U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-17335/94002(DRSS)

Docket No. 030-17335

EA No. 94-217

License No. 13-18881-01 Category G Priority III

Licensee: Memorial Hospital
615 North Michigan Street
South Bend, IN 46601

Inspection Conducted: October 6 and 7, 1994 - onsite
through October 12, 1994 - in-office review

Inspectors: _____ 10/26/94
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Approved By: _____ 10/26/94
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Nuclear Materials Safety Branch

Inspection Summary

Inspection on October 6 and 7, 1994 with NRC in-office review through October 12, 1994 (Report No. 030-17335/94002(DRSS))
Areas Inspected: This was a special, announced safety inspection conducted to review: (1) the licensee's September 23, 1994 notification of a brachytherapy misadministration; (2) the licensee's notification of a brachytherapy event that occurred on September 13, 1994; and (3) the effectiveness of the licensee's quality management program (QMP). This report summarizes the NRC's review and findings in the areas of: organization and management controls; scope of program; misadministration review; notifications and reports; and the licensee's implementation of the Quality Management Program (QMP) requirements contained in 10 CFR 35.32. Other program areas that were reviewed include the iridium-192 event and certain aspects of the licensee's teletherapy program.

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Results: Three apparent violations were identified and consist of failure to: (1) establish and maintain QMP procedures to meet the objective that final plans of treatment and related calculations for brachytherapy are in accordance with the respective written directives (Section 6); (2) adequately instruct supervised individuals regarding the written QMP (Section 4); and (3) adequately investigate the misadministration and implement appropriate corrective action as necessary (repeat) (Section 4). The inspection also identified programmatic weaknesses regarding: (1) a lack of effective management oversight of the licensee's radiation safety program during a staff transition period; and (2) the licensee's inability to be self critical regarding incident investigation (Section 4). In addition, the inspection identified a concern regarding the licensee's failure to adequately train a dosimetrist in the use of its treatment planning system (Section 4).

DETAILS

1. Persons Contacted

Memorial Hospital

*George E. Soper, Senior Vice President
*Marti Verfurth, Cancer Center Director
*Becky Starzynski, Director, Risk Management
*Billie Shook, Manager, Radiation Oncology Department
+David A. Hornback, M.D., Radiation Safety Officer
*Russ Johnson, M.D., Authorized User
oKarl Wei-Han King, M.D., Authorized User
*Alessandro Ricci, Ph.D., Medical Physicist
*Richard E. Haas, Radiation Physicist
Norberto Joyas, Dosimetrist
Marge Johnson, Dosimetrist
Bob Lou, Junior Physicist
Chris Lutz, Chief Teletherapy Therapist

*Denotes those individuals present during the exit summary conducted on October 7, 1994
+Denotes the individual present during a pre-exit meeting conducted on October 7, 1994
oDenotes the individual contacted during a telephone conversation on October 12, 1994

2. Program Summary and Inspection History

Memorial Hospital (licensee or hospital) is authorized to possess and use byproduct material for medical use as described in 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400 and 10 CFR 35.500. Additionally, the licensee is authorized to use iridium-192 as sealed sources in a Nucletron Corporation MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy.

The NRC last inspected the licensee on May 4 and 5, 1994. Three violations were identified and consisted of failure to: (1) adequately investigate a misadministration and implement appropriate corrective action as necessary; (2) provide a written report to the patient following the discovery of a misadministration and verbal notification of the patient; and (3) measure the contamination levels prior to offering packages containing radioactive material for shipment. This inspection identified an apparent repeat violation regarding the licensee's investigation of misadministrations and determined that the licensee corrected violation 2. The scope of this inspection did not include followup of corrective actions taken regarding violation 3.

3. Organization and Management Controls

The responsibility for overall licensee operations rests with the hospital's president. The licensee has established a radiation safety committee to oversee the use of byproduct material under the license. Since approximately June 1994, the licensee changed its radiation safety officer (RSO), hired a temporary physicist, hired a new chief medical physicist, and hired a new dosimetrist. After the former RSO, also the former chief medical physicist, left the licensee's employ, the licensee named an authorized user physician to that position. To assist with the technical duties previously performed by the former chief medical physicist, the licensee hired a temporary physicist. Both the RSO and temporary physicist were appointed to their respective positions until a permanent RSO could be hired. Subsequently, a new chief medical physicist was hired and, as of the date of the inspection, the licensee was preparing him to be the future RSO. During this period of personnel change, licensee management did not provide adequate oversight of the radiation safety program resulting in failures to self-identify programmatic weaknesses and deficiencies in its radiation safety program.

