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34-00746-03

Mt. Sinai
Excellence. It's our heritage.

May 2, 1994

Ms. B. J. Holt
Chief, Nuclear Materials Inspection Section #1
United States Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Ms. Holt,

Enclosed is the final report for the misadministration first reported to your office on April 19, 1994, in accordance with regulations promulgated under 10 CFR §35.33.

Sincerely Yours,

Mark S. Rzeszotarski, PhD

Mark S. Rzeszotarski, Ph.D.
Radiation Safety Officer

Barbara Hollefreund

Barbara Hollefreund
Senior Vice President, Patient Care

Enclosure

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THE MT. SINAI MEDICAL CENTER
One Mt. Sinai Drive Cleveland, Ohio 44106-4198
Affiliated with Case Western Reserve University, School of Medicine and the Jewish Community Federation

MAY 6 1994

B. J. Holt:

Please review the attached and indicate whether or not this is a **REPORTABLE EVENT/INCIDENT**. After review, please initial in the top right hand corner of the original, and if reportable, please NOTE UNDER WHAT REG OR LIC CONDITION. Then remove copy for yourself and pass package on to MARCIA PEARSON for further review. PLEASE BE SURE TO RETURN ORIGINAL TO ME

Thanks,

Irene

yes, Reportable - 10 CFR 35.33

Misadministration Report

Licensee Name:

The Mt. Sinai Medical Center, One Mt. Sinai Drive, Cleveland, OH 44106-4198, U. S. N.R.C. License # 34-00746-03

Prescribing Physician Name:

Henry F. Blair, M.D.

Brief Description of the Event:

On the afternoon of April 18, 1994, during routine chart review, the teletherapy physicist discovered a possible cobalt-60 teletherapy misadministration as defined under 10 CFR 35.2. The following morning the event was immediately voluntarily presented for review to Wayne Slawinski and Robert Gattone, Jr., Nuclear Regulatory Commission Inspectors, who had just arrived for a unannounced routine inspection. They evaluated the case and determined that it was, in fact, a misadministration. The N.R.C. Operations Center was notified of the misadministration at 9:45 A.M., E.D.T. on April 19, 1994. Information regarding the misadministration was provided to the N.R.C. by the Medical Center's Radiation Safety Officer.

The patient had received radiation treatment to decrease the risk of recurrence of breast cancer. The original written directive, dated February 28, 1994, called for 5000 rads (cGy) of cobalt-60 radiation using twenty-five (25) fractions of 200 rads (cGy) per day, five (5) times a week. Following further evaluation of computer treatment plans, the written directive was revised by the prescribing physician on March 1, 1994, prior to the first dose administration. The revised dose prescription called for 4000 rads (cGy) of cobalt-60 radiation in twenty (20) fractions of 200 rads (cGy) each, followed by 1000 rads (cGy) of linear accelerator radiation treatment in five (5) fractions of 200 rads (cGy) each. The teletherapy technologists wrote the revised dose prescription information on the upper left hand corner of the Daily Treatment Record, in accordance with our Quality Management Plan directives when a dose prescription is revised. The prescribing physician followed our Quality Management Plan directives for writing a revised dose prescription. The patient began treatments on March 1, 1994. She completed her 20th fraction on March 28, 1994.

On March 29, 1994, the patient should have begun receiving linear accelerator radiation treatments. Instead, the patient received four (4) additional cobalt-60 treatments of 200 rads (cGy) over the next four (4) weekdays, and a fifth (5th) treatment of 200 rads (cGy) on the following Monday. The treatments were completed on April 4, 1994.

Three different teletherapy technologists performed the treatments during this time period. None of the technologists recognized the revised dose prescription, which was clearly visible in the upper left hand corner of the Daily Treatment Record, where they daily recorded dose administration information.

The routine teletherapy physicist physics chart review following completion of the treatments was delayed due to a family emergency which required the teletherapy physicist to be out of town when the charts normally would have been checked. Hence, the error was not discovered until April 18, 1994.

