

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02669/93001(DRSS)

Docket No. 030-02669

License No. 34-01055-01

Category G

Priority 2

Licensee: Riverside Methodist Hospital
3535 Olengtangy River Road
Columbus, OH 43214

Inspection At: Riverside Methodist Hospital
3535 Olengtangy River Road
Columbus, OH 43214

Site Inspection Conducted: March 10-12, 1993

Inspectors:

Wayne Slawinski
Wayne Slawinski
Senior Radiation Specialist

3-23-93
Date

Thomas Young for
Thomas Young
Radiation Specialist

3/25/93
Date

Reviewed By:

B. J. Holt
B. J. Holt, Chief
Nuclear Materials Inspection
Section 1

3/25/93
Date

Approved By:

Roy J. Caniano for
Roy J. Caniano, Chief
Nuclear Materials Safety Branch

3/25/93
Date

Inspection Summary

Inspection on March 10-12, 1993 (Report No. 030-02669/93001(DRSS))

Areas Inspected: Special, announced, limited scope safety inspection to review a licensee reported cesium-137 brachytherapy misadministration event involving a Low Dose Rate (LDR) remote afterloading device. The inspection also included an evaluation of the licensee's Quality Management Program related to remote afterloader device uses, and other selected aspects of its remote afterloader treatment program.

Results: The licensee's Quality Management Program (QMP) governing brachytherapy source implants utilizing remote afterloader devices is adequately developed and implemented, with limited exceptions. The exceptions

appear to be isolated and not representative of QMP programmatic deficiencies. However, the exceptions contributed to the misadministration event, are considered unresolved issues, and consist of the following:

- Failure to adequately verify that the radioisotope agrees with the written directive and plan of treatment before administering the treatment (Section 7).
- Failure to adequately check computer generated dose calculations and related data for accuracy (Section 7).

An operating procedure implementation problem involving the failure to independently verify treatment time calculations was also identified and contributed to the misadministration. This problem is also considered an unresolved issue (Section 7).

In addition, two cited and two non-cited violations unrelated to the misadministration event were identified. The cited violations involve the failure to: (1) instruct nursing staff personnel caring for patients undergoing LDR afterloader device treatments in device operating and emergency procedures; and (2) perform adequate radiation surveys of patients treated with temporary implants using an LDR remote afterloader unit to confirm that all sources were removed after completion of the treatments and include all required information on records of patient surveys after completion of HDR remote afterloader device treatments (Sections 6 and 9, respectively). The two non-cited violations involve the failure to: (1) provide personnel monitoring devices to nursing staff caring for patients treated with the LDR remote afterloader device (Section 9); and (2) conduct a QMP review within the required interval (Section 8).

DETAILS

1. Persons Contacted

- *M. Crnkovich, M.D., Radiation Oncologist
- *M. Hamm, Senior Vice President, Patient Services
- *S. Jayaraman, Ph.D., Radiation Safety Officer
- *R. Kennaugh, M.D., Director, Radiation Oncology
- C. Lundahl, Dosimetrist
- *P. Lundahl, Medical Physicist
- *J. Niemkiewicz, Chief Medical Physicist
- *T. Pedrick, M.D., Radiation Oncologist
- +G. Reid, M.D., Associate Director, Gynecologic Oncology
- *B. Sweeney, Assistant, Patient Affairs
- *G. Taylor, M.D., Medical Director, Radiology
- *S. Zembar, Assistant General Counsel

The inspectors also contacted members of the licensee's nursing staff and were accompanied during the inspection by Mr. C. Heller from the Ohio Department of Health.

*Denotes those present at the site exit meeting on March 12, 1993.

+Denotes telephone contact only.

2. Purpose and Scope of Inspection

A limited scope special safety inspection was conducted to evaluate the circumstances associated with a licensee identified cesium-137 Low Dose Rate (LDR) remote afterloader device misadministration event. The inspection also included a review of the licensee's Quality Management Program (QMP) governing remote afterloader device uses and selected aspects of its routine remote afterloader device treatment program.

3. Licensed Program and Inspection History

Riverside Methodist Hospital is authorized in its NRC license to conduct any diagnostic and therapeutic medical procedure described in 10 CFR 35.100 - 35.500. The licensee is also specifically authorized to conduct cesium-137 and iridium-192 brachytherapy source implants using Nucletron Selectron LDR and Nucletron Microselectron HDR remote afterloader devices, respectively. The license was last amended (no. 73) on October 25, 1991 and expires on August 31, 1995.

The licensee initiated brachytherapy treatments utilizing its LDR remote afterloader unit in 1988 and its HDR unit in 1990. Brachytherapy treatments utilizing these two devices have been routinely conducted since these initiation dates. In the twelve months between January 27, 1992 and January 26, 1993, the licensee treated thirty-one and twenty-three patients using its LDR and HDR remote afterloader units, respectively. A similar number of patients was treated during 1991.

