U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-20829/94001(DRSS)

Docket No. 030-20829

EA No. 94-126

License No. 24-16652-02 Category G1 Priority 1

Licensee: Lucy Lee Hospital
Poplar Bluff, MO

Inspection Conducted: June 15 through June 28, 1994

Inspector: for Evelyn R. Matson — Date: 7-15-94
Radiation Specialist

Reviewed By: John A. Grobe, Chief — Date: 7-15-94
Nuclear Materials Inspection
Section 2

Approved By: Roy J. Caniano, Chief — Date: 7-15-94
Nuclear Materials Safety Branch

Inspection Summary
Inspection on June 15 through June 28, 1994 (Report No. 030-20829/94001(DRSS))
Areas Inspected: This routine announced safety inspection was conducted to assess the licensee's radiation safety program related to the use of cobalt-60 in human treatment. During the inspection, the inspector discovered a previously unidentified teletherapy misadministration. The inspection was expanded to include a review of the teletherapy misadministration and the licensee's adherence to and implementation of its Quality Management Program (QMP).
Results: During treatment of a patient for large cell lymphoma of the lower left leg, an incorrect tumor depth was used in the original dose calculations. The full diameter of the lower leg was used in stead of the lower leg centerline depth. The error resulted in a dose of 3965 cGy (centigray) (3965 rads) in 15 fractions instead of the prescribed 4000 cGy in 20 fractions. As a result, the calculated weekly administered dose was 32% greater than the weekly prescribed dose.

Eleven apparent violations were identified during the course of this inspection:

1. Approval of a treatment plan that did not provide sufficient information and direction to meet the objectives of the written directive is an apparent violation of 10 CFR 35.32(a)(3). Inspection Report Section 5.

2. Failure to verify that the correct data for the patient were used in the dose calculations is an apparent violation of 10 CFR 35.32(a)(3). Inspection Report Section 5.

3. Failure to include the dose per fraction and the overall treatment period in written directives is an apparent violation of 10 CFR 35.32(a)(1)(i). Inspection Report Section 6.

4. Failure to include procedures in the QMP for assuring that written revisions to written directives are made prior to administering the revised prescription is an apparent violation of 10 CFR 35.32(a)(1)(i). Inspection Report Section 6.

5. The failure to assure that the related calculations were performed after the plan of treatment was revised (adding a block) is an apparent violation of 10 CFR 35.32(a)(3). Inspection Report Section 6.

6. Failure to perform a weekly chart check is an apparent violation of 10 CFR 35.32(a)(3). Inspection Report Section 6.

7. Failure to include written policies and procedures to evaluate unintended deviations from the written directive is an apparent violation of 10 CFR 35.32(a)(5). Inspection Report Section 6.

8. Failure to instruct an individual in the written quality management program is an apparent violation of 10 CFR 35.25(a)(1). Inspection Report Section 6.

9. Failure to determine timer constancy and linearity on an annual and monthly basis is an apparent violation of 10 CFR 35.632(b)(4) and 10 CFR 35.634(a)(1). Inspection Report Section 7.

10. Failure to determine the uniformity of the radiation field and its dependence of the orientation of the useful beam is an apparent violation of 10 CFR 35.632(b)(3). Inspection Report Section 7.

11. Failure to test the operation of the electrical stops that limit the primary beam to the beam stopper is an apparent violation of 10 CFR 35.634(d)(1). Inspection Report Section 7.

DETAILS

1. Persons Contacted

+ David Archer, Chief Executive Officer
+ John Sanders, Chief Operating Officer
*+Gene Smith, Group Manager Facility Services
*+Subhash Gujarati, M.D., Radiation Safety Officer, Director Radiation Oncology
+ Terri Powell, Department Manager, Cancer Center
# Douglas Tai, Ph.D., Teletherapy Physicist
*+William Lewis, M.S., Medical Physicist
* Brian Aikey, Chief Therapy Technologist
Tammy McWilliams, Human Resources Assistant
George Charles, Radiology Administrator
Ray Peters, M.D.

* Indicates persons present at the on site exit meeting on June 15, 1994.
+ Indicates persons present at the exit teleconference on June 28, 1994.
# Indicates individuals contacted by telephone.