No apparent violations of NRC regulatory requirements were identified; however, management oversight problems were identified in the licensee's radiation safety program. These are fully described in Sections 4 and 6 of this report.

4. Misadministration Review

The inspection included a review of the events and causal factors related to the brachytherapy misadministration that occurred on September 15, 1994. The licensee identified the misadministration on September 22, 1994, and reported it to NRC on September 23, 1994. Below is a description of the inspectors' findings.

Background

A physician authorized user prepared a written directive for the administration of 6500 rads (65 Gy) to a point on the patient's vaginal mucosa using two cesium-137 brachytherapy sources in an ovoid applicator over a 56 hour period.

A treatment simulation was performed after insertion of the ovoid applicator. The simulation included anterior-posterior (AP) and lateral radiographs of the patient's abdomen. The images on the radiographs included crosshairs to define spacial coordinates for both views. A six millimeter shift of the z-axis (i.e., the superior/inferior axis) occurred between the AP and lateral views resulting in a mismatch of the point of origin on each film. The shift occurred as a result of either table motion or patient motion.

After source implant on September 13, 1994, but prior to treatment completion, a dosimetrist developed a treatment plan using a Theratron

Theraplan V05 treatment planning system. To input data defining source positions relative to the target, the dosimetrist used a light pen and the simulation films. The dosimetrist identified the spacial origins (mismatched), source positions and target points for both the AP and lateral views. Although the dosimetrist recognized that the axis shifted between the AP and lateral views, it appears that the shift was not accounted for during the planning process, and the dosimetrist entered incorrect data into the computer. The incorrect data indicated that the sources were closer to the target. Therefore, the plan indicated a dose rate to the target that was erroneously high, and a total treatment time that was less than required to achieve the prescribed total dose.

The licensee's QMP requires that brachytherapy dose calculations be checked prior to the completion of treatment. The dose calculations were not checked prior to completion of treatment. Furthermore, the licensee's procedure was inadequate in that it did not include verification of proper data entry into the computer planning system. The check was limited to multiplication of the computer generated target dose rate and the estimated treatment time, and a check of proper source position.

Prior to the completion of the treatment, and based on personal practice, the physician authorized user attempted to check the dose to the target through review of isodose curves superimposed on the simulation films. The authorized user determined the isodose curves were generated on a plane that did not traverse a source and the target point. The authorized user requested the dosimetrist to generate new isodose curves so that the dose could be properly checked. The dosimetrist then indicated that he did not know how to generate the isodose curves requested by the authorized user. Individuals capable of generating the requested isodose curves were not available until the sources had been explanted. The treatment continued because the authorized user had no indication of any treatment plan error.

The treatment was conducted in accordance with the incorrect treatment plan, and the sources were explanted on September 15, 1994.

After source explantation, the temporary physicist generated the isodose curves through the plane requested by the authorized user. Upon further review, the authorized user determined that the target point received 4165 rads (42 Gy), a 36 percent underdose. The licensee compensated for the underdose by modifying accordingly the radiation dose delivered by external beam treatment.

Initial Licensee Investigation

The licensee determined the misadministration was caused by the dosimetrist's failure to: (1) properly enter source position data in the treatment planning system; and (2) have the dose calculations checked prior to completion of treatment.

Licensee Corrective Actions

The licensee developed the following measures to be adopted and enforced before the next brachytherapy treatment:

A. Pairs of simulation films will be monitored by the dosimetrist so that no patient shift is measurable between two films.

B. A physicist will verify the simulation films to determine adequacy (e.g., absence of patient shifts).

C. Whenever feasible, a physicist will verify the accuracy of the dose to the prescription point with an independent calculation without consideration of scatter and attenuation, and require an agreement of 10% or better.

D. Whenever possible, the location of the prescription point in the treatment plan will be simplified by approximate rotation(s) and translation(s) of the calculation plan.

E. The physicist check of the treatment plan and of its implementation of the physician's prescription, will be done either before treatment or before 25% of the dose is delivered, and shall be done before 50% of the prescribed dose is delivered.