Activities conducted under License No. 34-01055-01 have been reviewed by the NRC on two occasions within the past three years. Licensed activities were last reviewed during a routine inspection on October 22, 1992. Two non-cited Severity Level V violations were identified for failure to include all required information in Radiation Safety Committee meeting minutes and sealed source inventory records. A concern regarding timely review of nuclear medicine technologist bioassay results was also noted. A routine inspection conducted in May 1990 identified one violation for failure to perform daily surveys in dose preparation and injection areas.

Two misadministrations, one therapeutic and one involving a quantity of material greater than that typically used in a diagnostic study, were reported by the licensee between 1980 and 1992. In August 1991, a patient was administered 8.7 millicuries of sodium iodide-131 rather than the intended 10 millicuries. In August 1985, a patient was administered 200 millicuries of technetium-99m pertechnetate rather than the intended 20 millicuries. No violations related to either event were identified during NRC followup inspections.

4. Organization, Staffing, and Qualifications

The Medical Director of the Radiation Oncology Department is Dr. Ralph Kennaugh. This department reports to the Senior Vice President of Patient Services, Marian Hamm, who in turn reports to President and Chief Operating Officer, Nancy Schlichting.

Three staff radiation oncologists (authorized users) prescribe treatments and supervise the use of the licensee's two remote afterloader units. These three oncologists are approved as authorized users for the afterloader units in Condition No. 12 of the hospital's NRC license. Inspector interviews of these three physicians revealed that they understand their supervision responsibilities as delineated in 10 CFR 35.25.

The Radiation Oncology Department is staffed by a chief medical physicist, another medical physicist and junior physicist, a dosimetrist, several technicians, nurses, and administrative support personnel. However, only the two physicists and, to a lesser extent, the junior physicist are involved in remote afterloader device treatments. Other Oncology Department staff primarily support the licensee's two linear accelerator units. The two physicists develop all treatment plans and conduct related dose calculations, and also administer the remote afterloader device treatments. As a result of the misadministration event described in Sections 5 and 7, the licensee plans to further involve its junior physicist and dosimetrist in treatment planning and dose calculational checks.

The two medical physicists are well qualified and experienced in their disciplines. Each individual possesses a Master of Science Degree, is board certified in therapeutic radiologic physics by the American Board of Radiology, and have between 7-12 years related experience. The

inspection disclosed these individuals to be knowledgeable in remote afterloader brachytherapy treatments and dedicated to implementing a quality radiation safety program.

Based on the magnitude of the licensee's brachytherapy treatment program, staff responsibilities, and inspector interviews of the physicists and dosimetrist, no significant staffing problems or related weaknesses were identified.

No violations of NRC requirements were identified.

5. Misadministration Event Summary

On February 10-12, 1992, a patient underwent an intracavitary brachytherapy source implant procedure as part of a treatment for stage 1 adenocarcinoma of the cervix, subsequent to completing external beam (linear accelerator) radiation therapy treatments at another institution.

Nine cesium-137 brachytherapy sources, each 19.79 millicuries, were afterloaded into a Fletcher-Suit tandem and colpostat applicator using an LDR remote afterloader device, as determined by the treatment plan. However, the patient was treated for 35 hours rather than the 51 hours needed to deliver the intended dose. As a result, the total brachytherapy dose administered to the patient was 2201 rads, rather than the intended 3248 rads. This represented a 32% under-dose.

The treatment time error originated during the treatment planning and dose calculation process, when a medical physicist mistakenly selected iridium-192 as the treatment radioisotope in the licensee's treatment planning computer. As a result, the treatment dose rate generated by the computer program and consequently the total dose to be delivered to the patient, were based on iridium-192 characteristics rather than the intended cesium-137. No independent check of the treatment planning calculations and all related data was conducted prior to the treatment.

The error was identified by the licensee's medical physicists on February 25, 1993, during an audit of its QMP conducted pursuant to 10 CFR 35.32(b). The misadministration was reported to the NRC by the licensee on February 26, 1993. The licensee's written report of the misadministration event was submitted to the NRC Region III office by letter dated March 8, 1993 (Attachment 1). Both the licensee's initial notification and written report satisfied 10 CFR 35.33 requirements.

The inspectors independently verified that the licensee informed the patient's referring physician within 24 hours of event discovery as required. After consultation with the referring physician and based on medical judgment, the licensee initially decided not to notify the patient of the misadministration. However, after further consideration, the referring physician plans to discuss the misadministration with the patient during her next routine followup examination.

The NRC's evaluation of the misadministration event is provided in Section 7.

6. Training and Instruction

The inspectors reviewed the training and instruction provided to applicable radiation oncology staff physicians (authorized users) and medical physicists in the licensee's Quality Management Program related to remote afterloading brachytherapy device treatments. No significant problems were noted.