2. Inspection History

A routine inspection conducted on March 16-25, 1993, revealed two violations: Failure to assure that the teletherapy physicist reviewed the results of each spot-check within 15 days; and failure to apply and receive a license amendment prior to changing the teletherapy physicist. This inspection revealed that the previous violations have been corrected and have not recurred. These areas are considered to be closed.

Routine inspection performed in 1990 resulted in a violation for allowing four visiting authorized physicians to use licensed material without obtaining a copy of their licenses. In 1991, a violation was issued against the nuclear medicine license No. 24-16652-01 for allowing a visiting authorized user to use licensed material in nuclear medicine without first obtaining a copy of the individual's NRC or Agreement State license. A violation was issued for the teletherapy license for failure to mail a copy of the full calibration required by 10 CFR 35.632 to the NRC within thirty days following completion of the action.

3. Licensed Program

License No. 24-16652-02 authorizes the use of Co-60 and depleted uranium in a Picker Corporation Model 6296(C9M/80) isocentric teletherapy unit for medical use.

The radiation oncology department is staffed by approximately 4 radiation therapists, no dosimetrists, one contract physicist, one full time physician, and 1 part time physician. These individuals treat

approximately 5 to 10 patients per day using the cobalt-60 unit. The department also uses one accelerator, one superficial x-ray unit and one simulator. A treatment planning computer is in development.

On February 1, 1994, the licensee hired a full time physicist in the radiation therapy department. Currently, the licensee has requested an amendment to the license to have the physicist approved by the NRC as a teletherapy physicist. The request is under review in Region III to assess the physicist's training and experience. Licensee representatives and the physicist stated that the physicist does not perform activities with licensed materials that requires licensure such as full annual calibrations and monthly spot-checks. These activities are performed by Douglas Tai, Ph.D. who is listed as the authorized teletherapy physicist in License Condition No. 13. The licensee confirmed that Dr. Tai will continue performing these duties until an amendment is received adding the new physicist to the license.

No violations of NRC requirements were identified.

4. Misadministration Event Summary

During this routine inspection, the inspector conducted an independent evaluation of the licensee's quality management program by interviewing an authorized user, medical physicists, and radiation therapy technologists; and by reviewing 10 patient files that contain the written directives, treatment plans, and records of treatments.

During the review of one chart, the inspector identified a misadministration that had not been previously identified or reported by the licensee.

A female patient was being treated for large cell lymphoma of the left leg shin area. The written directive prescribed a tumor dose of 3000 centigray (cGy) over 15 fractions and a boost of 1000 cGy for 5 additional fractions for a total dose of 4000 cGy. The treatment set up prescribed was supine AP/PA.

The patient's first treatment occurred on Wednesday, March 16, 1994, and continued each weekday through April 5, 1994. A total of 15 fractions were delivered.

On April 6, 1994, after the delivery of fifteen fractions to this patient, the physicist discovered that the original treatment dose calculations that he performed on March 15, 1994, contained an erroneous tumor depth. As a result of the error, the midline delivered dose was 264.5 cGy per fraction rather than the prescribed dose of 200 cGy per fraction. This represents a dose increase of 32%. The error was discovered after fifteen fractions and a delivered dose of 3965 cGy. The original written directive prescribed 4000 cGy in 20 fractions. The physicist discussed the error with the prescribing physician who elected to stop the treatment immediately because the total prescribed dose had already been delivered. On or about April 6, 1994, the

physician modified the written directive in writing to prescribe 4000 cGy in 15 fractions to indicate treatment should be stopped immediately. The physician did not date the written modification. Footnote 1 of 10 CFR 35.32(a) allows physicians to modify written directives in writing provided the written directive revision is dated and signed by the Authorized User.

The error measurement of depth of the tumor occurred when the technologist who originally measured the patient for her set up entered the diameter (8.5 cm) of the shin on the simulation data sheet instead of the midline of the leg (4.25 cm). The technologist stated that the "calc depth" entry on the data sheet should be the depth of the tumor which for an AP/PA prescription would be at the midline of the treatment area. He could not explain why in this case he entered the diameter erroneously.

The administration of a teletherapy radiation dose when the calculated weekly administered dose in 30% greater than the weekly prescribed dose is defined as a misadministration in 10 CFR 35.2. In this case, the calculated weekly administered dose was 1322.5 cGy and the prescribed weekly dose was 1000 cGy. The administered dose was 32% greater than the prescribed dose. The licensee failed to recognize the error as a misadministration and, therefore, notifications and reports required were not made until the date of the inspection. Refer to Section 8 for additional information on notifications and reports.

