose. This misadministration was detected by a staff member immediately after the treatment, and the Authorized User and the Radiation Safety Officer were notified soon thereafter. The Radiation Safety Officer reported the event to the U. S. Nuclear Regulatory Commission within four hours of its occurrence.

AUG 22 1996

Why the Event Occurred

The University of Connecticut Health Center's Teletherapy Quality Management Program (QMP) and Oncology Department Policy require that the physics calculations for treatments involving three or fewer fractions be verified prior to the first treatment. The individual performing the original physics calculations inadvertently entered twice the prescribed dose into the physics calculations computer code. Subsequently, these calculations were not verified prior to the first treatment fraction on the Teletherapy unit. As a result, the patient received one fraction which was twice that prescribed for the day.

Effect on the Patient

The prescribing physician has stated that there should be no negative effect on the patient due to this event. The patient's total weekly dose was delivered as planned. In addition, the patient is being monitored for any acute effects. To date, none have been exhibited. The patient has completed the planned treatment course and the total delivered treatment dose was as prescribed. Please find attached the original interim note concerning this case written by the prescribing physician.

Improvements Needed to Prevent Recurrence

This incident has been extensively evaluated by involved staff members and management for the purpose of reducing the risk that such an event would occur again. In addition, there was extensive discussion with the NRC and State of Connecticut Inspection team during a follow-up inspection conducted on August 14, 1996 which proved to be very valuable in identifying policy changes needed. Evaluation of the sequence of events has resulted in the identification of certain components of the Quality Management Program which should be changed to minimize the risk of a future incident. These components are

A further refinement of the physics calculations verification process is needed using an additional review of the verification process and assignment of direct responsibility for this review

More specific and detailed prescription (ie: Written Directive) information is needed to ensure accurate interpretation and calculation of prescribed doses

Other improvements which have been identified, although not directly related to the root cause of this misadministration in the licensee's opinion, that will improve the overall Quality Management Program for Teletherapy are

The definition of a "Treatment Plan" needs to be clarified, as well as where the Authorized User's initial/signature and date are to be placed on this plan

Clarification of how Teletherapy prescriptions are to be entered on the Written Directive, including when patients are transferred from the linear accelerator to the Teletherapy unit for treatment

Adding procedures to the Quality Management Program concerning emergency treatments where qualified individuals perform simple dose calculations

Follow-up training sessions are needed with qualified users and authorized users wherein the details of each of their QMP responsibilities are emphasized

Actions Taken to Prevent a Recurrence

The following actions were taken and/or are planned to address this problem to prevent a recurrence.

Immediately after the occurrence, the Radiation Safety Officer met with all those involved to discuss the cause of the incident. The QMP requirement for verification of calculations prior to the first treatment for three or fewer fractions was reviewed with those responsible for the initial calculations and the verification. The qualified user Teletherapy staff was notified via correspondence from the authorized user dated August 9, 1996. This letter is attached.

No further treatments on the Teletherapy unit were performed after the event until the physicist reviewed the dose calculations for the remaining patients. All of the remaining dose calculations were accurate.

On August 8, 1996 the Radiation Safety Officer reviewed all teletherapy cases treated on August 7, 1996 and noted no other discrepancies between prescribed and administered Teletherapy doses. The results of this QMP audit indicated that a change in the method of entering information on the written directive is needed. In addition to the total dose per fraction, the dose per each port needs to be entered for a Teletherapy prescription. This change was implemented via a letter from the Authorized User to all other Teletherapy users(letter of August 9, 1996 attached).

Other improvements to the Quality Management Program were identified and will be implemented.

The Quality Management Program (QMP) for Teletherapy is being revised to include

A clarification of the requirement to enter a complete entry line on the Written Directive for any prescribed Teletherapy dose course. This will include patients transferred from a linac to the Teletherapy unit for a limited number of fractions.

A clarification of the meaning of "Treatment Plan" has been added to the QMP with specific location for an authorized user signature.

Language has been added to the QMP to require qualified users (ie: Technologists)to verify that the physics calculations have been verified at the correct time and that the authorized user has signed the treatment plan prior to the first fraction.

A requirement for the physicist and/or qualified user performing initial dose calculations to seek out a verification prior to the first fraction if the Written Directive is for three or fewer fractions has been added to the QMP.

An additional section has been added to the QMP detailing the requirements for Emergency Treatments. These would clarify requirements when qualified users perform very simple calculations. This includes a clarification of the requirement for an oral directive from an authorized user, a verification of the calculations by another qualified user prior to the treatment, and a verification by a physicist within 24 hours of the calculations.

The final component of the improvements and corrective actions is training. As soon as is practical, the revised QMP will be presented to all authorized users and qualified users by the Radiation Safety Officer. The details of the QMP, with specific emphasis on each individual's responsibilities, will be presented and documented. It is anticipated that this action will be completed within 30 days of the date of this correspondence, after which, no individual will be permitted access to the Teletherapy unit as an Authorized User or Qualified User until such training is documented.

As required by 10 CFR 35.32 (e), the revised QMP will be provided to the NRC within 30 days after its implementation. The date of implementation will be the earliest date that staff training may be arranged.

