U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-15270/94002(DRSS)

Docket No. 030-15270

License No. 34-00746-03

EA No. 94-085

Licensee: The Mt. Sinai Medical Center
Cleveland, Ohio

Enforcement Conference At: NRC Region III Office
Lisle, Illinois

Enforcement Conference Conducted: May 27, 1994

Inspection Conducted: April 19 and 20, 1994, with continued in-office review through May 5, 1994

Inspector: _____ 6/8/94
Robert G. Gattone, Jr. Date
Radiation Specialist

Reviewed By: _____ 6/8/94
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: _____ 6/9/94
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Meeting Summary

Enforcement Conference on May 27, 1994 (Report No. 030-15270/94002(DRSS))
Areas Discussed: A review of the findings from the April 19 through May 5, 1994 inspection, including a discussion of the apparent violations, the accuracy of the facts, causal factors, the corrective actions taken or planned by the licensee, and the Enforcement Policy.

DETAILS

1. Conference Attendees

The Mt. Sinai Medical Center

Barbara Hollefreund, Senior Vice President
Mark Rzeszotarski, Radiation Safety Officer
Michael Rutstein, Teletherapy Physicist

Nuclear Regulatory Commission

Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region III
Bruce Berson, Regional Counsel, Region III
Robert Gattone, Radiation Specialist, Region III
Robert DeFayette, Director, Enforcement and Investigation Coordination Staff, Region III
Darrel Wiedeman, Enforcement Coordination Staff

2. Enforcement Conference Summary

An Enforcement Conference was held in the NRC Region III office on May 27, 1994, between members of the NRC and The Mt. Sinai Medical Center staffs. The conference was held to discuss the findings of an NRC inspection conducted on April 19 and 20, 1994, with continuing in-office review through May 5, 1994. The inspection identified four apparent violations, one of which was a repeat item from the previous inspection in 1993. NRC inspection findings are documented in Inspection Report No. 030-15270/94001(DRSS) transmitted to the licensee by letter dated May 18, 1994.

The purpose of the conference was to: (1) review the apparent violations, including the root and contributing causes; (2) discuss the accuracy of the inspection findings; (3) discuss the licensee's corrective actions; (4) determine whether there were any aggravating or mitigating circumstances; and (5) obtain other information that would help determine the appropriate enforcement action.

The licensee did not contest the apparent violations and agreed with the accuracy of the information presented with the exception of the following:

a. The licensee disagreed with the NRC's characterization of the Medical Center's failure to include the dose per fraction and the overall treatment period in the written directive. The licensee contends that dose per fraction is inferred by indication of the total dose and total number of fractions. Furthermore, the overall treatment period is indicated as the total number of fractions and/or the number of fractions per week. The licensee

claimed its practice of recording overall treatment period as number of fractions or number of fractions per week is consistent with standard teletherapy practices.

b. The licensee disagreed with NRC's characterization of the Medical Center's failure to evaluate and take action regarding unintended deviations to written directives that occurred on April 29 and 30, 1993. The licensee presented information at the conference that was not available during the inspection. The information included incident reports outlining the licensee's evaluation of the unintended deviations and action taken to prevent recurrence.

The licensee described its corrective actions for the apparent violations that were discussed during the conference. Regarding the violations being considered for escalated enforcement action, the licensee's corrective actions include: (1) coordinating revised written directives with the teletherapy physicist who will provide verbal notification to the technologists; (2) auditing the effectiveness of the quality management program on a more frequent basis; (3) development of a revised quality management program to the NRC and submission of it by August 1, 1994; (4) standardizing patient charts to centralize the written directives and separate modalities; and (5) establishing a quality control committee responsible for developing corrective actions.

The NRC staff acknowledged the licensee's statements and indicated that they would be considered in the NRC's decision for enforcement action.

The licensee provided an information packet at the conference titled, "Supporting Documentation for U.S. Nuclear Regulatory Commission Enforcement Conference" dated May 27, 1994 (enclosed).

3. Concluding Statement

NRC representatives summarized the NRC Enforcement Policy and process and indicated that the licensee will be notified in writing of NRC's proposed enforcement actions.

Enclosure: As stated

The Mt. Sinai Medical Center

One Mt. Sinai Drive

Cleveland, OH 44106

Supporting Documentation

for

U.S. Nuclear Regulatory Commission

Enforcement Conference

May 27, 1994

Mt. Sinai
Excellence. It's our heritage.

May 26, 1994

TERRY A. DONNER
Legal Counsel

U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Re: N.R.C. Inspection Report No. 030-15270/94001

Dear Sirs:

The attached documentation is provided in response to information requested in N.R.C. Inspection Report No. 030-15270/94001. The documents entitled "Teletherapy Recordable Event - 4/29/93" and "Teletherapy Recordable Event - 4/30/93" contain incident reports, medical files and similar files which would constitute an invasion of personal privacy if disclosed to the general public. Hence, we request that these documents be exempt from public disclosure as permitted under 10 CFR § 2.790 a(6).

We also request that all clinical patient data obtained during and as a follow-up to your April 19-20, 1994 inspection or as a result of your investigation of the misadministration on April 19, 1994 also be exempt from public disclosure as permitted under 10 CFR § 2.790 a(6). This includes, but is not limited to: dose prescriptions, treatment plan summary sheets, daily treatment records, patient set-up sheets, dose calculation sheets, computer isodose contours, patient contour graphs, patient progress notes, incident reports, quality assurance forms, and other data pertaining specifically to clinical patients. Disclosure of this information would constitute an invasion of personal privacy if disclosed to the general public.

Very truly yours,

Terry A. Donner

Terry A. Donner

TAD/jo

cc: Barbara Hollefreund, Senior Vice President, Patient Care
Mark S. Rzeszotarski, Ph. D., Radiation Safety Officer

104.46

Quality Management Plan Training

Orally presented inservices on our Quality Management Plan (QMP) were provided by Mr. Tom Stefanakos, teletherapy physicist, to the teletherapy technologists during the last week of December, 1992 and the first week of January of 1993 (due to vacations). The authorized user and supervised authorized user were also given copies of the QMP in December 1992. In addition, the Policy on Recordable Events and Misadministration of Dose Events was reviewed. The attached documentation shows the initials of the technologists and the dates they reviewed the QMP and Events Policies documentation. (The above information was obtained by telephone interview of Mr. Stefanakos on May 12, 1994.)

Copies of the QMP and the Events Policy are in the Department of Radiology Radiation Therapy Division Policy and Procedure Manual, which is kept in the Radiation Therapy Department and is available for all personnel to review at any time.