Inspector interviews revealed that the three physicians involved in remote afterloader device treatments had reviewed and are familiar with the licensee's QMP and their supervision responsibilities under 10 CFR 35.25. The medical physicists developed the remote afterloader device QMP and are thoroughly familiar with its contents. The licensee's junior physicist reportedly reviewed the QMP and was instructed in his responsibilities by the physicists. Although the junior physicist does not administer remote afterloader treatments or develop the initial treatment plans, this individual does independently check treatment planning calculations. The licensee's dosimetrist has not yet been instructed in the QMP and applicable 10 CFR 35 requirements; however, this individual has not been involved in remote afterloader treatments. Since the dosimetrist may be used in the future to independently check treatment planning calculations, the licensee plans to provide the necessary training soon.

Based on the foregoing, the licensee has adequately instructed its medical/technical staff in the written Quality Management Program, as required by 10 CFR 35.25. However, nursing staff training problems were identified as described below.

Treatment times for LDR remote afterloader treatments typically range from about 30-60 hours. During the treatments, the patients are quartered in a designated private room on the ninth floor of the hospital, and are attended by the nursing staff assigned to that area. The licensee's physicists periodically provide the nursing staff inservice instruction on LDR afterloader device operating and emergency procedures and in 10 CFR 35.410 required topics. However, inspector interview of randomly selected nurses working the backshift and who have cared for implant patients, disclosed that all had not been instructed as required. Although these nurses were cognizant of certain device operating procedures and who to contact in the event of an emergency, they were not sufficiently familiar with area monitor operation and the procedures to follow should the sources not retract at the end of a treatment.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for training personnel are described in an application dated March 27, 1990, and letter dated June 5, 1990, and were approved by License Condition No. 18.

The letter dated June 5, 1990, states in Item 1 that the licensee will establish and implement the model training program that was published in Appendix A of Regulatory Guide 10.8, Revision 2.

Appendix A of Regulatory Guide 10.8, Revision 2, "Model Training Program," requires that the licensee instruct personnel, including ancillary (nursing) personnel, in part, in appropriate radiation safety procedures and response to emergencies or unsafe conditions. Personnel will be instructed: (1) before assuming duties with, or in the vicinity of, radioactive material, (2) during annual refresher training, and (3) whenever there is a significant change in duties, regulations, or the terms of the license.

Contrary to the above, as of March 12, 1993, the licensee failed to instruct at least two nurses who cared for patients undergoing brachytherapy treatments in 1992 involving its low dose rate remote afterloader unit, in important device operating and emergency procedures. One nurse reportedly provided care for a patient in 1992 and another provided care on three or four occasions in 1992 and neither received appropriate training to date. Failure to provide required training to applicable nursing staff members is a violation of 10 CFR 35.21(a) and License Condition No. 18.

One violation of NRC requirements was identified.

7. Misadministration Event Evaluation

An appropriate written directive was executed and signed by one of the licensee's authorized users prior to the initiation of the February 10, 1992 treatment. The directive initially specified an approximate dose rate range to a specific location, a treatment time, and was written on a "Selectron LDR Programming Worksheet" which listed cesium-137 as the radioisotope. Based on this initial information, a physicist generated a recommended source and dose rate distribution with the aid of a treatment planning computer. After physician approval of the source distribution and dose rate, the total dose was calculated and the written directive completed. The physician reviewed and approved the isodose distribution and dose rate results generated by the treatment planning computer; however, neither the physician or other qualified person independently reviewed all treatment planning calculations and computer printout information. The physicist involved in the treatment planning calculations self-checked the calculations and computer printout but failed to discover that iridium-192 was selected and listed on the computer printout as the treatment radioisotope rather than cesium-137. As a result of this error, the dose rates and consequently

the total dose prescribed were based on nine, 19.79 millicurie iridium-192 sources, rather than cesium-137 sources. Since cesium-137 sources were used in the implant procedure, the total dose administered to the patient was actually 32% less than prescribed. The root cause of the misadministration was an error made by a physicist in selecting the treatment radioisotope for the computer calculation. The failure to adequately verify the accuracy of all treatment data and perform an independent dose calculation check allowed the error to go undetected.

A three part Quality Management Program (QMP) was submitted by the licensee to NRC Region III by letter dated January 21, 1992, and the program was implemented on or before January 27, 1992, as required by 10 CFR 35.32(f). The three part program covers the following treatment modalities: (1) low dose rate/conventional brachytherapy; (2) high dose rate brachytherapy; and (3) administration of diagnostic/therapeutic radiopharmaceuticals. The low dose rate/conventional brachytherapy QMP governs the administration of licensed material using the licensee's LDR remote afterloader unit.

10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b), shall require the supervised individual to follow the instructions of the supervising authorized user and follow the written radiation safety and quality management procedures established by the licensee.

10 CFR 35.32(a) requires, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include, in part, written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Items 3 and 5 of the licensee's quality management program entitled "Low Dose Rate Selectron/Conventional Brachytherapy" require that: (1) the radioisotope be confirmed by the person administering the treatment to verify agreement with the written directive and plan of treatment; and (2) an authorized user or a qualified person under the supervision of an authorized user (e.g., physicist) verify that the radioisotope to be used is in agreement with the written directive and plan of treatment before implanting the sources.