The NRC has referred this case to an NRC consulting physician for an assessment of the health significance of the increased dose per fraction to the leg.

5. Teletherapy Misadministration Evaluation

10 CFR Part 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.

Pursuant to 10 CFR Part 35.32(a)(3), the quality management program must include written policies and procedures to meet the specific objective that final plans of treatment and related calculations for teletherapy are in accordance with a written directive.

The licensee had several opportunities to detect the error in the measurement of the tumor depth but failed to do so. As described below, two steps in the QMP were not carried out effectively and, therefore, the error was not detected as early as it could have been.

The licensee's written quality management program implemented on January 13, 1992, Item 3.3, requires, in part, that "The authorized user shall only approve treatment plans which provide sufficient information and direction to meet the objectives of the written directives."

On March 14, 1994, the licensee did not meet the specific objective that final plans of treatment and related calculations for teletherapy were in accordance with the written directive. Specifically, the authorized user approved a plan of treatment which did not provide sufficient information to meet the objective of the written directive. The authorized user failed to assure that the treatment plan was accurate with respect to the tumor depth. Approval of a treatment plan that did not provide sufficient information and direction to meet the objectives of the written directive is an apparent violation of 10 CFR 35.32(a)(3).

The licensee's typical procedures are that the technologist and the physician either simulate the patient on the simulator or place the patient on the cobalt unit to determine the treatment set up parameters. The set up information is recorded on a data sheet. While the physician does not sign or initial the sheet to indicate approval, the physician involved in this case stated that his approval was based on his physical presence during the initial set up and his discussion with and supervision of the technologist. If the physician had reviewed the information on the data sheet for accuracy, the error may have been detected before the erroneous tumor depth was used for treatment calculations. The physician stated that after this error had occurred, he now routinely reviews the treatment parameters entered onto the data sheet.

The licensee's written quality management program implemented on January 13, 1992, Item 3.8, states, in part that, "When the prescribed dose is to be administered in more than three fractions, the authorized user or qualified person under the supervision of the authorized user (radiation therapist, dosimetrist, medical physicist, radiographic technologist, licensed practical nurse) who whenever possible did not make the original dose calculation, shall have no more than three working days to check the dose calculations after administering the first teletherapy dose. Computer generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculation (e.g. patient contour, patient thickness at the central ray, depth at target, depth dose factors, treatment distance, portal arrangements, field sizes, or beam modifying factors)."

The licensee failed to verify that the correct data for the patient were used in calculations. Specifically, the medical physicist, an individual working under the supervision of the authorized user, performed a check of the dose calculations on March 17, 1994, and did not verify that the patient thickness and depth at the target were correct. Failure to verify that the correct data for the patient were used in the dose calculations is an apparent violation of 10 CFR 35.32(a)(3).

As a result of the failure, an incorrect depth was used in treatment calculations causing an incorrect treatment dose to be delivered over the next 15 treatments. Had the patient thickness and depth at the

target been verified, the error would have been detected on March 17, 1994,the second fraction, rather than on the 15th fraction. A misadminitration could have been avoided.

The immediate cause of the misadministration was an error by the technologist in recording the correct tumor depth on the treatment data sheet. The technologist stated that he did not recall the specific case and did not have an explanation as to why he entered the leg diameter instead of the leg radius. His statements clearly indicate that he understood that the calculation depth meant the tumor depth which is assumed to be the midline of the body part when the written directive stated the treatment fields to be anterior posterior/posterior anterior.

Two apparent violations of NRC requirements were identified.

6. Review of Quality Management Program and Training Program

In addition to the unrecognized misadministration, the inspector identified several other instances were the QMP was deficient and where procedures were not followed.

A. Written Directive

10 CFR 35.32(a)(1)(i) requires, in part, that each licensee establish and maintain a written quality management program which must include written policies and procedures to meet the objective that, prior to the administration, a written directive is prepared for any teletherapy radiation dose. Footnote 1 describes the procedures for modifying written directives.

10 CFR 35.2 defines a written directive for teletherapy as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiation which contains the total dose, dose per fraction, treatment site, and overall treatment period.

The licensee submitted a quality management program (QMP) to the NRC on March 29, 1993. The plan was implemented on January 13, 1992.

