PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-IV-94-010A

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region IV staff on this date.

Facility
Deaconess Medical Center
Deaconess Medical Center
Billings,Montana
Dockets: 03002389 License No: 25-01051-01

Licensee Emergency Classification
Notification of Unusual Event
Alert
Site Area Emergency
General Emergency
X Not Applicable

Subject: NOTIFICATION ON MULTIPLE MISADMINISTRATIONS

On March 23, 1994, St. Vincent Hospital & Health Center (SVHHC) and Deaconess Medical Center (DMC) provided updates to a telephonic notification provided by both SVHHC and DMC on March 22, 1994, to the NRC Region IV office as well as the NRC Operations Center. The reports provided on March 23 constituted telephonic notification of additional misadministrations involving brachytherapy treatments performed at the above noted facilities between October 1992 and November 1993. The misadministrations were identified on March 22 and 23, 1994, as a result of the licensees' continuing review of brachytherapy treatments performed using treatment plans generated by a Theratronics Theraplan L treatment planning system. (The licensees' consultant reported on March 22 that software problems were identified in a computer program used by the treatment planning system to generate dose tables for brachytherapy treatments. Specifically, the source encapsulation linear attentuation coefficient used to generate dose tables defaulted to an incorrect value regardless of data entered by the user.) The licensees reported the misadministrations as described below.

SVHHC reported that based upon reviews completed after the notification provided on March 22 and subsequent discussions with Region IV personnel, SVHHC identified six cases in which it appeared that the calculated treatment dose delivered to the tumor site differed by more than 20 percent of the prescribed tumor dose. SVHHC also noted that based upon earlier reviews of cases involving treatment plans generated using the Theratronics treatment planning system, it initially appeared that the treatments were administered in accordance with the applicable written directives. (This was due to the fact that authorized users at SVHHC routinely specified the treatment in written directives by prescribing the source strength and exposure, or implantation, period.) However, upon further review of the radiation dose delivered to the tumor site, SVHHC determined that the treatment dose in these six cases was in excess of what the authorized users intended. The overdoses ranged from 24 to 30 percent of the applicable prescribed tumor dose.

DMC reported that based upon its continuing review of cases involving treatment plans generated using the Theratronics treatment planning system, DMC identified one additional potential misadministration. (DMC earlier reported one misadministration identified on March 22, 1994.) The case reported by DMC involved a treatment which was terminated prior to the prescribed implantation period due to medical complications. However, DMC noted that recent tumor dose calculations indicated that the actual dose delivered to the prescribed tumor site was approximately 21 percent greater than what was previously recorded for this case. The licensee is continuing its review of this case.

Region IV plans to conduct a special inspection during the week of March 28, 1994, to review the circumstances associated with the misadministrations as well as the problems identified with the software programs used in the Theratronics treatment planning system. NMSS is continuing its review with the Food and Drug Administration (FDA) to determine whether Theratronics has notified the FDA of the problem. (Theratronics informed the licensees' consultant on March 22, 1994, that a Product/Device Alert report had been submitted to FDA. However, NMSS has not yet been able to substantiate that a report was submitted.)

Both licensees have informed Region IV that they plan to issue local press releases. However, as of 0700 (CST) on March 24, 1994, the licensees had not yet informed Region IV of the content of the press releases.

The state of Montana has been informed.

Region IV received notification of this occurrence by telephone from Dr. Lionel Tapia (SVHHC) and Dr. Mark Edwards (DMC). Region IV has notified NMSS.

This information has been confirmed with a licensee representative.

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