ENCLOSURE 2

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-22280
License No.:	04-00181-12
Report No.:	030-22280/97-01
Licensee:	Department of Veterans Affairs Medical Center
Facility:	V.A. Medical Center West Los Angeles
Location:	11301 Wilshire Boulevard Los Angeles, California 90073
Dates:	September 3 through October 15, 1997
Inspector:	Mark R. Shaffer Senior Radiation Specialist
Approved By:	D. Blair Spitzberg, Ph.D., Chief Nuclear Materials Inspection and Fuel Cycle/Decommissioning Branch
Attachments:	1. Supplemental Inspection Information 2. Sequence of Events 3. NRC Medical Consultant's Report

EXECUTIVE SUMMARY

Department of Veterans Affairs Medical Center
NRC Inspection Report 030-22280/97-01

This was a reactive, announced inspection of licensed activities involving the use of cobalt-60 in a teletherapy unit. The inspection was limited to the review of a medical misadministration which occurred on August 26, 1997, involving irradiation of a wrong treatment site. The inspection was focused on the misadministration, the direct and contributing cause(s), the licensee's quality management program (QMP) and its implementation, and licensee oversight of use of byproduct material for teletherapy treatments.

Background Regarding Notification Of The Misadministration

- On August 26, 1997, while setting up treatment parameters, a licensee authorized user physician (AU) misread a patient's body treatment markings (tattoos) causing a 10 centimeter teletherapy beam misalignment, resulting in a delivered dose of approximately 300 centigray (cGy) to a wrong treatment site. A teletherapy radiation dose involving the wrong treatment site is a reportable misadministration as defined by 10 CFR 35.2 (Section 2).

Direct Cause

- The direct cause of the misadministration was determined to be the improper alignment of the radiation beam field by an authorized user (Section 3).

Contributing Cause(s)

- The inspection disclosed three issues which may have contributed to the misadministration. These contributing causes included: (1) reduced staffing level within the radiation therapy department on the day of the incident which resulted in the AU performing patient preparation and treatment activities normally performed by radiation therapists who were absent the day of the incident; (2) the failure of the treatment operator to review the patient's port and/or simulation films to verify the proper treatment site prior to beginning the treatment; and (3) the lack of clear and consistent departmental policies regarding treatment site tattoo markings (Section 4).

Root Cause(s)

- The inspection disclosed one issue which appeared to be a root cause of the misadministration. The root cause was identified as the failure on the part of the treatment operator to seek guidance, and not continue the treatment, when he had doubts regarding the correct treatment site during the set-up phase of the treatment (Section 5).

Consequences

- The licensee's assessment of the misadministration revealed that the additional dose would have no clinical significance and no adverse effects to the patient (Section 6).

- The NRC medical physician consultant contracted to review this misadministration issued a report dated September 12, 1997, which states that, "based on all available information, no injury or potential harm is expected in this patient (Section 6)."

Regulatory Issues

- A violation of 10 CFR 35.32 was identified involving the failure of an authorized user to follow procedures outlined in the licensee's written QMP which directly contributed to the misadministration (Section 7).

Licensee Corrective Actions

- On September 10, 1997, the licensee forwarded its written report of the misadministration to NRC. The report indicated that, as a result of the misadministration, the licensee intends to revise its QMP to clarify procedures which appear to have contributed to the incident (Section 8).

Report Details

1 Program Overview (83822, 87100, 87103)

1.1 Inspection Scope

The inspector reviewed the license application, supporting documents, and other records maintained by the licensee. Collectively, these documents describe the licensee's radiation safety program. Interviews with licensee personnel were also conducted.

1.2 Observations and Findings

The Department of Veterans Affairs Medical Center West Los Angeles (VALA) is authorized under NRC License 04-00181-12 to use a Theratron Model 780 teletherapy unit for patient treatments.

Teletherapy treatment procedures had been performed under the direction and supervision of the Chief, Radiation Therapy Service (CRTS), who is also the licensee's radiation safety officer (RSO). The radiation therapy service had been staffed by four physician authorized users (AU), two full-time teletherapy physicists, two full-time radiation therapists and one radiation therapist who worked part-time on a contractual basis. The licensee had performed approximately 15 patient treatments each day using the Theratron unit. The VALA also possesses a linear accelerator (not under NRC jurisdiction) which was used to treat an average of 15-20 patients each day.