The licensee's proposed corrective actions do not appear to adequately address the root cause and contributing factors of the misadministration identified by the NRC. The results of the NRC's analysis is described in the next subsection.

NRC Identified Root Cause and Contributing Factors

Based on the results of interviews with the licensee's staff and the review of licensee procedures, the inspectors identified the root cause of the misadministration to be the shift in the patient's position during treatment simulation and the licensee's failure to adequately compensate for the shift. The following are contributing factors to the occurrence of the misadministration:

A. The dosimetrist involved with the misadministration did not receive adequate training regarding the use of the treatment planning computer and the licensee's QMP. Prior to the misadministration, the dosimetrist observed approximately three brachytherapy treatment plans generated by other medical physics staff on the computer. The misadministration case was the first time the dosimetrist performed a treatment plan on the computer unobserved by a mentor. The licensee's failure to provide adequate training to the dosimetrist on the treatment planning system is an area of concern. In addition, the licensee did not provide the dosimetrist training on its QMP until it provided him a copy of it on the day before the inspection. Furthermore, both

physicists who were involved with brachytherapy treatments had not received training on the revised QMP. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material under the supervision of an authorized user shall instruct the supervised individual in the licensee's written quality management program. Failure to train supervised individuals in the licensee's QMP is an apparent violation of 10 CFR 35.25(a)(1).

B. The licensee had not formally adopted written procedures to adequately check dose calculations prior to treatment completion. The procedures used for dose calculation checks did not require verification of data entered in the treatment planning computer. Since the misadministration was due to incorrect data entry into the treatment planning computer, a dose calculation check, conducted in accordance with the licensee's procedure, prior to treatment completion would not have identified a problem and prevented the misadministration. In fact, a physicist performed a routine dose calculation check, in accordance with the licensee's procedure, after treatment completion and failed to identify a problem. The misadministration was identified only because the authorized user used a different method to check the dose.

C. Lack of effective management oversight of the radiation safety program. The licensee experienced several personnel changes since approximately June 1994. The changes included a new RSO, a temporary physicist and a new dosimetrist. Within the same time period, the workload in radiation oncology increased. Licensee management failed to ensure that the effectiveness of the radiation safety program was not compromised during these changes. Specifically, licensee management failed to ensure that the new RSO (the authorized user physician): (1) understood his responsibilities regarding training of new employees; and (2) was provided with management's expectations regarding incident investigations. Also, as noted in the last NRC inspection, the licensee's evaluations of misadministrations reflect a continuing reluctance to be self-critical when determining root cause and contributing factors. Rather, it focuses on individuals without exploring potential programmatic issues. These constitute programmatic weaknesses in the licensee's radiation safety program.

10 CFR 35.21(b)(1) requires, in part, that the licensee's radiation safety officer investigate accidents, misadministrations, and other deviations from approved safety practice and implement corrective actions as necessary. Failure to ensure the radiation safety officer adequately investigated the misadministration is an apparent violation of 10 CFR 35.21(b)(1). This is a repeat violation identified previously during an NRC inspection conducted in May, 1994.

Based upon the results of the inspection, the inspectors requested that the licensee provide adequate training to the dosimetrist prior to his working unattended on the treatment planning system, and develop procedures to perform independent dose calculation checks prior to completion of brachytherapy treatments. The licensee agreed to do so.

Two apparent violations of NRC regulatory requirements were identified. Two programmatic weaknesses in the licensee's radiation safety program and one area of concern were also identified.

5. Notifications and Reports

Based on interviews of licensee personnel, the inspectors determined that all notifications and reports, required under 10 CFR 35.33, concerning the misadministration had been made. The licensee identified the incident on September 21, 1994, and classified the incident as a misadministration on September 22, 1994. The licensee provided verbal and written notification of the misadministration to the patient on September 22, 1994, and September 23, 1994, respectively. The licensee notified the NRC Operations Center and Region III on September 23, 1994. The licensee notified the referring physician on September 21, 1994. The licensee submitted the required 15 day report to the NRC on October 6, 1994.

No apparent violations of NRC regulatory requirements were identified.

