U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-01625/92001(DRSS)

Docket No. 030-01625

License No. 13-06009-01 Category G1 Priority II

Licensee: Community Hospital of Indianapolis
Department of Medical Imaging
1500 North Ritter Avenue
Indianapolis, IN 46219

Inspection At: Community Hospitals of Indianapolis
East Pavilion

Inspection Conducted: June 25 through November 4 1992

Inspector: Toye L. Simmons — November 13, 1992
Toye L. Simmons
Radiation Specialist
Date

Reviewed By: B. J. Holt — 11/13/92
B. J. Holt, Chief
Nuclear Materials Inspection
Section 1
Date

Approved By: John A. Grobe — 11/24/92
John A. Grobe, Chief
Nuclear Materials Safety
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Date

Inspection Summary

Inspection on June 25 through November 4, 1992 (Report No. 030-01625/92001(DRSS))

Areas Inspected: This special inspection was conducted to review a concern received by the NRC Region III office on May 15, 1992, regarding an alleged unreported therapeutic misadministration. An on-site inspection was conducted on June 25 and 26, 1992. Additional follow-up inspection activities were performed in the Region III office through November 4, 1992. The inspection included a review of the licensee's radiation oncology operating procedures including the quality management program; patient treatment records; and interviews with personnel. The inspection was limited to the activities associated with use of the MicroSelectron High Dose Rate Afterloading Brachytherapy unit.

Results: Of the areas inspected, no apparent violations of NRC requirements were identified.

DETAILS

1. Persons Contacted

Arve Gillette, M.D., Medical Director Radiation Oncology
Conrad Stachelek, M.D., Radiation Oncology
Nini Bermudez-Webb, M.D., Radiation Oncology
Morris Bank, Ph.D., Physicist
Carl Warner, Physicist
Darryl Bolin, Dosimetrist

2. Purpose of Inspection

This special inspection was conducted to review concerns received by the NRC Region III office involving the licensee's failure to report a therapeutic misadministration which occurred during the course of a vaginal treatment with a MicroSelectron High Dose Rate (HDR) afterloading unit.

3. Licensed Program

The licensee possesses one MicroSelectron HDR afterloading device which contains a nominal 10 curie iridium-192 sealed source. Vaginal treatments account for approximately 50% of the workload with bronchial treatments accounting for most of the rest. The treatment planning program was developed by the licensee's physics staff. Data obtained from the program printout is entered manually into the HDR console.

4. Incident Summary

On July 3, 1991, a 38 year old female patient received the first of three HDR radiation therapy treatments to the vagina. Her treatment plan prescribed 500 rads at two centimeters from the center of the applicator with a treatment length of six centimeters per fraction for a total of 1500 rads (the treatment length is determined from the vaginal apex). Treatment parameters were entered into the computer by using the spatial coordinates method. This method requires the entry of three points; the tip of the source catheter, the treatment length and a predetermined point below the treatment length to ascertain source dwell positions and stay times. At the time of this incident the treatment planning program had not incorporated a visual identifier for the tip of the source catheter. The coordinates were entered into the computer in the wrong order which resulted in a treatment length of six centimeters as prescribed, however, the dose was delivered to a region 2.0 centimeters lower than the vaginal apex.

On July 19, 1991, when the patient returned for her second treatment a similar treatment plan was used and the dose was delivered in the same manner as the first treatment.

The patient returned for her third and final treatment on August 2, 1991. This treatment was supervised by a different physician who

ordered orthogonal films following insertion of the applicator. Treatment data was determined from the films. The physician noted that the previous treatments had not delivered the dose to the desired location, and adjusted the final treatment to dose the vaginal apex as originally prescribed. No adverse affects have been observed in follow-up examinations of the patient.

5. Inspection Findings

The inspector interviewed all of the individuals involved with this case with the exception of the physicist who was present during the first two treatments and is no longer employed by the licensee. At the time of the incident, the dosimetrist was newly hired and training on the HDR unit under the direction of the physicist. The training consisted of reviewing the treatment planning program manual and the HDR reference materials and on-the-job experiences. Although the dosimetrist had participated in several HDR bronchial treatments, the case in question was the first vaginal therapy in which he entered the treatment data.

Based upon a review of the patient's treatment records, the physicist and the treating physician concurred with the July 3rd and the July 19th programs as presented. The third and final treatment was adjusted and reviewed by a different physician and physicist.

The treating physicians and the second physicist discussed the treatment variance among themselves and determined that the prescribed dose had been delivered to the vaginal volume (hereafter referred to as volume A) as desired. During their review of the regulatory definition of a brachytherapy misadministration, the medical staff concluded that a misadministration did not occur. This conclusion was based on the fact that the total dose delivered to the tissue volume outside of the region of interest (hereafter referred to as volume B) was less than 10 percent of the expected dose. Upon reviewing the isodose curves provided by the licensee, the inspector noted that a small section of tissue within volume B may have received a dose in excess of 10 or 20 percent. However, the inspector concluded that the licensee's assessment is valid because the treatment dose was intended for a volume of tissue and not for specific points within that volume. Recognizing the uncertainties in quantifying the dose for brachytherapy treatments of this type, the inspector recommended that this event be considered a recordable event and that records be maintained as stated in 10 CFR 35.5.

No apparent violation of NRC requirements was identified.

6. Root Causes and Licensee Corrective Actions

There are several reasons for the occurrence of this treatment variance. This was the first vaginal treatment for which the dosimetrist entered treatment data into the computer. The physicist failed to adequately review and verify the treatment data before the patient was treated. The treatment planning program was not equipped with a visual identifier for the source tip.

The licensee has instituted several corrective actions to reduce the probability of future occurrences of this type:

- All personnel who work with the treatment planning program have been made aware of this incident.
- Data entry protocol has been revised and clarified.
- Independent reviews of treatment plans have been instituted.
- Treatment records have been revised to include all pertinent information on one sheet.
- Spatial coordinates will be used only when the digitizer is inoperable. (Digitizer is a measuring device directly linked to the computer which inputs treatment data)
- The treatment planning system has been upgraded to add a visual marker identifying the source tip.

7. Exit Interview

On June 26, 1992, the inspector met with Drs. Stachelek and Banks and summarized the scope and findings of the inspection. On July 7, 1992, the inspector discussed the event with Dr. Gillette by telephone. Two telephone conferences were held in August 1992 between NRC management representatives and those of the licensee. This matter was again discussed during a November 4, 1992 telephone conversation between Drs. Gillette and Bank of the licensee's staff and NRC representatives. Based upon those discussions, it was recommended that the licensee consider the treatment variance as a recordable event and maintain records in accordance with 10 CFR 35.5.