On February 10, 1992, the individual administering the treatment (physicist) failed to adequately verify that the radioisotope agreed with the written directive and treatment plan. Similarly, the authorized user or other qualified person failed to adequately verify that the radioisotope to be used agreed with the written directive and treatment plan before implanting the sources. Failure to adequately verify the appropriateness of the radioisotope selected in the treatment plan and used in the treatment dose calculations is contrary to Items 3 and 5 of the licensee's QMP.

Item 10 of the licensee's aforementioned quality management program requires that computer generated dose calculations be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations. The dose calculations shall be checked by an authorized user or a qualified person under the supervision of an authorized user (e.g., physicist, physician, or dosimetrist) who, whenever possible, did not make the original calculations.

As described above, on February 10, 1992, the computer generated dose calculations were checked by the same physicist who was involved in the treatment planning calculations and the error was not detected. Failure to adequately check computer generated dose calculations and related data is contrary to Item 10 of the licensee's QMP.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's operating procedures for its Selectron LDR remote afterloader unit are provided, in part, in letters dated October 26, 1987, and January 8, 1990, and were approved by License Condition No. 18.

The letters dated October 26, 1987, and January 8, 1990, both state in Item VI of an enclosure entitled "Operating Procedures," that treatment time calculations will be independently verified.

As described at the outset of this section, on February 10, 1992, the physicist involved in the treatment planning calculations self-checked the treatment time calculations and computer printout. Neither the physician or other qualified individual under the supervision of the authorized user independently checked all treatment calculations and related data. According to the licensee, they typically do not independently check treatment calculations associated with its LDR remote afterloader unit. The licensee estimated that only about 30% of the treatment calculations were independently verified prior to LDR unit treatments administered in 1991 and 1992. Independent checks were not routinely done primarily because of the need to initiate treatments expeditiously after dummy sources are implanted in the patient and radiographs are taken, and also due to unavailability of qualified personnel. The failure to independently verify treatment time calculations is contrary to 10 CFR 35.21(a) and License Condition No. 18.

The NRC is in the process of reviewing the above matters relating to the misadministration, the licensee's QMP, and the LDR remote afterloader device operating procedures for applicability to the requirements in the license and in 10 CFR 35. Consequently, these matters are considered unresolved at this time.

Licensee preliminary corrective actions for the misadministration event include the following:

- Restructure the radioisotope list on the treatment planning computer to improve the radioisotope selection process.
- Conduct independent checks of all treatment planning calculations prior to treatment initiation.

According to the licensee, the medical effect of this misadministration on the patient is not expected to be significant. A recent followup examination of the patient by the referring physician showed the patient to be disease free. The case is currently under review by an NRC medical consultant.

Three issues were identified that are currently unresolved.

8. Quality Management Program Audit

The licensee has developed procedures for review of its QMP to include a representative sample of patient administrations, recordable events, and misadministrations. The procedures were reviewed by the inspectors and satisfy 10 CFR 35.32(b) criteria. The number of patient cases sampled by the licensee is based on 10 CFR 32.110 tables, with a lot tolerance percent rate of 2%.

The licensee's initial review of its QMP was conducted by its two person medical physicist team on February 25, 1993, and included a review of all (56) brachytherapy patient cases conducted between January 27, 1992 through January 26, 1993. As a result of this review, the misadministration event described in Sections 5 and 7 was identified. No other QMP implementation problems were identified by the licensee's review. As a result of the misadministration, the chief medical physicist subsequently reviewed all brachytherapy patient administrations conducted in 1991 through January 26, 1992. No additional problems were identified by the licensee.

10 CFR 35.32(b) requires that QMP reviews be conducted by the licensee at intervals no greater than 12 months. The licensee's initial QMP review was conducted nearly 13 months after the program's January 27, 1992 implementation date. Failure to conduct the QMP review within the required 12 month interval is a violation of 10 CFR 35.32(b). However, this is considered a non-cited violation because the licensee committed to conduct future QMP reviews within the required 12 month frequency and other criteria of 10 CFR Part 2, Appendix C, Section VII.B., were met.

The inspectors independently audited implementation of the licensee's LDR and HDR remote afterloader treatment QMPs by evaluating a representative sample of patient administrations. The inspectors reviewed ten randomly selected brachytherapy patient cases conducted between February 13, 1992 and March 8, 1993. Five LDR and five HDR remote afterloader cases were reviewed. No significant QMP implementation problems were identified. Written directives were properly executed by authorized physicians, patient identities were

verified by more than one method and dose administrations were in accordance with the written directive and plan of treatment.

Based on the NRC and licensee QMP audits, it appears that the QMP implementation problems related to the misadministration event were isolated.

One non-cited violation of NRC requirements was identified.

9. Other Areas Inspected

The inspectors reviewed other selected aspects of the licensee's remote afterloader treatment program including portable survey instrument and area monitor availability and calibration, sealed source leak testing, treatment planning computer program acceptance testing, and patient/adjacent room radiation surveys. Inspection findings are provided below.