2 Background (83822, 87100, 87103)

The licensee's teletherapy physicist reported that a misadministration occurred on August 26, 1997, involving irradiation of a wrong site during a procedure performed using the licensee's cobalt-60 teletherapy unit. On August 26, 1997, while setting up treatment parameters, one of the licensee's AUs misread a patient's tattoos causing a 10 centimeter teletherapy beam misalignment, resulting in a delivered dose of approximately 300 cGy to the wrong site (lower thoracic spine area). Due to the misalignment, an equal area of the original intended treatment site received 300 cGy less than intended. The AU performed a second treatment on the patient on the afternoon of the 26th and successfully completed delivery of the intended dose prescribed in the written directive.

The original written directive prescribed a palliative dose of 3,000 cGy to a portion of the patient's thoracic spine to be delivered as 10 fractions of 300 cGy each over a two week period. The treatment field size was defined as a 8 x 19.5 centimeter (cm) area with a source to skin distance of 80 cm. The treatment fraction performed on the 26th was the ninth fraction. The patient returned on August 27, 1997, and received the tenth and last

treatment fraction resulting in a total delivered dose of 3,000 cGy to the intended treatment site as specified in the written directive.

Based on the information discussed above, the inspector was dispatched to VALA on September 3, 1997, to begin a reactive inspection of licensed activities, with primary emphasis on the circumstances surrounding the reported misadministration. The sequence of events leading to the misadministration is described in detail in Attachment 2 of this report.

3 Direct Cause (87103)

3.1 Inspection Scope

This portion of the inspection included interviews with VALA personnel, and a review of: (1) the department's policies and procedures for treatment planning; (2) the licensee's written QMP; and (3) the affected patient's treatment chart including the computer treatment plan, written directive, simulation film and port film.

3.2 Observations and Findings

For the purpose of this report, a direct cause is defined as the action or failure that led directly to the incident, without any additional intervening action or failure.

The inspection identified the direct cause of the misadministration to be the improper alignment of the radiation beam field by an AU. Specifically, the AU, who was the teletherapy treatment machine operator in this case, misread the patient's tattoos, and incorrectly aligned the center of the radiation beam field on a tattoo which was actually in place to denote the inferior border of the intended treatment field.

The intended treatment field size was 8 x 19.5 cm. The misalignment resulted in the inferior half of the intended treatment field receiving the correct dose of 300 cGy; however, the superior half of the intended field did not receive any treatment as a result of the misalignment. Additionally, an area equal to one half of the field size (8 x 9.75 cm) located below the inferior border of the intended treatment field received a dose of 300 cGy.

3.3 Conclusions

The direct cause of the misadministration was the improper alignment of the radiation beam field by an AU.

4 Contributing Causes (87103)

4.1 Inspection Scope

This portion of the inspection included interviews with VALA personnel, and review of: (1) the department's policies and procedures for treatment planning; (2) the licensee's written quality management program; and (3) the patient's treatment chart including the computer treatment plan, written directive, simulation film and port film.

4.2 Observations and Findings

For the purpose of this report, contributing causes are those conditions and/or events which, in combination with the root causes, increase the severity of the consequences of a mishap or otherwise change the outcome of the mishap. The contributing causes identified during this inspection may not have, in themselves, necessarily led to the alignment error, since a trained and attentive operator who had previously treated the patient would have likely known where to center the radiation beam. However, the existence of these factors at the time of this particular treatment made it more likely an error would occur, and hence may be contributing causes of the misadministration.

a. Reduced Staffing Levels on Day of Incident

As noted in Section 1, at the time of the inspection, the licensee employed two full-time therapists and utilized the services of a part-time therapist on a contractual basis. However, the inspector was informed that this staffing level was far less than desirable to accommodate the department's workload. In fact, until approximately 4 months before this incident, the department had employed four full-time therapists to perform the same number of patient treatments each day. The inspector was informed that two of the licensee's former therapists left the employ of the licensee and that these vacancies had not yet been filled, although the number of patient treatments had not declined.

Although the staff therapists had routinely been the only individuals to perform patient treatments, there had been some occasions when AUs were required to perform a teletherapy treatment without the assistance of a therapist; this occurred if an emergency procedure was required during evening hours or on weekends. The CRTS stated that this was an infrequent circumstance and occurred an average of once or twice each 6 months. Additionally, due to the reduced staffing level during the past several months, AUs have also been required to perform treatments on patients during days when one of the therapists was unavailable (due to sick leave, etc.). This occurred an average of once or twice each month.