Mark S. Rzeszotarski, PhD May 18, 1994

Prepared by Mark S. Rzeszotarski, Ph.D. on May 18, 1994.

cp 12/28/92
BK/229-91
651-493

copy Given to Dr Blain & Dr Goyal 12/28/92 BD 1-5-93

THE MT. SINAI MEDICAL CENTER
DEPARTMENT OF RADIOLOGY: DIVISION OF RADIATION THERAPY

QUALITY ASSURANCE

PREFACE

The Division of Radiation Therapy is organized to provide regular and convenient radiologic services required by the needs of patients as determined by the medical staff. Only those physicians who are on the medical staff of The Mt. Sinai Medical Center and approved by the Board of Trustees shall be allowed to practice within the areas of the Division of Radiation Therapy.

STATEMENT OF PURPOSE

The Division of Radiation Oncology of The Mt. Sinai Medical Center is dedicated to the principle of providing the highest possible quality of care with the most effective use of resources. The division's quality assurance activities are designed to enhance patient care and assure appropriate allocation of health care resources through ongoing objective assessment of important aspects of patient care and the correction of identified problems. The purpose of this plan is to define the quality assurance activities of the division.

KEY COMPONENTS OF THE PROGRAM FOR TELETHERAPY

A. WRITTEN DIRECTIVE

A written dose prescription (written directive) from a radiation oncologist on the staff of The Mt. Sinai Medical Center is required before starting radiation therapy on any patient. In case of an emergency where there is a clear benefit to the patient, an oral dose prescription may be substituted for the first treatment.

B. PATIENT IDENTITY VERIFICATION

Prior to delivering a teletherapy dose to a patient on each day of treatment, the treating technologist will verify the identity of the patient by at least two methods. Acceptable methods include asking and confirming the patient's name, birthdate, address, social security number, signature, name on patient's I.D. bracelet or confirming that the patient's face matches the photograph of the face that is in the patient's chart.

C. TREATMENT PLAN APPROVAL

Prior to initiating treatment on a patient, the plan of treatment will be approved by a radiation oncologist on the staff of The Mt. Sinai Medical Center.

D. CONFIRMATION OF TREATMENT FIELD SETUP

After the patient is on the treatment table, but before the beam is turned on, it is the responsibility of the treating technologist to confirm the treatment site, dose per fraction, and treatment setup. The treatment site and dose per fraction will be confirmed by comparing the dose set to be delivered to that contained in the treatment records. The beam setup will be confirmed by comparing the patient's setup to the information contained in the patient's chart.

E. POLICY ON QUESTIONS ABOUT PATIENT SETUP

It is the policy of The Mt. Sinai Medical Center for technologists treating radiation oncology patients to seek guidance and ask questions if there is any uncertainty on how to carry out a radiation oncologist's dose prescription. The following policy statement is in force and has been distributed to the radiation therapy technologists:

Policy on Questions: We have confidence in your ability and training to treat our patients. Furthermore, we believe that you are sincerely interested in our patients receiving the best possible care. If you have a question -- ASK! If you still have doubts, reservations, or uncertainties, ask the radiation oncologist. If you still feel things are not right, continue to ask until you are satisfied that you understand what is expected of you. If the technologists have questions or require clarification regarding a treatment plan, patient setup or dose calculation, those qustions are to be brought promptly to the attention of a physician or physicist prior to administering the treatment.

F. VERIFICATION OF PATIENT TREATMENT

Following the delivery of a teletherapy dose to a patient, i.e. after a patient's daily treatment, the technologist treating the patient will initial the patient's chart in the space corresponding to the treatment given and record the information, i.e. date, daily dose, cumulative dose, etc.

G. WEEKLY CHART REVIEW

The charts of all patients under treatment are normally reviewed on a weekly basis by the teletherapy physicist.

H. CHECK OF DOSE CALCULATIONS PRIOR TO TREATMENT

It is the policy of The Mt. Sinai Medical Center to have all dose calculations checked prior to delivering the third treatment by an individual who did not perform the initial calculation, except in cases of emergency treatments delivered outside of normal working hours. The initial check of he calculation will verify correct data entry of field

sizes, patient thicknesses, treatment unit, and agreement with written dose prescription. The dose calculation performed by the physicist will include a hand calculation using a table lookup method for beam data and machine output. The calculations made will be noted, as follows: Technologist making initial calculations will initial chart; technologist checking calculations will initial and date chart; physicist will also initial and date chart after his check.

For emergency cases that occur outside of the department's regular working hours, the calculation check may be omitted. The calculation will be performed during the next working day prior to treating the patient on that day. The treating radiation oncologist will enter a note in the patient's chart stating that "due to the emergent nature of the patient's condition, the dosage check may be delayed and done within two working days."

I. INDEPENDENT CHECK OF CALIBRATION MEASUREMENTS

To assure optimum quality treatments, it is important that the output calibration of the department's teletherapy units be checked on a regular basis.

After a source change, an independent check of output will be performed by a physicist who did not perform the initial calibration. The physicist checking the calibration will be approved by the Nuclear Regulatory Commission (NRC) as a teletherapy physicist, and he/she can use a calibrated dosimetry system different from that used in the initial calibration measurement. The calibration will measure the output of the unit in cGy per minute for a standard 10 x 10 cm field at a distance of 80.0 cm source calibration distance. In lieu of an independent physicist, the physicist performing the initial calibration can act as the independent checker, provided he uses a totally different calibrated dosimetry system than that used in the initial calibration measurement.

J. FULL CALIBRATION MEASUREMENTS

Full calibration of each teletherapy unit will be performed by a teletherapy physicist. Such a calibration is comprehensive and as a minimum meets the requirements of 10CFR35.632. It includes the measurement of the output for the standard 10 x 10 cm field size at 80.0 cm source calibration distance, measurement of the field size dependence on output, and measurement of th transmission factors for all beam-modifying devices such as trays and wedges that are in clinial use. Any beam modifying devices that are put into clinical use between calibration measurements will have their transmission factors measured before being used clinically. In addition, the first full calibration following a source change will also measure the transmission factors of standard and recastable blocks, bolus materials and materials used for compensators.

K. NON-STANDARD TREATMENT GEOMETRIES AND CONDITIONS

To assure accurate delivery of the dose prescribed by the radiation oncologist, beam on time calculations are based on output rates determined by physical measurement by a teletherapy physicist. Output rates at treatment geometries and field sizes under routine use will be measured as part of the annual calibration of each unit. In the event that a radiation oncologist prescribes delivery of a dose under non-routine geometry, the output rate of the teletherapy unit under that treatment geometry will be measured by a teletherapy physicist prior to providing the first fractional dose to the patient.

If, due to the emergent nature of the patient's condition, the treating radiation oncologist believes that delaying treatment to allow for physical measurement will jeopardize the patient's health, the prescribed treatment may be given prior to making the physical measurement of output rate. In such a case, (1) the treatment radiation oncologist will enter a note in the patient's chart waving the measurement due to the patient's emergent condition, and, (2) the physical measurement of output rate will be made within two working days. Reports of the acceptance test will be prepared by the teletherapy physicist and kept on file with the annual calibration.