As of June 15, 1994, the licensee's written quality management program failed to include written procedures to meet the objective that a written directive for a teletherapy dose include the dose per fraction and the overall treatment period. As a result, the licensee did not, prior to administration of radiation, prepare complete written directives. For example, in all ten cases reviewed by the inspector, written directives did not contain the dose per fraction and the overall treatment period. Failure to include the dose per fraction and the overall treatment period in written directives is an apparent violation of 10 CFR 35.32(a)(1)(i).

The radiation safety officer/authorized user stated that in the written directive the physician does record the total tumor dose and the number of fractions and feels that this contains sufficient information for the technologist and physicist to determine the dose per fraction. In addition, the radiation safety officer stated that he was not aware that the overall treatment period was required to be included. Nevertheless, the inspector explained that the regulations do require this information to be included.

In addition to the above apparent violation, as of June 15, 1994, the licensee's written quality management program failed to include written procedures to meet the objective that written directives must be modified in accordance with the criteria contained in Footnote 1 to 10 CFR Part 35.32(a)(1). Footnote 1 states, in part, that a written revision to a existing written directive may be made for a procedure provided that the revision is dated and signed by a authorized user prior to the administration of the teletherapy dose or teletherapy fractional dose. If a delay in order to provide a written revision would jeopardize the patient's health the physician could provide an oral revision. Failure to include procedures in the QMP for assuring that written revisions to written directives are made prior to administering the revised prescription is another apparent violation of 10 CFR 35.32(a)(1)(i).

The inspector noted that the licensee does not in practice, provide written revisions to written directives before the next teletherapy fraction is delivered. Based on a review of the licensee's annual report, it appears that the licensee accepts verbal orders for written directives routinely. For example, the licensee identified during the January 5, 1993, review of its QMP, that a patient was transferred from the cobalt-60 unit to the linear accelerator based on a verbal order from an authorized user. The recommendations for corrective action was that whenever verbal orders are used to change the written directives the patient's chart should be taken to the physician so he can sign his order as soon as possible.

The licensee's assessment of the problem was that the physician was delayed in signing the verbal order after the verbal change to the written directive was executed. The licensee failed to recognize that verbal changes to the written directive should be practiced only in unusual circumstances and that under normal daily conditions the written directive must be signed prior to executing the revision. The circumstances that would allow a verbal change to the written directive occur only when the patient would be harmed by a delay that could result from the physician taking time to modify the written directive in writing prior to treatment.

At this facility, at least one authorized user is usually physically located within the department and in close enough proximity that providing a written revision to the written directive before the dose is delivered would not normally cause a delay in the treatment of the patient that would jeopardize the patient's health. Even though the change in this case involved switching the patient to the accelerator which is not regulated by the NRC, this instance demonstrates the licensee's lack of awareness of the provisions of 10 CFR 35.32 and demonstrates a potential for serious errors to made with the cobalt-60 unit.

10 CFR Part 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.

Pursuant to 10 CFR Part 35.32(a)(3), the quality management program must include written policies and procedures to meet the specific objective that final plans of treatment and related calculations for teletherapy are in accordance with a written directive.

The licensee's written quality management program implemented on January 13, 1992, Item 3.3, requires, in part, that "The authorized user shall only approve treatment plans which provide sufficient information and direction to meet the objectives of the written directives."

A review of a treatment chart revealed that on April 8, 1993, the authorized user changed a treatment plan by adding a block to a treatment field and failed to assure that the final plans of treatment and related calculations were in accordance with the written directive. Specifically, the authorized user failed to assure that new calculations for the treatment set up change were made. As a result, treatment calculations for the revised treatment set up were not completed until 8 fractions later on April 19, 1993. The failure to assure that the related calculations were performed after the plan of treatment was revised (adding a block) is an apparent violation of 10 CFR 35.32(a)(3).

Based on discussions with the medical physicist, it appears that neither a recordable event or a misadministration resulted from the failure to immediately revise the dose calculations, because the difference between the calculated dose and the prescribed dose was less than 10%. However, the violation is significant in that it is another example of the licensee's failure to strictly adhere to the QMP procedures which are designed to assure the accuracy of delivered doses.