The nominal ten curie iridium-192 sealed source contained in the licensee's HDR remote afterloader unit is exchanged by the device manufacturer approximately every three months. Manufacturer source leak test certificates are maintained by the licensee but were not reviewed during the inspection. The licensee's Radiation Safety Officer leak tests the 25 cesium-137 source pellets contained in its LDR afterloader unit by wiping an outlet port on the device which the sources travel through during treatment. The tests are conducted every six months; the last test was conducted in November 1992. No leakage has been identified by the licensee.

The licensee's physics staff reportedly conducted performance testing on the treatment planning computer programs used to support both the LDR and HDR remote afterloader units. The testing was performed prior to initial use of the planning systems for patient treatment. Hand calculations were compared to computer generated dose rate calculation data for single and multiple dose rate locations. No problems were identified by the licensee.

The licensee conducts radiation surveys of patients treated with its HDR remote afterloader device immediately after treatment completion, pursuant to 10 CFR 35.404(a). The surveys are performed with a portable instrument that satisfies 10 CFR 35.420 requirements. An area radiation monitor (Primalert system) mounted in the HDR treatment room is also used to alert the licensee to potential radiological problems. The portable survey instrument is calibrated annually by the licensee, and was last calibrated in March 1993. Records of patient surveys, however, do not include all required information as described below.

10 CFR 35.404(b) requires that records of patient surveys conducted pursuant to 35.404(a) include the date of the survey, the name of the patient, the dose rate from the patient expressed as millirem per hour and measured at one meter from the patient, the survey instrument used, and the initials of the individual who made the survey. Contrary to the

survey record requirements, as of March 12, 1993, the licensee's record of patient surveys do not include the measured dose rate expressed in millirem per hour and the survey instrument used. The failure to include all required information on patient release survey records is a violation of 10 CFR 35.404(b).

The licensee treats patients using its LDR remote afterloader device in a designated patient room located on the south wing of the ninth floor of the main hospital. An area radiation monitor (Primaler system) mounted in the room is used to monitor the patient and treatment room. The area monitor consists of an energy compensated G-M tube and yields a visible alarm when the measured dose rate exceeds a preset threshold of 1.0 millirem/hour. The monitor is mounted on a wall about eight to ten feet from the patient's bed. The licensee relies on this area monitor to perform patient surveys upon source explant. The Nucletron Selectron LDR afterloader device is equipped with an internal safety system that monitors source/spacer position with optical sensors. According to the licensee, the Nucletron Selectron LDR remote afterloader device will not operate unless a total of 48 source and spacer pellet combinations is used in each treatment. If all 48 pellets are not returned to the shielded position within the device upon completion of treatment, an optical sensor alarm on the device's instrument panel is actuated. Although it may be unlikely that the optical sensor systems would fail, the licensee's reliance on this sensor system and its area monitor to ensure that all sources have been removed from a patient is contrary to regulatory requirements. NRC calculations show that the area monitor would not alarm should a single 20 millicurie cesium-137 source pellet remain in the patient. An unshielded 20 millicurie cesium-137 point source yields a dose rate of about 0.7 millirem per hour at ten feet. This radiation level is less than the area monitor's alarm threshold.

10 CFR 35.404(a) requires, in part, that the licensee immediately, after removing the last temporary implant source from a patient, make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The survey is to be performed at one meter from the patient with an appropriate radiation detection or measurement instrument, as specified in 10 CFR 35.420. However, as described above, the licensee failed to adequately conduct the required radiation surveys to confirm that all cesium-137 sources used in LDR remote afterloader brachytherapy had been removed from the patient. The failure to adequately survey patients at the conclusion of LDR remote afterloader brachytherapy treatments to confirm source removal is a violation of 10 CFR 35.404(a). The licensee had reportedly not received NRC Information Notice 92-84, "Release of Patients Treated With Temporary Implants," which outlines the requirements for patient surveys.

Nurses attending to patients treated with the LDR remote afterloader device have not been provided personnel monitoring devices for several years. According to the licensee, whole body film badges were previously provided to nurses and discontinued because radiation exposures were minimal. In addition, an optical interlock at the

patient room entrance retracts the cesium-137 sources back into the shielded position within the LDR device, upon personnel entry to the room. This interlock further reduced the potential for nurse radiation exposure. Nevertheless, the licensee failed to amend its license to request relief from an existing commitment to provide dosimetry devices to nurses.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for personnel monitoring are described in a letter dated June 5, 1990, and were approved by License Condition No. 18.

The letter dated June 5, 1990, states in Item 3 that nursing personnel associated with patient care when using the Selectron LDR remote afterloading system will be provided with personnel monitoring badges.

However, the licensee failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, during the last few years, the licensee failed to provide personnel monitoring badges to its nurses attending LDR remote afterloader treatment patients. Failure to provide the required personnel monitoring equipment to nurses is considered a non-cited violation because it was identified by the licensee during the inspection, the licensee committed to correct the problem at the next LDR brachytherapy treatment, and the other criteria of 10 CFR Part 2, Appendix C, Section VII.B., were met.

