ENCLOSURE 2

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-31840
License No.:	35-27041-01
Report No.:	030-31840/98-01
Licensee:	Memorial Medical Center & Cancer Institute, Inc.
Facility:	Memorial Medical Center & Cancer Institute, Inc.
Location:	Tulsa, Oklahoma
Dates:	January 15, 1998 through May 5, 1998
Inspector:	Jeffrey Cruz Radiation Specialist
Accompanied By:	D. Blair Spitzberg, Ph.D., Chief Nuclear Materials Safety Branch 2
	Danny L. Rice Radiation Specialist
Approved By:	D. Blair Spitzberg, Ph.D., Chief Nuclear Materials Safety Branch 2
Attachment:	Supplemental Inspection Information Medical Consultants Report

EXECUTIVE SUMMARY

Memorial Medical Center
& Cancer Institute, Inc.
NRC Inspection Report 030-31840/98-01

This routine, unannounced inspection was an examination of activities authorized by Byproduct Material License 35-27041-01. The scope of this inspection was limited to the licensed activities involving the use of a high-dose rate (HDR) afterloading brachytherapy unit. The inspection included a review of administrative aspects of the licensee's radiation safety program, selective examinations of procedures and representative records, independent radiation measurements, and interviews of licensee personnel.

Quality Management Program

- The NRC determined that an event which occurred on May 12, 1997, involving a HDR afterloading brachytherapy procedure should have been classified as a misadministration. The licensee's internal review of the event, conducted in May 1997, had incorrectly determined that the event did not meet the definition of a misadministration as defined in 10 CFR 35.2 (Section 2).

- A violation of 10 CFR 35.32(a) was identified involving the failure to adequately check the data entered into the HDR treatment planning software that controlled source position during treatment. The Memorial Medical Center & Cancer Institute, Inc. quality management program required that input data be checked to ensure that brachytherapy treatments were administered as directed by the authorized user. The data entry error resulted in a medical misadministration since the actual treatment site differed by 30 millimeters from that intended by the authorized user. Additionally, the calculated administered dose for a portion of the intended treatment site differed from the prescribed dose by more than 20 percent of the prescribed dose (Section 2).

Report Details

1 Organization and Scope of the Licensee Program (87100)

Memorial Medical Center & Cancer Institute, Inc. (MMC) is authorized by Byproduct Material License 35-27041-01 to utilize iridium-192 within a Nucletron Corporation Model MicroSelectron-HDR remote afterloading brachytherapy unit for the treatment of humans. The licensee was authorized to possess 20 curies of iridium-192 but individual sources were not to exceed 10 curies each. At the time of the inspection, the MMC HDR staff consisted of two authorized users, a medical physicist, a dosimetrist and three radiation therapy technologists. The licensee had conducted approximately ten HDR procedures per week during 1997 and 1998. All HDR procedures had been conducted in a dedicated treatment room which had been equipped with a radiation detection system and both continuous viewing and intercom systems. Additionally, an interlock system had been installed on the only door to the treatment room. Should the door be opened during the course of an HDR procedure, the iridium-192 source would automatically be returned to its fully shielded position within the HDR unit. On the day of the inspection, the inspector was able to observe three HDR procedures.

2 Quality Management Program (87100 and 83822)

2.1 Inspection Scope

This portion of the inspection included interviews with licensee personnel, independent radiation measurements and a review of licensee records.

2.2 Observations and Findings

During a review of MMC's radiation safety committee meeting minutes, the inspector identified documentation which described an error in entering a catheter length during an HDR brachytherapy treatment. On May 12, 1997, while entering the catheter length into the HDR treatment planning software, a radiation therapy technologist input an incorrect data point. The catheter length, which was used to determine the start point (first dwell position) for the treatment site, was entered as 954 millimeters as opposed to the prescribed length of 984 millimeters. The licensee's written quality management program dated January 27, 1992 (Revised 8/93), Part A, Item 9, requires, in part, that dose calculations be checked by a qualified oncologist, physicist, or dosimetrist before the total treatment has been completed. The check should be for appropriate input data and the appropriate use of input data. However, on this occasion, the authorized user who checked the data failed to recognize the error.