L. TREATMENT PLANNING AND DOSE CALCULATION SOFTWARE

All treatment times at The Mt. Sinai Medical Center are hand calculated by table look up or %DP, BSF, TAR, and TMRs provided by the treatment planning computer. The treatment planning computer is not used to calculate treatment times or dose decays (i.e. dose rates on a given date). Also, only in an irregular field calculation is the calculation output provided by the computer; and, in this situation, the planner provides the treatment planning computer with the appropriate output and the computer program adjusts for the blocks in the beam for the treatment output.

M. QUALITY MANAGEMENT PROGRAM REVIEW

The quality management program outlined in this section will be reviewed on an annual basis by the Radiation Safety Committee. Members of this committee are appointed by the Medical Executive Committee. The Radiation Safety Officer will annually review the effectiveness of the program and modify the program to improve its performance, as needed. As part of his review process, he will review all misadministration and recordable event reports that were filed in the previous year, review the overall program for workability and detection of problems, review the charts of a random sample of 5% of the patients who were treated in the previous year. He will present his report to the Radiation Safety Committee, who will make a written report of his findings and his recommendations. Such reports will be given to the Radiation Oncologist and the Vice President of Professional Services, and will be kept on file in Radiation Oncology for a period of five years.

THE MT. SINAI MEDICAL CENTER
DEPARTMENT OF RADIOLOGY: DIVISION OF RADIATION THERAPY

POLICY ON
RECORDABLE EVENTS AND MISADMINISTRATION OF DOSE EVENT

I. RECORDABLE EVENTS AND MISADMINISTRATION OF DOSE EVENTS
(Content from 10CFR35):

1. Recordable Event is defined as the administration of:

   A. A radiation dose to a patient without a written dose prescription (written directive) where a written dose prescription is required.

   B. A radiation dose to a patient without recording the dose in a patient's chart.

   C. A calculated teletherapy radiation dose to a patient that is 15% greater than the weekly prescribed dose.

2. Misadministration of Dose Event is defined as the administration of:

   A. A teletherapy dose involving the wrong patient, wrong treatment site, and wrong mode of treatment.

   B. An administered teletherapy dose that differs from the total prescribed dose by more than 10% for those patients whose treatment course consists of 3 or fewer fractions.

   C. A teletherapy dose to a patient where the calculated weekly administered dose is 30% greater than the weekly prescribed dose.

   D. A calculated teletherapy dose to a patient that differs from the total prescribed dose by more than 20% of the total prescribed dose.

II. DETECTION AND REPORTING OF ERRORS

An individual who notes an error in the treatment or suspects that a recordable event or misadministration event may have occurred will initiate the review process by filling out a radiation oncology quality assurance report form (see attached). A teletherapy physicist will conduct a preliminary investigation of the event whose purpose is to ascertain exactly what happened and, subsequently, to arrange for corrective action. The physicist will, upon completion of the preliminary investigation, notify the physician. The physician and physicist will review the case and determine whether the case meets the criteria for being either a recordable event or a misadministration of dose event, as defined above.

III. ACTIONS TO BE TAKEN FOLLOWING A RECORDABLE EVENT

If the physician and physicist determines that a recordable event has occurred, the following actions will be taken within 30 days after ascertaining that such an event has occurred:

1. The teletherapy physicist will assemble the relevant facts and ascertain the cause of the event.

2. The physicist will identify what corrective action, if any, is required to prevent a recurrence of a similar event.

3. The physicist will prepare a brief written report of the event which will include his findings and recommendations.

4. A copy of the report prepared by the physicist will be given to the radiation oncologist and a copy kept on file.

IV. ACTIONS TO BE TAKEN IN THE EVENT OF A MISADMINISTRATION EVENT

If the physician and physicist determines that a misadministration of dose event has occurred, the following actions will be taken:

1. A teletherapy physicist will notify the physicians.

2. The physicist will notify the Nuclear Regulatory Commission (NRC) Operations Center by telephone (301–951–0550) no later than the next calendar day after he has determined that a misadministration event has occurred. (In his absence, individual determining a misadministration has occurred will make this notification).

3. The physicist will prepare a written report of the event. The written report will include the prescribing radiation oncologist's name, a brief description of the event, why the event occurred, the effect on the patient, what improvements are needed to prevent a recurrence of a similar event, corrective action taken to prevent such a recurrence, whether the patient or the patient's responsible relative or guardian was notified and if not, why not, as well as the information that was provided to the patient. The report will not include the patient's name or other information that could lead to identification of the patient. A copy of the report will be submitted to the NRC Region III office within 15 days after the physicist determines that a misadministration has occurred. Copies of the report will be given to the physicians. If the physicist is not available, this report will be forwarded to the NRC by him within 15 working days of his return.

4. A radiation oncologist will notify the referring physician within 24 hours after the determination that a misadministration event event has occurred. The patient will also be notified within 24 hours after such a determiniation, unless the referring physician personally notified the radiation oncologist that he (the referring physician) will inform the patient or that, based on his medical judgment, informing the patient would be harmful. The patient will not be notified without first notifying the referring physician. If notification cannot be accomplished within 24 hours, the notification will occur as soon as possible thereafter.

5. In the event the patient was notified of the misadministration of dose, the patient will also be furnished with a written report within 15 days after the physicist determines that a misadministration had occurred. The report will either be the report furnished to the NRC or a separate report. The alternative separate report will include a brief description of the event, a description of the consequence to the patient, and a statement that the report submitted to the NRC is available for review.

6. Following the processing of the required notifications, the teletherapy physicist will prepare a final report of the event. The final report will contain the names of all individuals involved, the patient's name, social security number, unit number, a brief description of the misadministration event and why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and corrective actions taken to prevent such recurrence.

V. REPORTS

All reports prepared in response to either a recordable event or a misadministration event will be maintained in a file for a period of at least five years.

j

THE MT. SINAI MEDICAL CENTER
RADIATION THERAPY SECTION

QUALITY ASSURANCE FORM

DATE OF OCCURRENCE_____

PATIENT NAME_____ UNIT #_____

REFERRING PHYSICIAN_____ TREATING PHYSICIAN_____

TREATING TECHNOLOGIST(S)_____

DETAILED DESCRIPTION OF INCIDENT_____

DEPARTMENT INCIDENT REPORT FILED? ___YES ___NO DATE_____

IMMEDIATE ACTION TAKEN_____

---------- RESPONSE ----------

1. NOTIFICATIONS (NOTE DATE/TIME ON LINE)

	DATE	SIGNATURE	DATE	SIGNATURE
RADIOLOGY ONCOLOGIST			TREATING PHYSICIAN	
PHYSICIST				

2. THERAPY RECORDABLE EVENT OR MISADMINISTRATION PER 10CFR35.2

10CFR35 REGULATIONS APPLY?	___YES	___NO
DID A RECORDABLE EVENT OCCUR?	___YES	___NO
DID MISADMINISTRATION OCCUR?	___YES	___NO

DATE REPORT FILED_____ ___NOT APPLICABLE

EXPLANATION/NOTES_____

3. REPORT REVIEW

Quality Management Plan Modifications/Improvements Following N.R.C. Inspection on April 10-11, 1993.