Although AUs are trained and authorized to perform teletherapy treatments, AUs do not normally perform these treatments and are not as proficient at operating the treatment equipment as are therapists. Additionally, when an AU was required to perform

treatments on days when a therapist was out sick, the AU usually had other clinical support duties (patient exams, medical rounds, etc) which could have diverted the AU's attention.

b. Failure to Review Simulation Films and/or Port films Prior to Setting Up and Performing a Teletherapy Treatment

The AU performed a teletherapy treatment procedure and did not utilize a simulation or port film to verify the proper treatment site prior to initiating the procedure. Specifically, a simulation film, a port film, and Polaroid photograph of the port film was taken, but none of these films were reviewed until after the therapy treatment was underway. Although the AU had viewed the simulation and port films on the first day of treatment 13 days prior, the AU acknowledged that he should have reviewed these films immediately prior to the treatment. Interviews with each staff member who performed treatments, including the AU, confirmed that, at a minimum, it is expected that an operator review all necessary documents (simulation and port film, written directive, computerized treatment plan, etc.) before performing a treatment on a patient for the first time and during subsequent treatments until the operator is familiar with all treatment parameters. As this was the first time the AU had performed a teletherapy treatment on the patient, it was expected that he review the necessary documents prior to beginning the procedure. This expectation is also outlined in the licensee's QMP procedures which specify that, "the person administering the teletherapy treatment must verify agreement with the written directive and the plan of treatment with that of the treatment site and dose per fraction and method of treatment by reviewing the calculations along with the written directives and any computer treatment plans, and comparing that with the simulation films for the same patient." Although this section of the QMP refers mainly to the verification of computer treatment plans, the CRTS did inform the inspector that it is expected that a treatment operator review a patient's simulation and port films prior to the first treatment and thereafter until the operator becomes familiar with the proper set-up.

The AU did view the films when initially taken 13 days prior to the misadministration, but the failure to review these films immediately prior to the treatment was identified as a contributing cause of the misadministration.

c. Lack of Clear and Consistent Department Policy Regarding the Minimally Expected Tattoo Marking for Various Treatment Sites

The AU stated that during treatment set-up he noted only one tattoo on the patient's spine. He incorrectly assumed that the tattoo represented the center of the treatment field. After performing the treatment and upon re-examining the patient, the AU noted that the patient actually had two tattoos placed at the treatment site; one to denote the center and one to denote the inferior border of the treatment field. Although it is likely that the AU would have recognized that two tattoos were in place had he been more attentive to details of the treatment set-up parameters, the lack of clear and consistent guidance regarding the minimum acceptable number of tattoos may have led to the

confusion. Regardless of the number of tattoos to be placed, had a clear policy been in place to inform all treatment operators of the minimally acceptable (expected) number and placement of tattoos, the AU may have had a more questioning attitude when he observed fewer tattoos than expected.

The inspector's interviews with staff members disclosed that within the past year, during a radiation therapy staff meeting, the issue of tattoos was discussed in detail. Specifically, the issue of the minimum acceptable number of tattoos to be placed on a treatment field involving the spine was debated among the staff. Expectations for minimal tattoos ranged from only one tattoo to denote the center of the field to as many as five. Interviews with the CRTS disclosed that he expected a minimum of three tattoos. However, the discrepancy between staff members regarding the number of "required" tattoos for a treatment site was never resolved, and the expectation of the CRTS was never formalized in either a written, or un-written, department policy. The lack of a clear and consistent policy regarding the minimum expectation of tattoo markings used to identify the appropriate treatment site was identified as a contributing cause of the misadministration.

4.3 Conclusions

The inspection disclosed three issues which may have contributed to the misadministration. These contributing causes included: (1) reduced staffing level within the radiation therapy department on the day of the incident; (2) the failure of the treatment operator to review the patient's port and/or simulation films to verify the proper treatment site prior to beginning the treatment; and (3) the lack of clear and consistent departmental policies regarding treatment site tattoo markings.

5 Root Cause(s) (87103)

5.1 Inspection Scope

This portion of the inspection included interviews with VALA personnel, and a review of: (1) the department's policies and procedures for treatment planning; (2) the licensee's written quality management program; and (3) the patient's treatment chart including the computer treatment plan, written directive, simulation film and port film.

