

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-00242/89-002

Docket No. 030-00242

License No. 20-05969-03 Priority I Category G Program Code 2300

Licensee: Worcester City Hospital
25 Queen Street
Worcester, Massachusetts 01610

Facility Name: Worcester City Hospital

Inspection Conducted: August 28, 1989

Inspectors: John V. Stambaugh 10/6/89
for Lester M. Tripp, Health Physicist date

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Approved by: M. Shanbaky 10/6/89
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Section A

Inspection Summary: Special, Announced Inspection Conducted August 28, 1989
(Inspection Report No. 030-00242/89-002).

Areas Inspected: Review of the circumstances surrounding a therapeutic misadministration, including: organization and scope of licensed activities, notification of the misadministration, treatment prescription, review of the factors leading to the misadministration, events following the misadministration, training and instruction to employees, and corrective actions.

DETAILS

1. Persons Contacted

- *Francis A. Ascoli, M.S.
- *David M. Sherman, M.D.
- *Ricardo A. Rosales, M.D.
- *Robert Kinneberg

- *Present at exit conference

2. Organization and Scope of Licensed Activities

Worcester City Hospital is authorized by NRC License No. 20-05969-03 to perform radiation therapy treatments with a Picker C-9 Cobalt-60 (Co-60) teletherapy unit. The teletherapy unit houses a 4000 curie (Ci) Co-60 source. The last source exchange had taken place April 1985. The radiation oncology department treats approximately 7 to 10 patients per day. The department staff at the time of the event consisted of two radiation oncologists, a teletherapy physicist and two part time radiation oncology technologist who worked on alternate days. Treatments are given to patients for a variety of malignancies. The treatment goals can be curative, adjunctive or for palliation.

3. Notification of Therapeutic Misadministration

On July 24, 1989 at 2:55 p.m., NRC Region I received a call from the licensee's teletherapy physicist, Francis Ascoli. Mr. Ascoli stated that a therapeutic misadministration had occurred at 9:50 a.m. that day which involved the treatment of a patient with the Co-60 teletherapy unit. Mr. Ascoli confirmed that a written report was forthcoming. A report dated July 24, 1989 was submitted to NRC Region I. The licensee stated that a patient undergoing radiation therapy answered to another therapy patient's name and inadvertently received the wrong treatment for that day. The patient was set up and treated to an area not prescribed by his physician. The patient received 250 centigrays (cGy) to his lumbo-sacral spine and bilateral sacro-illiac (S.I.) joints. The licensee concluded that the cause of the misadministration was human error. The error occurred when a radiation oncology technologist failed to confirm a treatment patient's identity with an available photograph.

No apparent violations were identified.

4. Treatment Prescription

The therapeutic misadministration occurred resulting in a patient receiving another patient's prescribed dose. Patient A is a 77 year old male with locally advanced non-small cell carcinoma of the right upper lung and mediastinum. This patient was prescribed a radical course of radiation therapy utilizing parallel opposed, anterior/posterior, fields delivering 200 cGy per fraction. The patient was set up in the supine position. The portal encompassed the right upper lung, mediastinum and right superclavical area. The total dose for this field was 4000 cGy to be delivered over four weeks. The patient was then to be set-up to a cone down (smaller field) for an additional two weeks of treatment. The total dose planned for patient A was 6000 cGy. The patient had received seven treatments to the lung as of July 21, 1989.

Patient B is a 72 year old male with metastatic prostate carcinoma. This patient was prescribed a palliative course of radiation to a direct single posterior field delivering 250 cGy per fraction. The patient was set up in the prone position with a sponge under his head and ankles to assist with immobilization. The treatment portal included L4 and L5 of the lumbar spine, sacrum and bilateral S-I joints. The total dose for this field was 3000 cGy to be delivered in 12 fractions. The patient had received eight treatments to the spine as of July 21, 1989.

No apparent violations were identified.

5. Review of Therapeutic Misadministration

On August 28, 1989, the inspectors met with the licensee representatives identified in Paragraph 1 to review the circumstances surrounding the therapeutic misadministration, the licensee's immediate response and proposed corrective action.