April 10-11,1993 A routine safety inspection of N.R.C. license # 34-00746-03 was conducted by Wayne Slawinski and Kevin Null on April 10-11, 1993.

June 7-8, 1993 As a followup to the inspection, Mr. Tom Stefanakos, teletherapy physicist and Radiation Safety Officer, revised the operating procedures and duties of the therapists, and provided an oral inservice to the therapists regarding their duties and responsibilities with respect to proper implementation of a written directive. The inservice was provided on June 7, 1993. The technologists initialed the operating procedures document to confirm their attendance at this inservice and their understanding of its content. A copy of this document was forwarded to the N.R.C. on June 8, 1993. It was also placed in the Radiation Therapy Policies and Procedures Manual, which is kept in the Department and is available for staff review at any time. Sub-paragraphs 3a and 3b pertain to quality management aspects of their duties and responsibilities. (The above information was verified by telephone conversation with Mr. Stefanakos on May 12, 1994.)

July 13, 1993 The N.R.C. completes its inspection report for the April 10-11, 1993 inspection and mails it to the Medical Center. It is received at the Medical

Center several days later.

July 19, 1993 On July 19, 1993, Mr. Tom Stefanakos, teletherapy physicist and Radiation Safety Officer, submitted proposed Amendment #11 to our license, removing himself from the license and naming consultants Kunjan Pillai or Edward J. Began as teletherapy physicists. Diagnostic physicist Mark S. Rzeszotarski, a Mt. Sinai employee, was named as the Radiation Safety Officer.

July 20, 1993 The Medical Center's written Reply to the Notice of Violations was dated July 20, 1993. Enclosure 2 of the Reply is a copy of the revised operating procedures as described above. The Reply was prepared by Mr. Tom Stefanakos with the assistance of Mark Rzeszotarski. The Reply was one of Mr. Stefanakos' last functions at the Medical Center. He left the Medical Center to take a new position in the Cleveland area around August 1, 1993.

August 20, 1993 Kunjan Pillai and Edward J. Began, teletherapy physicist consultants, were named on our license on August 20, 1993 (Amendment #11). Mark S. Rzeszotarski was named as the Radiation Safety Officer. The Radiation Safety Officer provided copies of the July 13, 1993 Notice

of Violations and our July 20, 1993 Reply to the teletherapy physicist consultants, the technologists, and to the authorized user and supervised authorized user in late August of 1993.

No indication of problems with our Quality Management Plan were identified by the consultants. The consultants did not identify any recordable events during their term as teletherapy physicists for The Mt. Sinai Medical Center.

January 27, 1994 The annual Quality Management Plan audit was performed by the Radiation Safety Officer on January 27, 1994. Regulatory compliance was satisfactory, and no indication of deficiencies in the Quality Management Plan were identified at that time.

March 1994 In the first few weeks following his joining The Mt. Sinai Medical Center in March of 1994, Mike Rutstein, teletherapy physicist, expressed concern to the Radiation Safety Officer with respect to the methods used in preparing written directives and in documentation practices in general within the Radiation Therapy Department.

Notebooks were obtained in order to create a new charting method similar to one Mike Rutstein was familiar with from another facility. Mike was in the process of reviewing the overall documentation process in the

Department when the misadministration occurred. He had not yet implemented any changes in the Quality Management Plan, since he had not yet been formally named on the license as teletherapy physicist.

March 31, 1994 The Mt. Sinai Medical Center submitted proposed Amendment #12 to our license naming Mt. Sinai employee Mike Rutstein, M.S. as the new teletherapy physicist to replace the teletherapy physicist consultants.

April 19, 1994 The misadministration event occurred on April 19, 1994 while the consultants were still named on the license.

April 19-20, 1994 The Quality Management Plan review during the routine N.R.C. inspection on April 19-20, 1994 was made especially difficult because of the unfamiliarity of the teletherapy physicist and Radiation Safety Officer with past Q.M.P. practices in the Department.

Mark S. Rutstein, PhD 5/25/94

Prepared by Mark S. Rzeszotarski, Ph.D. on May 25, 1994.

June 8, 1993

Mr. Robert G. Gattone, Sr.
Nuclear Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60317

Dear Mr. Gattone:

In response to your letter of June 1, 1993, the following is submitted in the same order as in your correspondence:

1. License Name: As stated in my letter of April 7, 1993, the name of the license is The Mt. Sinai Medical Center.

2. Location of Use: Again, this information is listed in Paragraph D of my letter dated April 7, 1993.

3. Operating Procedures: Attached is the revised operating procedures you requested in sub-paragraphs 3.a.&b.

4. Survey Instrument Calibration: Survey instruments will be calibrated annually and the records of same maintained for three (3) years.

Sincerely yours,

Barbara Hollefreund

Barbara Hollefreund
Senior Vice President, Patient Care

BH/j
Enclosure

THE MT. SINAI MEDICAL CENTER OF CLEVELAND, OHIO
DEPARTMENT OF RADIOLOGY - RADIATION THERAPY DIVISION

RADIATION ONCOLOGY TECHNICIAN

1. Treatment Chart

   a. Prepare local and standard forms.
   b. Maintain patient logs.
   c. Chart folder.
   d. Prepare and maintain proper documents for protocols.

2. Laboratory and Radiologic Requests

   a. Prepare laboratory requests.
   b. Prepare radiologic requests.
   c. Report result to therapist and record in patient's chart.

3. Radiation Treatment

   a. Patient preparation, position patient properly; align treatment area with beam set proper field size + SSD.

   b. Insure physician's prescription and modifications are written on the treatment sheet by the physician, initialed and dated.

   c. Calculate treatment time/monitor units and initial.

   d. Administraion of treatment.

   e. Observe patient through TV monitors, stop treatment if patient moves, recheck patient to insure proper setup and restart.

   f. Record treatment.

   g. Technologist not making original treatment calculations will check calculations, initial and date.

   h. Ask physician to clarify any ambiguities that exist.

   i. Should a patient receive a dose greater than 10% of the prescribed dose, notify the physicist and the physician immediately. The physician will notify the referring physician within 24 hours. The physicians will determine if it is prudent to notify the patient or responsible relative. The physicist will notify the NRC, via phone, and within 15 days in writing with a copy to the referring physician and patient/family if notified previously. If the physicist is not available, the technologist will make the appropriate phone calls and written report. When calling the NRC (1-312-790-5500), state that you are reporting a misadministration and the operator will route you to the proper individual. Give them our license number (34-00746-03) and pertinent information.