Why the Event Occurred:

The event occurred due to a failure to read posted chart information by three teletherapy technologists. Despite clear indications of a revised dose prescription on the Daily Treatment Record, none of the technologists recognized the revised written directives, which were written on the chart.

The Effect on the Patient:

The patient received a total radiation dose of 5000 rads (cGy) of cobalt-60 irradiation to decrease the risk of recurrence of carcinoma of the breast. If the revised written directive had been followed, the patient would have received the identical total radiation dose, using two different teletherapy machines instead of one. As a result, the patient should expect no difference in results due to the form of treatment which was employed.

Depending on breast size and habitus, either only Cobalt-60 or Cobalt-60 with linear accelerator treatments are prescribed at this facility. Although both methods of treatment are commonly used, the prescribing physician elected to use the two machine technique for this patient. The difference between the two methods is a slight improvement in the uniformity of the dose distribution when two machines are utilized versus one, but does not decrease the risk of recurrence of breast cancer.

The two treatment methods prescribed for this patient were evaluated using our computer treatment planning system. The nonuniformity of dose distribution between the two methods of treatment is approximately 10% and is acceptable, according to the prescribing physician. No additional or corrective radiation treatments are required. No adverse effects are expected.

What Improvements Are Needed to Prevent Recurrence:

Teletherapy technologists must immediately recognize when changes occur in a dose prescription through revision, or when the mode of radiation treatment changes during the course of implementing the written dose prescription.

Actions Taken to Prevent Recurrence:

Immediately following the conclusion of the N.R.C. inspection, a meeting was held between the teletherapy technologists, the teletherapy physicist and the radiation safety officer. During the meeting a number of suggestions were made to reduce the likelihood of a repeat of this event. The suggestions included: 1) Pencil in when and where changes will occur on the Treatment Plan in advance to remind the technologist of upcoming changes; 2) Have a second technologist verify the pencilled in treatment plan changes and initial them; 3) Revise the format of the dose prescription forms to make it easier to identify the written directive; 4) Move the revisions notes to the left center of the Treatment Plan page to make them more prominent.

We immediately instituted the pencil in changes plan. Currently, the physicist is performing this task while we prepare a formal mechanism for the teletherapy technologists to do it with cross checking and initialling by a second technologist.

A draft proposal for new chart recording procedures was created on April 23, 1994. It includes changes in the method of documenting the written directive to insure that the dose prescription and any revisions are clearly written. It also spells out the procedures for performing the pencilling in of upcoming changes in the treatment plan, and the cross checking verification process by the technologists. This document will be further evaluated prior to implementation, since a significant change such as this could potentially increase the susceptibility of errors initially due to lack of familiarity with the revised procedures. We are committed to improving our procedures to insure the safe and effective treatment of our patients, and commit to implement these and/or similar appropriate changes within the next ninety (90) days.

The Radiation Safety Committee will oversee any revisions of the Quality Management Program (QMP) in the Radiation Therapy Department and will perform independent quarterly audits of the revised QMP implementation until such time as the Committee is confident that the QMP has been properly revised and is performing satisfactorily.

Notification of Referring Physician:

The referring physician was contacted via telephone by the prescribing physician on April 19, 1994 and informed of the misadministration. Later that same day, they met to discuss the misadministration. They reviewed the case, and a followup letter was generated from the prescribing physician to the referring physician, dated April 19, 1994.

Whether the Licensee Notified the Patient and What Information Was Provided to the Patient:

The patient was seen on April 20, 1994 at 9:30 A.M. in the office of the prescribing physician. The misadministration was explained to her by the prescribing physician. The patient's course of treatment was reviewed, and the patient was informed that she did not receive an inappropriate treatment. She did not have any followup questions. She was encouraged to contact the prescribing physician if she had any questions in the future. Progress notes reflecting this discussion, dated April 20, 1994, were forwarded to the referring physician.

Written Report Sent to Patient:

A letter prepared by the prescribing physician will be mailed to the patient indicating that the Misadministration Report is on file at our facility and that she may obtain a copy of it for review if desired.