Dr. Sherman and Mr. Ascoli reviewed the events leading to the therapeutic misadministration. In summary, the radiation oncology technologist, who had just returned from a one week vacation, called patient B for his daily spine treatment. The time was 9:50 a.m. and patient B's appointment was scheduled for 9:30 a.m. Patient A whose appointment time was 10:00 a.m., thought his name had been called so he responded to the technologist's summons. The technologist did not confirm the patient's identity with the available photograph located behind the treatment chart. The technologist followed patient A into the treatment room and proceeded to place patient A in the detailed position which was listed in the radiation therapy chart of patient B. The technologist placed him prone, face down, on the treatment couch with sponges under his head and ankles. Patient A indicated to the technologist that he did not recall having sponges under his head or ankles during previous treatments. The technologist then asked Dr. Sherman, the Radiation Oncologist, to verify the documentation in the treatment chart since she had been on vacation the previous week. Dr. Sherman confirmed that the chart was in order without mention of treatment position deviations. The technologist proceeded to complete the treatment set-up.

Patient A did not have field markings (tattoos) which are used to localize treatment margins. The technologist had mistaken freckles on patient A's back for tattoos and set-up the treatment field using anatomical landmarks. At this point, the teletherapy unit was activated and the spine treatment for patient B was administered to patient A. Patient A left the department immediately following his therapy.

No apparent violations were identified.

6. Events Following The Misadministration

At 10:00 a.m., patient B arrived at the hospital for his daily spine treatment. The technologist proceeded to position patient B for treatment when she noted that his name had already appeared in the patient daily log book, two patients earlier. The technologist informed Dr. Sherman immediately upon recognizing the error. Dr. Sherman informed the teletherapy physicist and patient A's referring physician, Dr. Jack Batbouta. Dr. Batbouta discussed with patient A's family the misadministration of radiation to the patient's spine area, rather than his chest. Dr. Sherman also reviewed the event with the patient's family the morning of July 25, 1989. Dr. Sherman explained that this exposure of radiation should present no significant clinical consequences to Patient A. Patient A was examined and questioned to ensure no gastrointestinal distress occurred as a result of the radiation dose to his lumbar spine and S.I. joint region. It was noted at this time that the patient had difficulty with his hearing. This may be a major factor which has contributed to his misunderstanding the technologist's request. The family of patient A decided to withhold the information of the misadministration from him, as they felt that the patient would refuse to finish his necessary course of radiation treatment to the lung. The family was satisfied with the physicians handling of the incident.

No apparent violations were identified.

7. Training and Instructions To Employees

The technologist were given informal training on the radiation safety aspects associated with operating a Co-60 teletherapy unit. Emergency procedures were posted at the machine's console area. The hospital was inspected routinely on April 13, 1989. The inspector informed the licensee that the therapy technologist had not been included in the formal training sessions given to the nuclear medicine technologist. The licensee agreed to include the therapy technologist in all future training sessions held by Masse' Associates, physics consultant for the hospital. As of July 1, 1989, the Radiation Oncology Department physician and physicist staff were replaced with staff members from St. Vincent's Hospital. The new teletherapy physicist assumed the responsibility of providing formal training to all employees who frequent radiation areas in the therapy department. Before this training session was conducted the misadministration occurred. The two part-time technologist resigned shortly after this event. The department, at the time of the special inspection, had hired two full time employees,

a technologist and a secretary. The inspectors reviewed the licensee's records which showed that a formal radiation safety training session was provided to these two new employees before they started working in a radiation area.

No apparent violations were identified.

8. Corrective Action

Licensee representatives outlined their corrective actions in a letter to the NRC dated July 24, 1989 and in discussions with the inspectors during the inspection on August 28, 1989. The actions taken or proposed included the following:

- Radiation Safety in-services include techniques for positive identification of all patients. The procedure instructs all technologist to visually confirm a patient's identity prior to the administration of treatment.
- Each patient's identification photograph, which is routinely taken, was re-located to the first sheet of the radiation therapy chart. This assures that the technologist will see the patient's photo before treatment parameters are reviewed for daily patient set-up.
- In July 1989, policy for simulations (treatment set-ups) was revised. All patients are to be tattooed at the time of simulation. The tattoo scheme was to include all field corners and the central axis of the treatment beam. As of the inspection, this procedures had been implemented.
- Department policy requires that all patient set-ups which cannot be re-created by using permanent markings (tattoos) or obvious visual marks must be brought to the attention of the physician immediately for confirmation and visual inspection.
- All technologist upon returning or leaving on vacation will work with the temporary technologist prior to their leave and upon their return. They will introduce patients and their set-ups to one another.

9. Exit Interview

The inspectors met with the licensee representatives denoted in Section 1 at the conclusion of the inspection. The scope and findings of the inspection were summarized. J. Stambaugh noted that no apparent violations were identified and the records and reports of the misadministration were in compliance with the requirements of 10 CFR Part 35.33.