Notification of the Patient

The patient was notified as soon as a qualified interpreter could be obtained. The referring physician was notified during the afternoon of August 7, 1996. The prescribing physician informed the patient utilizing the services of the interpreter on August 9, 1996 at approximately 11:00 am. The patient was told that on August 7, 1996 he had received a dose of 300 cGy instead of the prescribed dose of 150 cGy. He was also informed that the total weekly dose delivered was as planned. He was told that no acute adverse effects had been detected by the staff, and that it was unlikely that he would experience any long term negative effects. He was given the opportunity to ask questions concerning his therapy. The patient appeared satisfied and did not request any further information.

Sincerely,

Kenneth W. Price, Director
Office of Radiation Safety
Radiation Safety Officer

cc: Connecticut State DEP
Paul Davern
Sarah Locher
Leonard Paplauskas
Raymond Ryan
Andrew Salner
Nancy Williams
The Patient

JOHN DEMPSEY HOSPITAL
OF THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

DEPARTMENT OF
RADIATION ONCOLOGY
Tel: (860) 679-3225
Fax: (860) 679-1309

INTERIM NOTE: 8-7-96

NAME:
UNIT#:
THERAPY#:

Mr. was treated today on the Cobalt-60 unit because of prolonged downtime on the Linear accelerator. He was not treated yesterday because of the problems with the Linear accelerator. We did not want him to have two treatment days without therapy and elected to treat him today on the Cobalt-60 unit as we did not anticipate the Linear accelerator to be operational until 8/8/96. The calculation for Mr. was done for 300cGy fraction when the prescription was written for 150cGy per day. That dose was delivered today and the patient had no acute effects from it. Nevertheless it is a deviation from the daily prescribed dose even though his total dose for the week of radiotherapy will be that which was prescribed because he missed yesterday's dose.

I did inform Dr. Sporn today via telephone of this event as specified by the NRC guidelines. In addition the patient will be informed of the event when an interpreter can be available so that he can fully understand the situation and ask any questions. The patient will be monitored for any acute effects of this event but I do not anticipate any problems. He was sent for a CBC today as he is scheduled to have his Taxol on Friday and we will follow up on those results.

ROBERT J. DOWSETT, M.D.

cc: Ken Price

rjd/dh
10d8-7.bet

JOHN DEMPSEY HOSPITAL
OF THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

MEMORANDUM

DEPARTMENT OF
RADIATION ONCOLOGY
Tel: (860) 679-3225
Fax: (860) 679-1309

TO: Andrew Salner, M.D, Judith Buckley, M.D., Jacqueline Lyon, M.D., William Aberizk, M.D.

FROM: Robert J. Dowsett, M.D.
Radiation Oncology

DATE: August 9, 1996

SUBJECT: RECENT COBALT-60 INCIDENT

We recently had a incident on the Cobalt-60 unit when a patient receiving a single fraction on the Phoenix because of an accelerator break down received 300cGy instead of the 150cGy that had been prescribed by the physician. This was related to a calculation error that was not doubled checked before administration of the treatment.

In order to make the prescription more clear we are proposing to the NRC that in addition to our regular information on the Cobalt prescription we will specify the dose per port on the line directly below the normal prescription information. For example, if the patient were to received 200cGy with opposed AP/PA fields labeled A1 and A2, the physician would need to specify A1 dose 100cGy, A2 dose 100cGy on the line below the prescription. For more complicated plans that section would need to be filled in at a later date when the plan was available for review. With more complex plans the dose delivered to isocenter from the multiple field plan may be quite variable among the ports. The physics double check would then be done after the physician has completely filled out the prescription. It is our intent to implement this change after it has been reviewed by the NRC sometime during the week of 8/12/96.

If you have any further questions please contact me or Ken Price.

rjd:dl
10D8-9.ME2

cc: Ken Price

JOHN DEMPSEY HOSPITAL
OF THE UNIVERSITY OF CONNECTICUT HEALTH CENTER

DEPARTMENT OF
RADIATION ONCOLOGY
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MEMORANDUM

TO: Arthur Pinkerton, Danette Guay, Ellen Kurdzo, Tina Taft, Margaret Lane, Terri Dionne, Betsy Leary, Valerie LaVake

FROM: Robert J. Dowsett, M.D.
Radiation Oncology

DATE: August 9, 1996

SUBJECT: RECENT COBALT-60 INCIDENT

As most of you are aware we recently had a incident on the Cobalt unit where a patient received a 300cGy dose when a 150cGy was prescribed. The patient at the time was scheduled to receive one treatment on the Cobalt unit. The calculation was done for a dose of 300cGy and delivered by the technical staff. This was picked up by the technical staff after the completion of the treatment. We do not anticipate any acute or chronic problems associated with this incident for the patient, but I feel that it is important to review the procedures that are in place. If they had been followed we could have possibily prevented this incident.

Any patient receiving three or fewer doses of radiation on any machine must have a double check of the physics calculations prior to the initiation of treatment. In addition any patient on a more prolonged course of radiotherapy must have a physics double check performed by the time the third dose is delivered. In addition the technical staff should verify that the calculated dose is what has been prescribed by the physician before any delivery of radiation. I know that we all feel that it is important to achieve complete compliance concerning these policies.

rjd:dl
10D8-9.ME1

cc: Ken Price
Andrew Salner, M.D.