4. Miscellaneous

a. Insure treatment rooms are properly stocked and maintained.

b. Report to the therapist any patient complaints or problems.

c. Insure patient car/wheelchair wheels are locked when patient is awaiting transport and when transferring patient from cart to treatment table, and that side rails are up on the cart.

d. Inform patient about activities before they are carried out.

e. Insure that only the patient is in the treatment room when the primary beam is turned on. This is to be accomplished by the technician exiting the treatment room, checking to see no one remains in the room and by viewing the room via the TV monitors.

f. Insure treatment units, rooms and consoles are secured when unattended.

g. Inform physicist of any malfunctions, abnormalities, burned-out lights, etc. Malfunctions or defects of any safety devices will be recorded. The date of the malfunction or defect and the date corrective action was taken will be recorded and kept for three (3) years.

Revised: June 6, 1993

BK 6-7-93
GS 6.7.93
S 6/7/93

Corrective Actions Taken Since April 19-20, 1994

April 20, 1994

A meeting is held with the teletherapy technologists, the teletherapy physicist, the Radiation Safety Officer and the supervised authorized user folllowing the N.R.C. exit interview and subsequent physicist discussion. During the meeting a number of suggestions are made to reduce the likelihood of a repeat of the misadministration event. The suggestions include: 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 institute the pencil in changes plan. Initially, the physicist is performing this task while formal policies and procedures for the teletherapy technologists to do it with cross checking and initialling by a second technologist are prepared.

April 23, 1994

A draft proposal for a new chart recording procedure is 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.

May 13, 1994 An inservice is presented by Mike Rutstein, teletherapy physicist, to the technologists. Their roles and responsibilities as radiation therapists are reviewed. The importance of delivering a planned course of radiation therapy exactly as prescribed by a radiation oncologist is stressed.

A revised version of the new method for chart recording is reviewed with the technologists and is implemented. It provides for additional checks and balances to verify that the written directives are being properly adherred to.

May 16, 1994 A new tracking sheet for recording patient starts and finishes is implemented. The tracking sheet is posted by the console and provides immediate visual verification of compliance with various required checks.

May 25, 1994 A quality assurance committee specific to the Radiation Therapy Department is formed to provide a mechanism for creating policies and procedures and for self-policing of Departmental functions.

May 26, 1994 Preliminary drafts of revised dose prescription, simulation and isodose planning information worksheets are generated. These

will be reviewed/revised by the quality assurance committee prior to implementation.

August 1994 This is the proposed date for completion of implementation of revised corrective measures. Note that formal Quality Management Plan revisions will probably occur last and will be submitted to the N.R.C. after all policies and procedures have been established and properly evaluated.

Quarterly

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. Routine quarterly reviews of incidents, recordable events, misadministration events and annual QMP audits will continue as usual.

Mount Sinai Medical Center
Division of Radiation Therapy

To: Technical Staff (MSMC and IMC)

From: Mike Rutstein, M.S.

Date: 5/13/94

Subject: The role of the radiation therapist as defined by TG-40

The radiation therapist is responsible for accurately delivering a planned course of radiation therapy as prescribed by a radiation oncologist. The radiation therapist is also expected to recognize any change in the patient's condition and determine when a treatment should be with held until a physician is consulted. Additionally, the radiation therapist should be able to detect any equipment deviations or malfunctions, understand safe operating limits of the equipment and should be able to judge when, due to equipment malfunctions and problems, or errors in the proposed treatment, to withhold or terminate treatment until the problem has been resolved. It is recommended that therapists be registered with the ASRT or possess suitable equivalent qualifications.

cc: Dr. R. Goyal
Dr. H. Blair
Dr. M. Rzeszotarski

Mount Sinai Medical Center
Division of Radiation Therapy

To: Mark Rzeszotarski

From: Mike Rutstein, M.S.

Date: 5/13/94

Subject: Inservice of new charting method

In response to our mis-adminstration, I have implemented a new charting procedure that should prevent this type of incident from happening again. A copy is enclosed for your files. I have reviewed it with the therapists, and it will implemented effective immediately.

Mount Sinai Medical Center
Division of Radiation Therapy

BK 5-13-94
13.94 GS
GG 5/13/94

To: Technical Staff (MSMC and IMC)

From: Mike Rutstein, M.S. MR

Date: 5/13/94

Subject: New Method for Chart Recording

In response to the recent mis-administration, I would like to institute the following changes in how we are documenting our charts in an attempt to prevent a situation like this from happening again. The new procedure is very simple. It is as follows:

1. Upon receiving the chart from physics, a therapist will review, initial and date the prescription on the front of the chart (to the right of the prescription) and the treatment summary. After initialing, it shall be assumed that the therapist understands the course of treatment. Under no circumstances is a patient to be treated if there is any confusion about prescription or the patient's course of treatment. **If there is any confusion, need for further clarification or an error detected, the therapist shall immediately consult a member of the physics staff for clarification.**

2. The therapist will then transcribe the treatment summary into the upper left hand corner of the treatment sheet. The therapist will then initial and date the summary on the treatment page.

3. In the left hand margin to the right of the day of the week, the therapist will write a note indicating which field is being treated first.

4. The therapist will then count down the appropriate number of days in the left margin and annotate in pencil any known adjustment that will be made in the patients treatment.

5. The therapist will also pencil across the horizontal treatment line and write the proposed change once again.

6. As per current policy, a second therapist shall check the dose calculation, initial and date the chart within 48 hours (two treatments). This therapist will now also be required to review the prescription, the treatment summary and the treatment chart. The checking therapist, will also initial and date the prescription, the treatment summary and the treatment chart. It will be the responsibility of the recording therapist to initiate the review of the chart by the second therapist. If a second therapist is unavailable, a physicist or physicians' initials may be obtained instead.

7. The physicist will perform an audit of the chart within three days of the first treatment or 10% of the total prescribed dose which is ever less. In the event that this is not performed, the therapist will no longer be authorized to treat the patient and must have the chart reviewed (initialed and dated) by either the physicist, a member of the physics staff or the physician prior to resuming treatment.

8. As treatment advances, the therapist recording change will erase the pencil annotations and write in the margin in pen the change, initial and date it. Subsequently, each therapist must initial and date the change in the treatment on the treatment sheet upon their first administration of the prescribed change.

Enclosed is an example of what has been outlined. If you have any questions, please see me. Thank you for your cooperation.

cc: Dr. R. Goyal
Dr. H. Blair
Dr. M. Rzeszotarski

OLD METHOD

MT. SINAI MEDICAL CENTER
RADIATION THERAPY PRESCRIPTION AND DAILY TREATMENT RECORD

Patient Name: [redacted] Age: [redacted] Sex: [redacted]

Diagnosis: [redacted] Treatment Objective: [redacted]

DATE	SITE	UNIT / ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.
2/22/94	(1) Breast	(6L)	50 Gy	200 cGy	25	5		[redacted]

NOTES: (1) med / lat - tangents
(2) SSD = 80 cm, d = port dim.
(3) ~~A~~ Supine

Tumor 3/2/

DATE	SITE	UNIT / ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.