One cited and one non-cited violation of NRC requirements was identified.

10. Exit Meeting

At the conclusion of the inspection on March 12, 1993, the inspectors met with those individuals identified in Section 1 of this report. The inspectors summarized the scope and findings of the inspection and the likely information content of the inspection report. The licensee did not identify any of the information likely to be included in the report as proprietary.

The inspectors also reviewed the NRC Enforcement Policy delineated in 10 CFR Part 2, Appendix C, and discussed its applicability to the inspection findings.

Attachment: Licensee Misadministration
Report Dated March 8, 1993

Report of Misadministration
to
Nuclear Regulatory Commission - Region III

March 8, 1993

This report is submitted as required in 10 CFR 35.33 and includes all relevant information regarding the misadministration of a single brachytherapy treatment.

Licensee name: Riverside Methodist Hospitals
3535 Olentangy River Road
Columbus, Ohio

License no.: 34-01055-01

Prescribing Physician: Mark J. Crnkovich, M.D.

Director of Radiation Oncology: Ralph C. Kennaugh, M.D.

Description of the event:

During a yearly review of brachytherapy implant treatments performed by the Department of Radiation Oncology, a single case was found where the delivered radiation dose did not agree with the prescribed dose. The yearly review took place on February 25, 1993. The date of the brachytherapy treatment was February 10th-12th, 1992. The patient actually received 2201 cGy to point A from the implant part of the therapy when 3248 cGy was prescribed, a difference of -32%. The patient also received 4080 cGy to the same location from external beam radiation therapy via a linear accelerator at Marion Regional Cancer Center, as prescribed. The difference between prescribed and given radiation dose for the total treatment was -14%.

Why the event occurred:

The wrong radioisotope was selected for the computer calculation of the radiation dose rate to point A. Iridium-192 was selected instead of Cesium-137. The radioisotope used for the brachytherapy treatment was Cesium-137, as prescribed.

This error was not detected when a self-check of the work was done.

The effect on the patient:

The effect on the patient is expected to be not significant. In support of this expectation, recent follow-up examination of the patient by the referring physician indicates that she is disease free and it has been one year since her radiation treatment.

Improvements to prevent recurrence:

Two improvements were identified. One was the restructuring of the radioisotope list on the treatment planning computer such that it is easier to select the correct one. The second was to have an independent person check the treatment planning calculations prior to initiation of the patient treatment.

Actions taken to prevent recurrence:

A number of actions have been taken to prevent recurrence.

Firstly, the radioisotope list on the treatment planning computer was edited to remove unused isotopes. There is now only the two radioisotopes we currently use remaining on the list.

Secondly, there is now a gap between these two radioisotopes so that they are not directly adjacent to each other on the list.

Thirdly, the Cesium-137 source used with the Selectron Remote Afterloading unit has been renamed from "Cesium-137" to "Selectron Cs 137."

Fourthly, the treatment planning aspects of this type of brachytherapy treatment have been reviewed with the group of three physicists and the dosimetrist.

The editing of the radioisotope list, the separation of the isotope choices, and the relabeling will make it more difficult to select the wrong radioisotope.

The treatment planning review will result in three people, other than the original planner, available to check the treatment plan prior to treatment.

The misadministration will be reported to the Radiation Safety Committee on March 10, 1993.

Notification of the patient, or the patient's responsible relative or guardian:

The patient has not been notified. The reasons for this have been documented in letters by both the prescribing physician and the referring physician (attached).

Summary of events to date:

The misadministration was discovered by John Niemkiewicz and Paul Lundahl during a routine yearly chart review on February 25, 1993 at approximately 2:00 pm.

The prescribing physician, Dr. Mark Crnkovich, was informed of this finding on February 25, 1993 at approximately 4:00 pm.

Dr. Crnkovich informed the referring physician, Dr. Gary Reid, on February 26, 1993 at approximately 10:00 am. by telephone.

Paul Lundahl notified the NRC Operations Center by telephone on February 26, 1993 at approximately 1:00 pm.

NRC Region III office contacted Paul Lundahl by telephone on February 26, 1993 at approximately 2:30 pm. and then again at approximately 4:00 pm.

Dr. Kennaugh, Director of Radiation Oncology, was notified on March 1, 1993, when he returned from vacation.

The radioisotope list on the treatment planning computer was edited on March 1, 1993.

The treatment planning aspects of brachytherapy treatments were reviewed with the physicists and dosimetrist on March 2, 1993.

An information update meeting was held on March 2, 1993. In attendance were: Dr. Ralph Kennaugh, Director of Radiation Oncology, Fred Krummel, Director of Patient Affairs/Risk Management, Barbara Sweeney, Patient Affairs/Risk Management Assistant, Stephanie Zembar, General Council Assistant, Dr. Gordon Taylor, Chairman of the Radiation Safety Committee, Paul Lundahl, Medical Physicist, and John Niemkiewicz, Chief Medical Physicist.