The event concerned a patient who was being treated for metastatic lung cancer. The intended full therapy included four separate HDR treatments with a dose of 500 rads to a specified volume of tissue during each procedure. Each of the four treatments was prescribed in a separate written directive. Additionally, the authorized user planned to

deliver 5040 rads using fractionated external beam irradiation to a larger area which enclosed the intended HDR treatment site. The data entry error occurred during the first HDR procedure and resulted in the treatment zone being shifted proximally by 30 millimeters. Both the intended and actual treatment sites were within the planned external beam treatment area.

Approximately 30 minutes after completing the first HDR treatment, the radiation therapy technologist, who had both entered the data and treated the patient, realized that the first dwell position did not appear correct. Upon further research, the technologist realized that the catheter length was incorrectly entered, and she immediately notified the physician authorized user and medical physicist. The physician and physicist reviewed the intended treatment and determined that the error was not clinically significant. In fact, based on the evidence of a subsequent bronchoscopic exam which identified the risk of microscopic disease, the 30 millimeters of tissue incorrectly treated during the first HDR procedure were added to the treatment site for the following three HDR procedures. It was also determined that the distal 30 millimeters that were not treated as prescribed would receive sufficient dose from the upcoming HDR and external beam therapies. After reviewing the incident and determining the medical implications, the MMC radiation safety officer (RSO) and radiation safety committee determined that the event did not constitute a medical misadministration.

The RSO and radiation safety committee determined that the root cause of the event was human error. To attempt to prevent recurrence of the error, the licensee modified its HDR quality management program checklist to include an area in which the programmed catheter length must be checked and documented prior to the administration of treatment. Prior to this modification, the data entry verification was not documented for HDR procedures.

10 CFR 35.2 defines, in part, a brachytherapy related misadministration as the administration of a brachytherapy radiation dose involving: (1) the wrong individual, wrong radioisotope, or wrong treatment site, or (2) when the calculated administered dose differs from the prescribed dose by more that 20 percent of the prescribed dose. MMC had determined that the dose administered during first treatment should be compared to the total dose intended from the four planned HDR treatments plus the external beam treatments. MMC determined that the administered dose differed from the prescribed dose by approximately seven percent when calculated in this manner.

Upon return to the NRC Region IV office, the inspector provided the details of the event to the Office of Nuclear Material Safety and Safeguards (NMSS) for determination if the licensee had incorrectly classified the event as not being a misadministration. After completing a review of the event circumstances, NMSS informed Region IV that the event did meet the definition of a misadministration. The proximal 30 millimeters incorrectly treated during the first HDR procedure met the requirements of a wrong treatment site. Additionally, the most distal point of the 30 millimeters (which were not

treated as prescribed during the first HDR treatment) was calculated by the licensee to have received a dose of approximately 140 rads during the first HDR treatment. Since the written directive for the first treatment prescribed 500 rads to the specified tissue volume, this was a difference of greater than 20 percent. On January 23, 1998, the NRC informed MMC that the event should be classified as a misadministration and that MMC was required to comply with the notification, reporting and record keeping requirements specified in 10 CFR 35.33. On the same date, the MMC RSO notified the NRC Operations Center of the misadministration, and the physician authorized user notified the referring physician of the event. The referring physician, based on medical judgement, elected not to inform the patient/family. The NRC Region IV office received a written report regarding the misadministration on February 6, 1998.

On January 27, 1998, the NRC requested that an NRC contracted medical consultant review the event. In a report dated March 28, 1998, the medical consultant provided the NRC her findings. The consultant determined that MMC's written report adequately addressed the cause of the event and the effect on the patient. Additionally, the consultant determined that the promptness and effectiveness of the licensee's immediate actions in response to the incident and the corrective actions implemented were also acceptable.

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The MMC quality management program required that input data be checked to ensure that HDR brachytherapy treatments were administered as directed by the authorized user. However, a check of input data for a treatment performed on May 12, 1997, failed to recognize an error. A data entry error resulted in a medical misadministration since the actual treatment site differed by 30 millimeters from that intended by the authorized user. Additionally, the calculated administered dose for a portion of the intended treatment site differed from the prescribed dose by more than 20 percent of the prescribed dose. The failure to adequately check the input data was identified as a violation of 10 CFR 35.32(a) (030-31840/9801-01).