NOTES:

DATE	SITE	UNIT / ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.

NOTES:

DATE	SITE	UNIT / ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.

NOTES:

Date	Platelets	WBC	HCT	Weight	BP	Temp
3/10/94	264	10.7	37.2	147		
3/25/94				146		

1000 CU
10 OPEN
10 4K WEA
1000 MEV

OLD METHOD

1994

	number	date	elap. days	signed	Rt. MED TANG mu/time	daily depth dose	cumu depth dose	Rt. LAT. TANG mu/time	daily depth dose	cumu depth dose	Lt. MED TANG LAT. TANG total tumor dose	total cumu t.d
MON.												
TUE.	1	3/1	0	BS	1.68	100	100	1.68	100	100	200	200
WED.	2	3/2	1	BS	1.68	100	200	1.68	100	200	200	400
THU.	3	3/3	2	BS	1.68	100	300	1.68	100	300	200	600
FRI.	4	3/4	3	BS	1.68	100	400	1.68	100	400	200	800
MON.	5	3/7	6	BS	1.68	100	500	1.68	100	500	200	1000
TUE. WEIGHT	6	3/8	7	BS	1.68	100	600	1.68	100	600	200	1200
WED.	7	3/9	8	BS	1.68	100	700	1.68	100	700	200	1400
THU.	8	3/10	9	BS	1.68	100	800	1.68	100	800	200	1600
FRI.	9	3/11	10	BS	1.68	100	900	1.68	100	900	200	1800
MON.	10	3/14	13	BS	1.68	100	1000	1.68	100	1000	200	2000
TUE. 45° wedges started	11	3-15	14	BK	2.60	100	1100	2.60	100	1100	200	2200
WED.	12	3-16	15	BK	2.60	100	1200	2.60	100	1200	200	2400
THU	13	3/17	16	BS	2.60	100	1300	2.60	100	1300	200	2600
FRI.	14	3-18	17	BK	2.60	100	1400	2.60	100	1400	200	2800
MON. NC	15	3/21	20	BS	2.60	100	1500	2.60	100	1500	200	3000
TUE.	16	3/22	21	BS	2.60	100	1600	2.60	100	1600	200	3200
WED.	17	3/23	22	BS	2.60	100	1700	2.60	100	1700	200	3400
THU.	18	3-24	23	BK	2.60	100	1800	2.60	100	1800	200	3600
FRI.	19	3/25	24	BS	2.60	100	1900	2.60	100	1900	200	3800
MON.	20	3/28	27	BS	2.60	100	2000	2.60	100	2000	200	4000
TUE.	21	3/29	28	BS	2.60	100	2100	2.60	100	2100	200	4200
WED.	22	3/30	29	BS	2.60	100	2200	2.60	100	2200	200	4400
THU.	23	3/31	30	BS	2.60	100	2300	2.60	100	2300	200	4600
FRI. NSR	24	4/1	31	BS	2.63	100	2400	2.63	100	2400	200	4800
MON.	25	4-4	34	BK	2.63	100	2500	2.63	100	2500	200	5000
TUE.												
WED.												
THU.												
FRI.												
MON.												
TUE.												
WED.												
THU.												
FRI.												
MON.												
TUE.												
WED.												
THU.												
FRI.												

NSR 3/28/94

NSR 3/11/94

NSR 3/22/94

NSR 3/28/94

4/6/94 NSR

NSR 4/12/94

OLD METHOD

49

FIELD SITE RT MED/LAT TANG. BREAST

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING
3.1.94	CO/80	18x9 (12.0)²	92.1	1.011	.988	*	~~1.03[illegible]~~ 102.7 1.037	59.82	100	1.68
WED 3.14.94	CO/80	18x9 (12.0)²	92.1	1.011	.570 .988	*	.711 1.037 ~~1.03[illegible]~~	38.6[illegible]	100	2.60

3/1
3/
3/
3/14/94

NOTES: Y.SP 2.60 x 1.01 = 2.63 4/8/94 * PER COMPUTER

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

OLD Method

MT. SINAI MEDICAL CENTER
RADIOTHERAPY TREATMENT PLAN SUMMARY

PATIENT Jane Doe DIAGNOSIS Breast CA

External Beam Planning by Dosimetrist On ___/___/___

Contour Location Rt Breast

UNIT	FIELD	SIZE	WEDGE	ANGLE	TARGET DOSE (REL. WT).	
T80	MED	17×7	OPEN	~~60~~	500	—
T780	LAT	17×7	OPEN	320	500	—
T780	MED	17×7	45W	60	1500	—
T780	~~MED~~ LAT	17×7	45W	320	1500	—
MEV 77	MED	17×7	45W	60	500	—
MEV 77	LAT	17×7	45W	320	500	—

Target 5000 MAX 5840 MIN _____ AVE _____

Hot Spot _____ Critical Organs: _____

Calculations: _____

NOTES: Treat ~~5~~000 cGy. 4000 using Co^{60}.
Treat 5 fx open and 15 fx with 45 W
Treat 1000 on Mev 77 10 fx with 45W
Co^{60} OPEN %DD = 70.2 BSF = 1.03 45W %DD = 84.0 BSF = 1.03 Mev 77 %DD = 98 BSF = 1

M.D. Review: _____

MT. SINAI MEDICAL CENTER
RADIATION THERAPY PRESCRIPTION AND DAILY TREATMENT RECORD

Patient Name: Jane Doe Age: 60 Sex: F

Diagnosis: Breast CA Stage II Treatment Objective: Avoid recurrance

DATE	SITE	UNIT/ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.
1/25/94	Rt Breast	T780/Co^{60}	4000	200	20	5		
NOTES: Technique - Tangential 100 SSD or ISO Calculation depth								

R.T.T. I Date
R.T.T. II Date
Physics

DATE	SITE	UNIT/ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.
4/25/94	Rt Breast	1MEV/10MV	1000	200	5	5		
NOTES: Finish per Treatment Summary								

RTT 1 Date
RTT 2 Date
Physic

DATE	SITE	UNIT/ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.
NOTES:								

DATE	SITE	UNIT/ENERGY	TOTAL DOSE	DAILY DOSE	# FRACTIONS	#/WK	REST	M.D.
NOTES:								

Date	Platelets	WBC	HCT	Weight	BP	Temp

T780 OPEN
X T780. W/45°W
X MEV 7 W/45°W

RTT 1 Date
RTT 2 Date

	number	date	elap. days	signed	m u / time	daily depth dose	cumu depth dose	m u / time	daily depth dose	cumu depth dose	total tumor dose	total cumu t d
MON. Open												
TUE.												
WED.												
THU.												
FRI.												
RTT 1 Date MON. Add 45°W		5/2	—	—	45 Wedge			—	—	—	—	—
TUE.												
WED.												
THU.												
FRI.												
RTT 2 Date MON.												
TUE.												
WED.												
THU.												
FRI.												
MON.												
TUE.												
WED.												
THU.												
FRI.												
MON. Linac W/45		5/12	—	—	Linac		15 V	—	—	—	—	—
TUE.												
WED.												
THU.												
FRI.												
MON.		—	—	—	STOP	—	—	—	—	—		
TUE.												
WED.												
THU.												
FRI.												
MON.												
TUE.												
WED.												
THU.												
FRI.												
MON.												
TUE.												
WED.												
THU.												
FRI.												