The misadministration will be reported to the Radiation Safety Committee which is scheduled to meet on March 10, 1993.

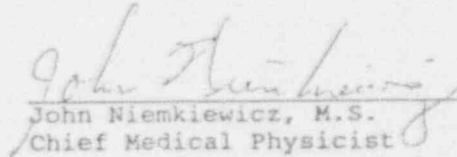
Other comments:

Riverside's brachytherapy program is safe and state-of-the-art. Great effort is made to ensure that the brachytherapy treatments are accurate. This is accomplished through careful documentation, organization, establishment of procedure, routine quality assurance checks and case reviews.

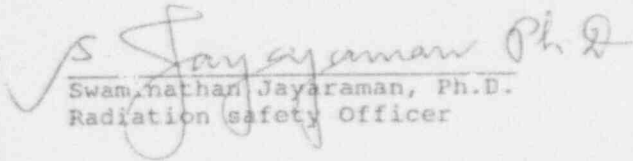
Indeed, Riverside has not had a misadministration or a reportable event in this area for over nine years. Compliance with NRC regulations has been, and is, good. The recent NRC inspection in October, 1992, as well as past inspections, has indicated that the brachytherapy program in Radiation Oncology was, and is, in full compliance with NRC regulations.



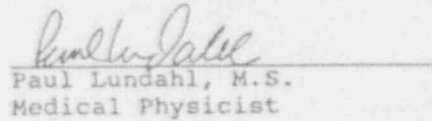
Ralph C. Kennaugh, M.D.
Director, Radiation Oncology



John Niemkiewicz, M.S.
Chief Medical Physicist



Swam. Nathan Jayaraman, Ph.D.
Radiation safety Officer



Paul Lundahl, M.S.
Medical Physicist



ERIE CHAPMAN, JD
President and
Chief Executive Officer

3535 Olentangy River Rd.
Columbus, Ohio 43214

Telephone
(614) 566-5000

March 4, 1993

RE:XXXXXXXXXXXX

To Whom It May Concern:

XXXXXXXXXXXX was a patient under my care and received intracavitary brachytherapy in February 1992 as part of her treatment for Stage 1_b adenocarcinoma of the cervix. She was referred by Dr. Gary Reid from the GYN Oncology service at Riverside Methodist Hospitals for primary radiation therapy treatment. Since the patient lived in Marion, Ohio, she received her initial external beam irradiation in Marion and received a dose of 4080 cGy using four field technique and came to Riverside for the brachytherapy component of her treatment as this was not available in Marion.

She underwent intrauterine and vaginal brachytherapy using a Fletcher-suit model tandem and colpostats modified for use with our low dose rate Selectron unit and received treatment for 35 hours extending from 2/10/92 through 2/12/92. Treatment was well tolerated with a complete response and she remains without evidence of disease now one year since completion of all treatment.

During our yearly QA review of all implant procedures, an error was discovered in the dosimetry for the cesium brachytherapy implant for this patient. The wrong isotope was entered into the computer during the dosimetry planning which was not detected and the dosimetry planning was actually for an iridium source rather than cesium. This error resulted in an underdose so that the actual dose to Point "A" was only 2201 cGy versus 3248 which we had thought.

Riverside, the flagship
of U.S. Health Corporation,
also includes:

Riverside Regional
Cancer Institute

Riverside Heart Institute
of Ohio

The Elizabeth Blackwell
Center and Hospital

Wesley Health Center

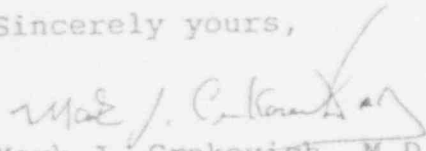
Member -
Voluntary Hospitals of America

RE: XXXXXXXX

Page 2

After learning of this error, the NRC and referring physician were contacted within 24 hours. After discussion with Dr. Reid, the referring physician, I felt it was appropriate not to inform the patient since this change does not seem to be of clinical significance and she remains without evidence of disease one year post-treatment. She is also a very nervous person and I felt that discussing this newly discovered dosimetry error may cause her unnecessary anxiety. Dr. Reid may discuss this with her at her next scheduled follow-up when he has some time to spend with her personally.

Sincerely yours,


Mark J. Crnkovich, M.D.
Radiation Oncologist

MJC/lfc

CENTRAL OHIO GYNECOLOGIC ONCOLOGY, INC. WY 93
3-11

Jeffrey G. Bell, M.D., F.A.C.O.G.
Director Gynecologic Oncology
Riverside Methodist Hospital

500 Thomas Lane, Suite 3B
Columbus, Ohio 43214
(614) 538-0440
FAX (614) 538-0443

Gary C. Reid, M.D., F.A.C.O.G., F.
Associate Director
Gynecologic Oncology
Riverside Methodist Hospital

COPY

March 7, 1993

Mark Crnkovich, M.D.
3545 Olentangy River Road
Columbus, Ohio 43214

RE:

Dear Mark;

This letter is to confirm that I was notified by you that
- had received approximately 1,000 aGy less than what you
desired in her radiation treatment because of the mistaken
calculation using Iridium instead of Cesium as the isotope. As
you pointed out Helen has had excellent response to the therapy.
I will inform her of the radiation discrepancy at her next office
visit.