B. Chart Checks

10 CFR Part 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.

Pursuant to 10 CFR Part 35.32(a)(3), the quality management program must include written policies and procedures to meet the specific objective that final plans of treatment and related calculations for teletherapy are in accordance with a written directive.

The licensee's written quality management program submitted on March 29, 1993, Item 3.7, states, in part that, "A weekly chart check shall be performed by a qualified person under the supervision of an authorized user (radiation therapist, dosimetrist, radiographic technologist, licensed practical nurse) to detect mistakes (e.g. arithmetic errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative teletherapy dose administrations from all treatment fields or in connection with any changes in the written directives or treatment plan."

During review of the patients' charts, the inspector noted that from September 10, 1993 through September 30, 1993, a patient was given 13 radiation therapy dose fractions and the licensee failed to perform weekly chart checks. In addition, August 4, 1993, through August 13, 1993, a patient received 8 teletherapy dose fractions and the licensee failed to perform a weekly chart check until August 13, 1993. Further, a patient received 5 treatments from April 12 through 16, 1993 and a weekly chart check was not completed. Failure to perform a weekly chart check is an apparent violation of 10 CFR 35.32(a)(3).

The inspector noted that prior to the arrival of the full time physicist in February 1994, the licensee routinely did not perform the weekly chart checks. Chart checks were performed by the contract physicist during his visits to the hospital approximately once every two to three weeks. Apparently, the reason the weekly chart checks were not performed was due to insufficient staff. The licensee, prior to February 1994, had 4 technologists, two physicians and one contract physicist. The licensee stated that as corrective actions to the previous situation, they hired the full time physicist. The inspector reviewed several charts for 1994 and did not find any examples were the weekly chart checks were not performed.

C. QMP Evaluations of Unintended Deviations

10 CFR Part 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.

Pursuant to 10 CFR Part 35.32(a)(5), the quality management program must include written policies and procedures to meet the specific objective that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

As of June 15, 1994, the licensee's quality management program did not contain written policies and procedures to meet the specific objective that any unintended deviation from the written directive is evaluated and the appropriate action is taken. In addition, an unintended deviation from the written directive was identified by the physicist and authorized user on April 6, 1994, and was not correctly evaluated and was not correctly characterized as a misadministration. Failure to include written policies and procedures to evaluate unintended deviations from the written directive is an apparent violation of 10 CFR 35.32(a)(5).

The misadministration occurred from March 16, 1994 through April 5, 1994. On April 6, 1994, the medical physicist discovered the unintended deviation from the written directive. The physicist discussed the error with the authorized user/RSO. However, neither the physicist nor the authorized user/RSO recognized that a misadministration had occurred until the inspector identified it during the inspection. The authorized user stated that on April 6, 1994, he reviewed the unintended deviation and concluded that a misadministration had not occurred because the total dose delivered to the patient (3965 cGy) was within 20% of the total prescribe dose of 4000 cGy. He stated that he was not aware that when the weekly administered dose is 30% greater than the weekly prescribed dose a misadministration has occurred.

D. Training in QMP

10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall instruct the supervised individual in the licensee's written quality management program.

The inspector learned through interviews that as of June 14, 1994, the licensee did not instruct a medical physicist in the licensee's written quality management program. Failure to instruct an individual in the written quality management program is an apparent violation of 10 CFR 35.25(a)(1).

Interviews with the physicist indicated that he was generally knowledgeable regarding the broader aspects of the 10 CFR 35.32 regulations, however, he stated that he had never seen or read the licensee's QMP since the beginning of his employment on February 1, 1994.

The physicist's duties include intimate involvement in treatment planning, simulations, dose calculations, and chart checks. It is imperative that he have a complete understanding of the exact provisions of the licensee's QMP in order to carry out his duties in an effective and compliant manner. The inspector confirmed that the physicist read the licensee's QMP and has become familiar with the policies and procedures following the inspection.

Six apparent violations of NRC requirements were identified.

7. Other Teletherapy Program Areas

The inspector performed an inspection of the routine aspects of the teletherapy program in accordance with the procedures contained in NRC Manual Chapter 87100, Appendix A. Several violations were identified.

10 CFR 35.632(b)(4) requires that full calibration measurements performed on each teletherapy unit include determination of timer constancy and linearity over the range of use.

10 CFR 35.634(a)(1) requires that a licensee perform output spot-checks once in each calendar month that include determination of timer constancy, and timer linearity over the range of use.