5.2 Observations and Findings

For the purpose of this report, root cause(s) are defined as the reasons which by themselves or in combination lead to the occurrence of a mishap.

The failure on the part of the treatment operator (AU) to seek guidance, and not continue the treatment, when he had doubt regarding the correct treatment site during the set-up

phase of the treatment was identified as the probable root cause of the misadministration.

Interviews with the AU who treated the patient disclosed that during set-up of the patient, he had doubts regarding the correct treatment site. The AU stated that while aligning the radiation beam, he noted only one tattoo on the patient's thoracic spine area although he expected to see more. Specifically, the AU stated that he expected to see three tattoos to denote the treatment site of a spinal treatment; one placed at the superior border, one placed at the inferior border, and one placed at the center of the treatment site. The AU further stated that at a minimum he would expect to see at least two tattoos; one denoting the center and the other denoting the inferior border of the treatment area. However, rather than seeking positive confirmation of the correct beam position, by asking the radiation therapist for help and/or by reviewing the simulation film, the AU positioned the radiation beam without confirmation and began the teletherapy treatment.

As noted in Section 4, the AU did not review the simulation and port films until he returned to the control console, and after he had begun the treatment. It was at this time that he realized that the radiation beam may have been misaligned. However, by this time, the treatment fraction was nearly complete. Immediately following the treatment, the AU entered the treatment room, examined the patient, and confirmed that he had misaligned the radiation beam. The inspector determined that it is likely that the misadministration would not have occurred had the AU sought positive guidance when he had some doubt regarding the correct position of the radiation beam, and prior to commencing the treatment.

5.3 Conclusions

The inspection disclosed one issue which appeared to be a root cause of the misadministration. The root cause was identified as the failure on the part of the treatment operator to seek guidance, and not continue the treatment, when he had doubt regarding the correct treatment site during the set-up phase of the treatment.

6 Consequences (83822, 87103)

6.1 Licensee's Assessment of Consequences

The licensee's written report of the misadministration, pursuant to 10 CFR 35.33(a)(2), was received by NRC on September 15, 1997. The report contained the information required to meet the reporting requirements and provided information gathered by the licensee during its investigation of the incident, including contributing causes and corrective actions. Additionally, the report stated that according to the referring physician, the AU and the CRTS, the additional dose received by the patient was of no clinical significance and should not have adverse effects on the patient.

6.2 NRC Medical Physician Consultant's Review

On September 2, 1997, NRC contracted a medical physician consultant to: (1) provide an estimate of the radiation dose to the patient and the probable error associated with the estimation of the dose; (2) assess any probable deterministic effects on the patient; (3) evaluate the promptness and effectiveness of the licensee's immediate actions in response to the incident and corrective actions taken or planned to prevent recurrence; and (4) evaluate the licensee's notification to the patient and referring physician. The consultant's review consisted of an on-site visit conducted on September 10, 1997, to perform interviews with the AU involved with the medical event and to review the patient's medical records, departmental policies and procedures, and the licensee's investigation report of the incident.

The consultant's report was received by NRC on September 16, 1997, and indicated that no injury or potential harm was expected as a result of the misadministration. Additionally, the consultant's report noted that: (1) "it is contrary to good medical practice not to check port films prior to the administration of an actual treatment to a patient;" (2) "it is not a recommended practice of medicine to have even fully qualified physicians to occasionally, but routinely, treat patients with external beam radiotherapy;" and (3) "a physician should always be present during such treatments but only in a supervisory capacity."

The consultant's review and recommendations concerning the incident is provided as Attachment 3 to this report.

7 Regulatory Issues (87100)

7.1 Inspection Scope

This portion of the inspection included interviews with VALA personnel and a review of: (1) the department's policies and procedures for treatment planning; (2) the licensee's written quality management program; and (3) the patient's treatment chart including the computer treatment plan, written directive, simulation film and port film.

7.2 Observations and Findings

10 CFR 35.32(a) requires, in part, that the licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. Pursuant to 10 CFR 35.32(a)(4), the quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with a written directive, which is defined in 10 CFR 35.2.

The licensee's written quality management program dated May 8, 1996, page 13, Section D, requires that "the person administering the teletherapy treatment must verify agreement with the written directive and plan of treatment with that of the treatment site...and comparing that with the simulation films for the same patient;" and Section E specifies that "the policy for all workers is to seek guidance if they do not understand how to carry out the written directive...that is, workers must ask if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt."