Sincerely,


Gary C. Reid, M.D.

GCR/jh

DATE: 3/1/93

RE: XXXXXXXXXXXXXXXXXXXX

BY: RALPH C. KENNAUGH, M.D.

Note Dr. Crnkovich's note in the patient's chart of 2/26/93.

The source error occurred when the patient received her brachytherapy implant approximately one year ago. An iridium dosage was calculated instead of the cesium calculation, and the patient received 2201 cGy at point "A" instead of the prescribed 3248 cGy.

The NRC was notified within the appropriate time, once the error was discovered. Additional reports are being written today, together with a letter from both physicians. Fred Krumel, of Risk Management, was notified today. A copy of the chart and relevant data is to be sent to him when it is completed. (This is being compiled for mailing to the NRC.) It will be put through the Radiation Safety Committee at Riverside Methodist Hospitals at the next meeting, and a copy will be sent to the physicians insurance carriers.

The patient is reportedly disease free at this time.

DEPARTMENT OF RADIATION ONCOLOGY
RIVERSIDE METHODIST HOSPITALS
COLUMBUS, OHIO

PROGRESS NOTES

RE: XXXXXXXXXXXXXXXXXXXXXXXXXXXX

DATE: 2/26/93 DR. CRNKOVICH IJB
DURING YEARLY QA REVIEW OF ALL OUR IMPLANT PATIENTS, AN ERROR WAS DISCOVERED IN THE DOSIMETRY FOR THE CESIUM BRACHYTHERAPY IMPLANT FOR THIS PATIENT. APPARENTLY THE WRONG ISOTOPE WAS ENTERED INTO THE COMPUTER DURING THE DOSIMETRY PLANNING WHICH WAS NOT NOTICED AND THE DOSIMETRY PLAN WAS ACTUALLY USING AN IRIDIUM SOURCE RATHER THAN CESIUM. THIS ERROR RESULTED IN A 32% UNDERDOSE, SO THAT THE ACTUAL DOSE TO POINT "A" WAS ONLY 2201 cGy VERSUS 3248 cGy WHICH WE HAD THOUGHT.

THE PATIENT IS NOW OVER 1 YEAR OUT FROM COMPLETION OF ALL THERAPY AND REMAINS NED WITH NO PROBLEMS DESPITE THE LOWER THAN PRESCRIBED DOSE. THIS WAS DISCUSSED WITH THE REFERRING PHYSICIAN, DR. GARY REED, AS PER NRC REGULATIONS. I DO NOT PLAN ON BRINGING THE PATIENT BACK FOR ADDITIONAL DOSE AT THIS POINT SINCE THERE IS NO CLINICAL EVIDENCE OF DISEASE RECURRENCE. THE NRC WILL BE NOTIFIED AS REQUIRED. PLANS WILL BE MADE TO CHANGE THE QA EVALUATION TO ADDRESS THE POTENTIAL PROBLEM.

SUMMARY OF EVENTS

3/2/93

Licensee name: Riverside Methodist Hospitals

Prescription Physician: Mark J. Crnkovich, M.D.

Description of event: Patient received 4080 cGy via linear accelerator to the pelvis area, Marion, Ohio. Tandem and ovoids insertion was to deliver 3248 cGy to point "A." Patient actually received 2201 cGy to point "A" (-32%). Total dose to the patient was 6281 cGy instead of the prescribed 7328 cGy (-14%).

Reason: Iridium-192 was entered into the treatment plan as the radioisotope. The person who calculated the dose rate and treatment time also checked the computer printout and did not detect the error.

Improvements needed: A more thorough inspection of the treatment plan before the treatment is initiated.

Actions taken:

1. Deleted seed types that are not used in our Department.
2. Renamed Cesium-137 in the "seeds" menu; it is now "Selectron Cs137".
3. At the Physics staff meeting on 3/2/93, the computer printout was reviewed so that staff members who do not routinely perform these calculations are able to check the treatment plan for accuracy.

This error was discovered by John Niemkiewicz and Paul Lundahl during a routine Quality Management chart review on 2/25/93 at 2:00 P.M.

Dr. Crnkovich was informed of the incident at 4:00 P.M. on 2/25/93.

Dr. Crnkovich informed the referring physician, Dr. Gary Reid, on 2/26/93 at 10:00 A.M. by telephone.

Paul Lundahl telephone the NRC Operations Center on 2/26/93 at approximately 1:00 P.M. to report the incident.

Paul Lundahl received two phone calls from the Region III office that afternoon: the first at approximately 2:30 P.M. and the second at approximately 4:00 P.M.