RT Breast

example √With Blocks Bionix tray

FIELD SITE MED/LAT TANGENTS OPEN [Room describe any Correction Factor:]

	DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING
MED	4/25/94	Co^{60}/80	17×7 ( )	95.0		.967 .986	☆				
LAT	4/25/94										

NOTES:

FIELD SITE MED/LAT TANGENTS W/45 [Room to describe any correction Factors]

	DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING
MED/LAT	5/2/94	Co^{60}/80	17×7 ( )	95.0		.986	☆				

NOTES:

example .957 - blocking t.

FIELD SITE MED/LAT TANGENTS W/45 [Room to describe any correction factors]

	DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING
MED/LAT	5/23	18MV/100	17×7	1		.986 .957	☆				

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

FIELD SITE

DATE	UNIT/SSD	FIELD SIZE/ EQUIV. SQU.	STANDARD OUTPUT	F.S.F.	C.F.	d	TAR, TMR BSFxPDD	RADS/MIN RADS/MU	DAILY DOSE	SETTING

NOTES:

New Method

MT. SINAI MEDICAL CENTER
RADIOTHERAPY TREATMENT PLAN SUMMARY

PATIENT Jane Doe DIAGNOSIS Breast CA

External Beam Planning by Dosimetrist On __/__/__

Contour Location Rt Breast

UNIT	FIELD	SIZE	WEDGE	ANGLE	TARGET DOSE (REL. WT).
T780	MED	17x7	—	60	500
T780	LAT	17x7	—	320	500
T780	MED	17x7	45W	60	1500
T780	LAT	17x7	45W	320	1500
MEV77	MED	17x7	45W	60	500
MEV77	LAT	17x7	45W	320	500

Target 5000 MAX 5840 MIN ____ AVE ____

Hot Spot ____ Critical Organs: ____

Calculations: ____

NOTES: Treat 4000 cGy using Co^{60}, 1000 cGy using 18 MV

Unit	T780	T780	T780	T780	MeV77	MeV77
Field	MED OPEN	LAT OPEN	MED 45W	LAT 45W	MED 45W	LAT 45W
# of Treat	5	5	15	15	5	5
Dose/Treat	100	100	100	100	100	100
%DD	70.2	70.2	84.0	84.0	98	98
TSF	1.03	1.03	1.03	1.03	1.0	1.0
Wedge factor	—	—	.64	.64	.73	.73

Dose to be delivered 5 fractions/week in 5 weeks

M.D. review ____ Physics review ____ Therapist Review

Department of Radiation Therapy
Mount Sinai Medical Center

Date: 5/16/94

To: Technical Staff

From: Mike Rutstein MR

Subject: New Sheet for recording new patient starts and old patient finishes.

In an attempt to help track the initial checking of treatement charts, I have created a patient log to be kept on each machine. The purpose of this chart is to document new patient starts, old patient finishes and remind us to perform our checks and double checks. Using this log is simple:

For all new patient starts:

1. Record the patient's name and date in the appropriate column.
2. If you are the first reviewer, please initial and date in the Therapist Review column.
3. Please ask someone else to review the chart as soon as possible.
4. Therapists must have a second check of the chart within 48 hours (before the third treatment).
5. The therapist that performs the double check should initial and date in the Double Check column.
6. The physics check shall be performed within 72 hours (before the fourth treatment) and checked off in the Physics Review Column.

If short staffed, the therapist double check may be performed by either a member of the physics staff (Mike Rutstein or Mark Rzesotarski) or a physician. Remeber: You are not authorized to treat patients, if a second check has not been performed before the third treatment or a physics review has not been performed prior to the fourth treatment.

For old patient finishes:

1. Record the name and date of the finishing patient in the right hand columns of the chart.

Thank you for your cooperation.

cc: Dr. R. Goyal
Dr. H. Blair
Dr. M. Rzesotarski

BK 5-16-94
MS 5/16/94
BS 5.26.94

Patient Treatment Log
Radiation Therapy
Mt. Sinai Medical Center

Mevatron 77

Patient Starts

Patient Name	Date	Therapist Review (initials\date)	Double Check (initials\date)	Physics Review (initials\date)
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\
		\	\	\

Patient Finishes

Patient Name	Date

Mount Sinai Medical Center
Division of Radiation Therapy

To: Radiation Therapy Division Staff

From: Mike Rutstein, M.S.

Date: 5/25/94

Subject: Formation of a Quality Assurance Committee (QAC) for our division

In accordance with the recommendations outlined in the AAPM's Task Group (TG) 40 report entitled "Comprehensive QA for Radiation Oncology", the Division of Radiation Therapy is forming a Departmental Quality Assurance Committee (QAC). The primary function of this committee will be to establish quality assurance and administrative policies and procedures for the Radiation Therapy Division within the Radiology Department. In addition, the Committee will evaluate the effectiveness of these policies and procedures, define appropriate corrective measures when necessary, and review the effectiveness of the corrective measures.

The committee shall consist of: a hospital administrator, the Radiation Safety Officer, the teletherapy physicist, an authorized user and a teletherapy therapist. Other Radiation Therapy staff are also encouraged to attend. This committee will be directly reporting to the Medical Director of Radiology and will provide minutes of their meetings to the Radiology Department Quality Assurance Committee, the Senior Vice President of Patient Care and the Radiation Safety Committee. It has been decided that the Radiation Safety Officer will initially be the chairperson of the committee. The committee will meet approximately monthly, or as appropriate.

I would like to extend an open invitation to anyone in the Radiation Therapy Division interested in becoming a member of the Committee. If you are interested in becoming a member, please let me know by Friday June 3,1994.

cc: Avram Pearlstein, M.D.
Barbara Holliefreund
Sigfried Ditzig
Mark S. Rzeszotarski, Ph.D.