As noted in Sections 4 and 5 on August 26, 1997, prior to performing a teletherapy treatment, the AU did not review the simulation film for the patient to be treated. Further, during the set-up phase of the treatment the operator was uncertain about the correct positioning of the radiation treatment field, but failed to ask questions about what to do or how it should be done, and he continued the procedure when there was doubt. This was identified as a violation of 10 CFR 35.32(a)(4) (030-22280/9701-01).

7.3 Conclusions

A violation of 10 CFR 35.32(a)(4) was identified regarding the failure of an AU to follow the licensee's QMP procedures, which resulted in a teletherapy misadministration.

8 Licensee Corrective Actions (87100)

8.1 Inspection Scope

The inspector's review of this area included interviews with licensee personnel, a review of the departmental policies and procedures, and a review of the licensee's written report of the misadministration dated September 10, 1997.

8.2 Observations and Findings

The licensee's written report indicated that corrective actions and improvements will be implemented to prevent recurrence of this type of incident, including a revision to the QMP to clarify that: (1) the simulation films and photographs of the patient's port must be reviewed prior to the first time a therapist or physician treats a patient and prior to any subsequent treatments of the patient if there has been a change in the prescription; (2) even after familiarization with the treatment setup parameters, during subsequent patient treatments (treatment fractions) the operator must still review the photographs of the patient's port to confirm the treatment site; (3) if any ambiguity remains in the operator's mind regarding patient set-up, the operator will consult the physician or therapist already familiar with the patient's set-up and will not treat until there is confirmation of the set-up. In addition to modifying the QMP, a procedure will be established for the number of tattoos and where anatomically on the patient the tattoos are placed for reference which will be used for set-up by the treatment operator. Documentation will be placed in the patient's chart when the number of tattoos or anatomical location differs significantly from

the set procedure. The licensee committed to discuss the misadministration with the entire radiation therapy staff by October 10, 1997.

8.3 Conclusions

The licensee's corrective actions noted above appear to address the concerns identified during this inspection and, if properly implemented, will likely prevent a recurrence of this type of incident.

ATTACHMENT 1

PARTIAL LIST OF PERSONS CONTACTED

Licensee

* A. Sadeghi, M.D., Chief, Radiation Therapy Service and RSO
  B. Jabola, M.D., Authorized User
* B. Krutoff, Teletherapy Physicist
  N. McCreary, Teletherapy Physicist
  P. Robertson, Radiation Therapist
  R. Weaver, Radiation Therapist
  O. Turner, Radiation Therapist
  D. Norman, M.D., Chief of Staff
* P. McIntyre, Administrative Assistant to the Chief of Staff
* E. Liedholdt, Jr., Ph.D., VA Western Region Program Manager

NRC

* Mark Shaffer, Senior Radiation Specialist
* D. Blair Spitzberg, Ph.D., Chief, Nuclear Materials Inspection & Fuel Cycle Decommissioning Branch
  Zbigniew Petrovich, M.D., Medical Physician Consultant

* Indicates those individuals who participated in the final telephonic exit briefing conducted on October 15, 1997.

INSPECTION PROCEDURES USED

83822 Radiation Protection
87100 Licensed Materials Programs
87103 Inspection of Incidents At Nuclear Materials Facilities

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-22280/9701-01	VIO	Failure of an AU to follow procedures outlined in the licensee's QMP required by 10 CFR 35.32 which directly contributed to a misadministration.

Closed
None

Discussed
None

LIST OF ACRONYMS USED

AU	authorized user
cGy	centigray
CFR	Code of Federal Regulations
cm	centimeter
CRTS	Chief, Radiation Therapy Service
NRC	Nuclear Regulatory Commission
QMP	quality management program
RSO	radiation safety officer
VALA	Department of Veterans Affairs Medical Center, West L s Angeles

ATTACHMENT 2

SEQUENCE OF EVENTS

- On August 12, 1997, the patient was referred to radiation therapy for consultation and treatment for a developing spinal cord compression.

- On August 12, 1997, the patient was seen by a VALA physician AU within the radiation therapy service, and a written directive was prepared. The AU prescribed a total of 3,000 cGy to be delivered in 10 fractions (300 cGy each) over a 2-week period.