2.3 Conclusions

The inspector identified a misadministration involving a HDR afterloading brachytherapy procedure. The licensee's internal review of the event had incorrectly determined that the event did not meet the definition of a misadministration as defined in 10 CFR 35.2.

The inspector also identified a violation of 10 CFR 35.32(a) involving a failure to adequately check the data entered into the HDR treatment planning software as required by the MMC quality management program.

3 Exit Meeting Summary

Region IV staff presented the inspection results to licensee management via telephone on May 5, 1998. Licensee representatives acknowledged the inspector's findings and confirmed that no proprietary information was reviewed during the inspection.

ATTACHMENT 1

SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee
Patty Brown, Director of Clinical Services
Art Kerr, Director of Radiology
Carolyn Robinson, Interim Director of Radiology
Patrick Lester, M.D., RSO
Thomas Padikal, Ph.D. Medical Physicist
Douglas Kelly, M.D.
James Flynn, M.D.
Beth Stearns, Chief Radiation Therapist
Chuck Pearce, Dosimetrist

INSPECTION PROCEDURES USED

87100	Licensed Materials Programs
83822	Radiation Protection

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-31840/9801-01	VIO	The failure to adequately check the data entered into the HDR treatment planning software as required by the MMC quality management program was identified as a violation of 10 CFR 35.32(a).

Closed
None

Discussed
None

LIST OF ACRONYMS USED

HDR	High-dose Rate
MMC	Memorial Medical Center & Cancer Institute, Inc.
NMSS	Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
VIO	Violation

ATTACHMENT 2

Medical Consultant Form

Medical Consultant: Judith Anne Stitt, M.D.
Date: March 28, 1998

Signature: _____

Licensee Name:
Mary Brown Stephenson Radiation Oncology Center
Tulsa, Oklahoma

Incident Date: April - May 1997

Patient's Physician Name:
Dan Nader, D.O.
James P Flynn, M.D.

Individuals Contacted During Investigation:
James P Flynn, M.D.

Records Reviewed:
NRC documents
Mary Brown Stephenson Radiation Oncology Center patient records

Description of Incident:

The patient was a 68 year-old man with locally advanced adenocarcinoma of the left lower lobe, left hilum and mediastinum. He had an extensive lesion of the LLL bronchus on bronchoscopy. He underwent combination external beam irradiation therapy and endobronchial irradiation with a planned dose of 5,040 cGy external beam to the primary and nodal volume, 1,000 cGy boost to the primary and four fractions of HDR endobronchial therapy to approximately 2,000 cGy.

During the first HDR an error in entering the catheter length was made resulting in the total treatment length being shifted proximally by 3 cm. The subsequent 3 fractions included this 3 cm area in the treatment volume as well as the distal 3 cm that were not included in the first fraction. It should be noted that all the bronchial anatomy included in the HDR treatment fractions was part of the external beam therapy target volume.

Medical Consequence of Exposure: None. The brachytherapy was a small component of the total dose to the lung primary and lymph node treatment region. All the dose from brachytherapy treatments 1-4 were included in the high dose regions treated with external beam therapy.

Was individual or individual's physician informed of DOE Long-Term Medical Study Program? No

Would individual like to be included? Deceased

Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC (10 CFR 35.33) in the following areas:

a. Why the event occurred Yes

b. Effect on patient Yes

c. Licensee's immediate actions upon discovery

The Licensee viewed the first fraction dose as a part of the total treatment plan and did not report it as a misadministration. I agree with their perspective.

c. Improvements needed to prevent recurrence Yes

e. Licensee's plan for follow up of patient Deceased

f. Report submitted to patient or guardian Deceased

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with medical ethics?

The Licensee viewed the first fraction dose as a part of the total treatment plan and did not report it as a misadministration. They altered their target brachytherapy volume for subsequent treatments. All brachytherapy fractions were given to anatomic regions that were receiving high total doses from the combined external beam therapy.

Briefly describe the medical condition of the exposed individual and the cause of the short-term medical care being provided to the individual.

The patient developed widespread visceral disease and died of metastatic disease. He did not manifest local evidence of tumor progression or adverse sequelae of irradiation.