Division of Radiation Therapy
Mount Sinai Medical Center

Simulation Orders

Patient Name: _____ Date: _____

Pre-Simulation Work-up:

[ ] Consult with Dr. _____ of _____.
[ ] Pre-Radiation Dental Evaluation

[ ] Obtain _____

from Name: _____ For: _____
Address: _____ _____
_____ _____
_____
Tel #: _(___)_____
Fax #: _(___)_____

[ ] X-ray of _____
[ ] CT scan of _____
[ ] MRI of _____
[ ] Other radiographic exam _____

[ ] Bone Scan
[ ] Renal Scan
[ ] Other Nuclear Medicine exam _____

[ ] CBC
[ ] SMAC
[ ] PSA
[ ] Thyroid Profile
[ ] Chem-7
[ ] Acid phosphatase
[ ] CEA
[ ] Urine analysis
[ ] Other laboratory work _____

Simulation:

[ ] Schedule simulation of _____ (site).
[ ] Utilize _____ (fields).
[ ] Contour
[ ] Obtain CT scan for treatment planning of _____ (site).
[ ] Schedule simulation on treatment unit _____ for _____ (site).
[ ] Special Physics Consultation
[ ] Other _____

Reviewed by:
M.D. _____ Physics _____ Treatment Staff: _____
_____
_____

Division of Radiation Therapy
Mount Sinai Medical Center
Treatment Plan

Patient Name: _____ Date: _____
Diagnosis: _____ Treatment Objective: _____
Staging: _____

Protocol Information:
Is this a protocol patient? _____
Protocol Name/Number? _____ Tel. # _(___)_____
Protocol Contact Person? _____ Fax # _(___)_____

External Beam:
Prescription:
Treat _____ (site) utilizing _____ fields.

Deliver [ ] 180 cGy ( ) QD
[ ] 200 cGy ( ) BID
[ ] ___ cGy (other) ( ) _____ (other),

to a **depth** of _____ or the _____ **% line** times _____ **fractions**

for a **dose** of _____ cGy, and a **total dose** of _____ cGy, using,

Patient to be treated _____ **days/week** for _____ **weeks**.

_____ Cobalt-60 _____ MV photons (Linac) _____ MeV electrons

( ) Comment _____
and then:
( ) STOP ( ) Re-evaluate for further treatment.
( ) Simulate for reduced field size.
( ) Reduce field size on treatment machine.
( ) Other _____.

( ) Special Treatment Procedure _____
_____

Treatment Aides:
[ ] Cerrobend Blocks [ ] Bolus [ ] Tissue Compensator
[ ] Hand Blocks [ ] Wedges

Continuing Medical Physics Support:
[ ] Initial Dosimetry Check [ ] Cerrobend Block Calibration
[ ] Weekly Chart Check/QA [ ] Other _____

Concurrent Studies (weekly unless otherwise stated):
[ ] Weight _____ [ ] Separation _____ [ ] CBC _____ [ ] Films _____

M.D. _____ Physics _____ Treatment Staff: _____
_____
_____

Division of Radiation Therapy
Mount Sinai Medical Center
Isodose Planning Information

Patient Name: _____ MR: _____

Date: _____ Treatment Start Date: _____

Planning to be done from:

[ ] Contour [ ] CT Scan

Site: _____ CT Date: _____ Tape # : _____

Site: _____

CAX slice: _____ Offset slices: _____

Type of Planning requested:

[ ] Isodose Plan [ ] Irregular Field [ ] Hand Calculation

Proposed Total Dose and Plan: _____

_____

_____

_____

_____

_____

Outline Structures:

[ ] Spinal Cord
[ ] Lung
[ ] Kidney (RT / LT)
[ ] Liver
[ ] _____
[ ] _____
[ ] _____

Calculate Point Doses:

[ ] Spinal Cord
[ ] Lung
[ ] Kidney (RT / LT)
[ ] Liver
[ ] _____
[ ] _____
[ ] _____

Special Instructions or Comments: _____

_____

_____

_____

_____

M.D. _____

Mark Stephen Rzeszotarski, Ph.D.

Senior Physicist
Radiation Safety Officer

American Board of Radiology
Certified Diagnostic and Medical Nuclear Physicist

Adjunct Assistant Professor
Department of Biomedical Engineering
Case Western Reserve University
Cleveland, Ohio
44106

Mail Address:
Mt. Sinai Medical Center
Department of Radiology
One Mt. Sinai Drive
Cleveland, Ohio, 44106

Voice: 216-421-4689
Beeper # 2244

E-mail (INTERNET):
msr7@po.cwru.edu

FAX: 216-421-5343

May 26, 1994

Mike Rutstein, M.S.
Radiation Therapy Department
The Mt. Sinai Medical Center
One Mt. Sinai Drive
Cleveland, OH 44106

Dear Mike,

I have been performing periodic independent audits of the patient charts in your area since the N.R.C. inspection on April 19-20, 1994. So far, I have reviewed 45 patient charts over the past five weeks.

Yesterday, on May 25, 1994, I reviewed eleven charts (all current cobalt-60 patients undergoing treatment). This was my first inspection of the charts since you instituted your new method of chart recording on May 13, 1994. All of the charts were properly recorded with appropriate initialing and dating as per the new methodology. There were no deviations from the new requirements, and regulatory compliance was satisfactory.

I will be reporting my findings to the Radiation Safety Committee at their next meeting. In the meantime, I plan to continue spot checking the charts on an unscheduled basis to gather further supporting information for the Committee.

I have placed my original chart audit sheets in your charts check notebook for your future reference.

Sincerely,

Mark S. Rzeszotarski, Ph.D.

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

Mt. Sinai
Excellence. It's our heritage.

May 26, 1994

U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Sirs,

The Mt. Sinai Medical Center is committed to providing the highest possible quality of care. We recognize that there were significant, serious deficiencies in our Quality Management Plan implementation in the Radiation Therapy Department. The root causes of these deficiencies include inattention to detail on the part of the technologists, and inconsistent dose prescription and treatment planning documentation. In addition, mitigating circumstances relating to the change of teletherapy physicists contributed substantially to insufficient followup and evaluation of corrective measures to our Quality Management Plan.

The Mt. Sinai Medical Center is committed to correcting these deficiencies in an expedient manner consistent with high quality medical care and appropriate regulatory compliance.

The Medical Center voluntarily identified the misadministration event to the N.R.C. and has promptly provided all requested documentation in cooperative manner. The Medical Center immediately took corrective action following the misadministration event, and is continuing to evaluate and implement additional corrective measures. In addition, we have instituted audits to evaluate the effectiveness of the corrective measures, and have organized a quality assurance committee specifically to provide ongoing long-term audits and improvements of our Quality Management Plan.

We respectfully request that the N.R.C. exercise discretion in their enforcement of the violations identified in their Inspection Report No. 030-15270/94001 on the basis of the above information and related supporting documentation provided for this inspection and Enforcement Conference.

Sincerely Yours,

Barbara Hollefreund
Barbara Hollefreund
Senior Vice President, Patient Care

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

Michael R. Rutstein
Michael R. Rutstein, M.S.
Teletherapy Physicist