6. Quality Management Program (QMP)

The inspectors reviewed the licensee's implementation of the quality management program (QMP) requirements contained in 10 CFR 35.32. The licensee submitted its original QMP policies and procedures to the NRC by letter dated January 24, 1992. The NRC notified the licensee in a letter dated June 17, 1994 that the submitted QMP did not meet all of the objectives contained in 10 CFR 35.32. The licensee revised its written QMP policies and procedures and submitted the revisions to the NRC in a letter dated August 17, 1994. The revisions became effective on August 17, 1994.

10 CFR 35.32(a)(3) requires that the licensee's QMP include written policies and procedures to meet the objective that final plans of treatment and related calculations for brachytherapy are in accordance with the written directive. 10 CFR 35.32(a)(4) requires that the licensee's QMP include written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Item 6 of the licensee's revised QMP requires that the dose calculations be checked prior to the completion of a brachytherapy treatment. Inspector interview of the physicist who performed the check of dose calculations indicated that the check was not made prior to the completion of treatment. Additionally, and more importantly, the licensee had not adopted written procedures to adequately check dose

calculations prior to treatment completion. The procedures used for dose calculation checks did not require verification of data entered in the treatment planning computer. The failure of the licensee to implement policies and procedures to adequately check brachytherapy dose calculations prior to treatment completion is an apparent violation of Item 6 of the licensee's August 17, 1994 QMP and 10 CFR 35.32(a)(3).

Other aspects of the licensee's implementation of the QMP requirements appeared to be adequate.

One apparent violation of NRC regulatory requirements was identified.

7. Other Areas Inspected

Iridium-192 Event

Background

A physician authorized user prepared a written directive for the administration of 13 ribbons containing 5 seeds per ribbon of iridium-192 in a Syed-Neblett template. The plan called for an activity required to give 50-60 rads (cGy) per hour to the treatment area for a total dose of 3000 rads (30 Gy).

The physicist developing the treatment plan entered "0.3" thinking in terms of milligrams-radium-equivalent (MEQ) per seed rather than units of millicuries (mCi) per seed which the computer used. He entered 0.3 MEQ because he had recently ordered that quantity for a previous case, and the material is ordered from the supplier in units of MEQ (1 MEQ equals 1.79 mCi). The physicist determined that the dose rate was too low for that activity and increased it to "0.7." The computer calculated an acceptable plan, and the physicist ordered 0.7 MEQ (i.e., 1.3 mCi) per seed without realizing that the plan was based on 0.7 mCi per seed.

The seeds were implanted on September 13, 1994. After implanting the 0.7 MEQ seeds, but prior to treatment completion, the physicist performed a treatment plan check. When he entered the correct (1.3 mCi) seed activity in the computer, he noticed the dose rate was nearly double the preplan dose rate. The authorized user was informed and he removed the seeds four hours post implant. New seeds of lower activity were ordered, and they were implanted the next day. The authorized user modified the written directive to account for the initially higher dose rate and continued the treatment with the prescribed lower dose rate to achieve the same total dose (i.e., 3000 rads (30 Gy)). The treatment continued as prescribed and the patient received the total dose as originally intended.

Initial Licensee Investigation

The licensee determined the event was caused by the physicist's error in entering the source activity. The event did not constitute a recordable event or misadministration as defined in 10 CFR 35.2.

Licensee Corrective Actions

The licensee developed and implemented the following corrective actions prior to the inspection:

A. The Syed-Neblett Template Form will include units of both MEQ/seed and mCi/seed in the preplan section.

B. Seeds should not be loaded prior to completion of the treatment plan.

C. Computer data entry should be independently verified before treatment begins.

The licensee's proposed corrective actions appear to be adequate.

No apparent violations of NRC regulatory requirements were identified.

Teletherapy

The inspectors observed a posted chart illustrating conversion of gantry angles from the licensee's Varian-TEM Ximatron CX simulator to its Theratron 780 cobalt-60 teletherapy unit. Based on interview of teletherapy personnel and review of all teletherapy cases conducted since the last inspection, it appeared that the staff understood the need for and adequately converted gantry angles when necessary.

No apparent violations of NRC regulatory requirements were identified.

8. Exit Summary

At the termination of the inspection, the inspectors conducted an exit summary with those individuals denoted in Section 1 of this report. The summary included a discussion of the root cause and contributing factors of the misadministration, the apparent violations, the licensee's proposed corrective actions, and the NRC Enforcement Policy. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.