  Following the AU's determination of the dose to be delivered, the physics staff prepared a computerized treatment plan, a simulated treatment was performed to obtain treatment parameters, and a port film was taken to verify the simulation. A staff radiation therapist performed the simulation and port films; however, the AU was physically present and worked with the therapist to denote the desired treatment site, and outline the treatment field borders with violet ink. After the field borders were outlined, a Polaroid film of the site was taken and placed in the patient's treatment chart.

- On the morning of August 13, 1997, the patient arrived at the therapy department, and a therapist placed two tattoos on the patient's spine; one to denote the center of the treatment field and another to denote the inferior border of the treatment field. Following placement of the tattoos, the first of 10 treatment fractions was delivered. Treatment was performed by a radiation therapist.

- On August 14, 15, and 18-22, one treatment fraction was delivered each day. These treatments were performed by a radiation therapist.

  [Note that each of the eight treatments noted above were performed by the same individual.]

- On the morning of August 23, 1997, one of licensee's two therapists notified the licensee that he would need to take sick leave for the day. This left only one therapist to perform patient treatments. The one remaining therapist was assigned to operate the licensee's linear accelerator, and staff AUs were assigned to operate the cobalt-60 teletherapy unit on an "as-needed" basis. Due to type of treatment for the above referenced patient, and the clinical importance of administering a treatment each day, the AU decided to treat the patient himself.

  [Note that the remaining therapist was the same individual who performed the initial set-up (simulation, port films, tattoos), and administered each of the eight treatments to date.]

- At approximately 9:30 a.m. on August 26, 1997, the patient arrived at the therapy department and was escorted by the AU to the treatment room. Upon a brief examination of the patient, the AU aligned the center of the radiation beam on a tattoo on the patient's spine that he believed was denoting the center of the treatment field.

[Note that at this point, the AU noticed only one tattoo marking on the patient. Although he expected to see at least three tattoos denoting the treatment field, he did not question the therapist about the presumed omission and he continued to set the radiation beam.]

Interviews with the AU disclosed that he set-up some of the treatment parameters prior to the patient's arrival. The AU stated that he did review the written directive to obtain the field size (8 x 19.5 cm) and the source to skin distance (80 cm), and set these parameters on the machine prior the patient's arrival; however, he did not review the simulation film, port film or photograph of the port prior treating the patient. Although he was present during the simulation two weeks before, he admitted that written departmental procedures and good medical practice dictates that a treatment operator review simulation or port films immediately prior to administration of a treatment.

- At approximately 9:45 a.m. the treatment was initiated. The treatment time was set for 3.52 minutes. During the 3.52 minutes of treatment, the AU began to question the beam alignment. He then began to review the patient's treatment chart in detail to confirm the correct treatment site. This review included viewing the simulation and port films of the treatment site.

  [Note: When questioned as to why he thought to review the chart during treatment, the AU informed the inspector that he had some doubt regarding the treatment field position and number and placement of tattoos while he was setting up for the treatment. However, the AU did not ask the therapist what to do or how it should be done before continuing the treatment.]

- At approximately 9:50 a.m., upon completion of the treatment, the AU entered the treatment room, and re-examined the patient. During re-examination of the patient, the AU observed two tattoo markings on the patient, one at the center of the treatment site and one at the inferior border of the treatment site. It was at this time that the AU affirmed that he had misaligned the radiation beam. After confirming the error, the AU released the patient and informed him that he may need to return later in the day for "re-treatment".

- At approximately 10 a.m., the AU informed one of the licensee's physicist of the error. The physicist discussed the incident with the licensee's other physicist who, in turn, notified the CRTS. The CRTS was on annual leave on the day of the incident but was notified telephonically.

  The CRTS instructed the staff to have the patient return so that the superior portion of the intended treatment site could be treated.

- Following discussions with the CRTS, the physics staff performed a "gap calculation" to determine the size of the field required to treat the upper half of the treatment field which did not receive radiation as a result of the misalignment.

- At approximately 1:20 p.m. on August 26th, the patient was re-treated, receiving 300 cGy to the upper portion of the original treatment site.

- On the afternoon of the 26th, the licensee's physicist contacted the NRC Region IV Walnut Creek Field Office to discuss the incident and ask for clarification as to whether the incident constituted a misadministration. The licensee was informed that NRC staff would review the details of the incident and contact the licensee as soon as a determination was made.

- On the morning of August 27, 1997, NRC contacted the licensee to inform the staff that the misalignment of the radiation beam, causing a dose of 300 cGy to an unintended treatment site, did constitute a misadministration as defined in 10 CFR 35.32.