The inspector reviewed records of the full annual calibration and records of spot-checks and interviewed the teletherapy physicist who performed these tests. The inspector observed that the annual full calibration measurements performed on the licensee's teletherapy unit on March 12, 1994, and as of June 15, 1994, spot-checks performed monthly did not include a determination of timer constancy and linearity over the licensee's full range of use, 45 seconds to 3 minutes. Failure to determine timer constancy and linearity on an annual and monthly basis is an apparent violation of 10 CFR 35.632(b)(4) and 10 CFR 35.634(a)(1).

The teletherapy physicist stated that he was not aware of the requirement to perform timer constancy and linearity and therefore, overlooked performing the tests.

He stated that he would begin testing these items. Tests on the cobalt-60 unit performed after the inspection revealed that the timer constancy and linearity were within accepted ranges. Therefore, there does not appear to be an immediate safety problem with the unit at this time. However, tests must be performed as required to assure that the unit continues to operate within acceptable parameters.

10 CFR 35.632(b)(3) requires that full calibration measurements performed each teletherapy unit include determination of the uniformity of the radiation field and its dependence on the orientation of the useful beam.

The inspector reviewed the records of full annual calibrations and interviewed the teletherapy physicist and determined that, the annual full calibration measurements performed on the licensee's teletherapy unit on March 12, 1994, did not include a determination of the uniformity of the radiation field and its dependence on the orientation of useful beam. Failure to determine the uniformity of the radiation field and its dependence of the orientation of the useful beam is an apparent violation of 10 CFR 35.632(b)(3).

The teletherapy physicist stated that this test was not done because the licensee lacked the necessary equipment (such as a densitometer) to be able to analyze the test results. He stated that he did not have the equipment available to him.

A uniformity test performed by the teletherapy physicist after the inspection revealed that the beam is uniform in the orientations used during clinical practice. Therefore, at this time the safety significance appears to be minimized, however, as required the test must be performed annually to assure proper operation of the teletherapy unit.

10 CFR 35.634(d)(1) requires that a licensee authorized to use a teletherapy unit for medical use perform monthly safety spot-checks on each teletherapy unit that assure proper operation of electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism).

Based on a review of spot-check records and statements made by the teletherapy physicist, the inspector determined that, from December 1993 to May 1994, the licensee's monthly safety spot-checks on its teletherapy unit did not assure the proper operation of electrical stops that limit the primary beam of radiation to the beam stopper by testing the operation of the on-off mechanism. Failure to test the operation of the electrical stops that limit the primary beam to the beam stopper is an apparent violation of 10 CFR 35.634(d)(1).

During the inspection, the inspector tested that operation of the electrical stops and observed that when the beam was directed away from the beam stopper the source could not be exposed. Licensee representatives stated that the indicator light on the gantry is tested to assure that it goes out when the beam is directed away from the beam stopper, however, they admitted that they have not tested the electrical stop by attempting to turn the machine on in that orientation.

Three apparent violations of NRC requirements were identified.

8. Notifications and Reports

10 CFR 35.33(a) require, in part, that when a misadministration involves any therapy procedure, the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the misadministration and requires that a written report be submitted within 15 days.

The misadministration was discovered by the inspector during the inspection on June 15, 1994, at approximately 2:30 p.m. The inspector informed the authorized user/RSO immediately. At 3:11 p.m. (CDT) on June 15, 1994, the licensee notified the NRC Operations Center that a misadministration had occurred.

The inspector verified with the referring physician that on June 15, 1994, the treating physician informed him (the referring physician) about the error in treatment.

The treating physician stated that at the time the unintended deviation was discovered on April 6., 1994, he informed the patient verbally that her treatment was stopped early because she had received a higher dose per fraction. The treating physician also informed the patient's daughter on June 15, 1994, and he stated that a letter will be sent to the patient explaining the circumstances.

The licensee submitted a written report to Region III dated June 22, 1994. A review of the written report indicated that all required items were addressed.

No violations of NRC requirements were identified.

9. Exit Meeting

During the exit meeting with those individuals identified in Section 1 of this report, the inspector and section chief summarized the preliminary inspection findings including the violations and the apparent causes. The section chief also described the NRC's enforcement options. The licensee identified the patient's name as personal privacy information. The licensee did not indicate that any information was proprietary.