  Following the discussion with Region IV, the licensee telephoned the NRC Operations Center and reported the incident as a misadministration as required by 10 CFR 35.33(a).

- Also on August 27th, the tenth and final treatment fraction was delivered. Treatment was performed by a radiation therapist.

- On August 29, 1997, the CRTS informed the patient and his referring physician that the misadministration took place and that clinically there would be no significant effects from the error.

- On September 3, 1997, Region-IV dispatched an inspector to the VALA to begin a reactive inspection of the incident.

USC
UNIVERSITY
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CALIFORNIA

ATTACHMENT 3

September 12, 1997

Ellis W. Merschoff
Regional Administrator
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

School of Medicine

Department of Radiation Oncology

Zbigniew Petrovich, M.D., F.A.C.R.
Professor and Chairman

Re: Teletherapy Misadministration at West Los Angeles Medical Center, Los Angeles, California.
Dockets: 03022280 License No: 04-00181-12

Dear Ms. Merschoff:

This is a report on the above incident at West Los Medical Center which is based on information directly obtained from the licensee during a site visit on September 10, 1997.

The events of August 26, 1997 are accurately represented in your letter of August 28, 1997 and in the letter from VA Medical Center West Los Angeles to the Commission of September 10, 1997 (copy is enclosed).

Patient is a 70 year old male who had original diagnosis of adenocarcinoma of the prostate made in an outside medical center in 1989. He was treated with prostatectomy followed by a course of postoperative pelvic irradiation. A total radiation dose was 67 Gy. No details regarding radiotherapy technique used in the treatment of this patient is available at the present time. As far as it can be determined, patient developed signs of metastatic disease in April 1996. He was treated with bilateral orchiectomy and responded well to this therapy. In the Summer of 1997, patient developed progressively severe back pain. An imaging study has demonstrated gross tumor involvement of multiple thoracic vertebral bodies particularly T3, T4 and T8. There was no evidence of spinal cord compression. Patient has had a long history of hypertension and type II diabetes mellitus.

Due to severe back pain patient was began on a palliative course of external beam radiotherapy with the cobalt-60 beam. A total planned radiation dose was 30 Gy given in 10 equal fractions of 3 Gy each. Dr. Benjamin R. Jabola, who is the patient's radiation oncologist treated this patient himself out of compassion. Because of a severe shortage of radiation therapist (technologists) in Veteran Administration West Los Angeles Medical Center if not for Drs. Jabola's action patient could not have received his radiation treatment. The physician, however, did not follow the well established procedure and proceeded to treat the patient without proper identification of the treated field. The error, however, was promptly recognized by that physician and only a single dose of 3 Gy was given to the approximately 50% of the prescribed volume. As a result about 10 cm length of the lower thoracic and upper lumbar spine received 3 Gy.

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Comments

1. It is contrary to good medical practice not to check port films prior to the administration of actual treatment to a patient. In this particular case the explanation is difficult to find since Dr. Jabola himself simulated the treatment of this patient.

2. Based on all available information, no injury or potential harm is expected in this patient with advanced metastatic disease.

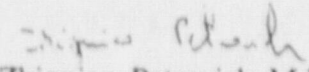
3. Based on the review of radiation safety and quality assurance records in this VA Radiation Oncology Service the above misadministration is highly unlikely to be repeated in the future.

4. It is not a recommended practice of medicine to have even fully qualified physicians to occasionally but routinely treat patients with external beam radiotherapy. Annual in-service sessions as conducted at the above medical center are not enough to maintain physician expertise. This consultant strongly believes that only fully qualified radiation technologists should routinely treat patients with external beam radiotherapy. It is difficult to accept a statement that no such persons are available in the Los Angeles area. In fact one could find several such persons even on a short notice. Furthermore, the medical center administration should provide funds to allow the therapists-technologists to be on call instead of requiring physicians to treat patients after regular work hours. A physician should always be present during such treatments but only in a supervisory capacity.

5. During this site visit I have found that while external beam radiotherapy with the cobalt-60 beam is under the jurisdiction of US NRC, linear accelerator generated external beam radiotherapy does not have any agency supervising its quality or safety. NRC is ideally suited to assume this responsibility in Federally controlled medical centers.

Should you require any additional information please do not hesitate to contact me at your convenience.

Sincerely yours,



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