REVISION

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

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	Licensee Emergency Classification
Deaconess Medical Center	Notification of Unusual Event
Deaconess Medical Center	Alert
Billings, Montana	Site Area Emergency
Dockets: 03002389 License No: 25-01051-01	General Emergency
	X Not Applicable

Subject: MISADMINISTRATION NOTIFICATION AND NOTIFICATION OF POTENTIAL PROBLEM WITH TREATMENT PLANNING COMPUTER SYSTEM

On March 22, 1994, representatives from Northern Rockies Cancer Center (NRCC), Deaconess Medical Center (DMC), and St. Vincent Hospital & Health Center (SVHHC) provided telephonic notification of a misadministration to the NRC Region IV office as well as the NRC Operations Center. The misadministration involved a brachytherapy treatment performed at DMC on September 24, 1993, that was not discovered until March 20, 1994. The three licensees noted above participated in the call because a contributing factor to the misadministration appeared to be a discrepancy in software parameters used by a computerized treatment planning system which has been used by all three licensees. Based upon initial information developed by the physics staff at NRCC (which provides treatment planning services for DMC and SVHHC), it appeared that the potential for treatment errors may exist at both DMC and SVHHC, as described below.

The reported misadministration involved a gynecological brachytherapy treatment performed using cesium-137 sources in a Fletcher-Suit applicator. The authorized user prescribed a treatment intended to deliver a total dose of 3,500 centigray (cGy) (rads) to a predetermined point (Point A). The treatment plan was completed using a Theratronics Theraplan L computer planning system, and the treatment was completed without complication over the prescribed implantation period. However, based upon NRCC's subsequent review of this and other cases, as discussed below, the physics staff at NRCC has determined that the actual dose delivered to Point A during the treatment was 4,357 cGy (rads), an increase of approximately 24 percent of the prescribed treatment dose. The NRCC physics staff has reviewed this information with DMC, and DMC concurs with the physicists' evaluation. DMC has notified the referring physician, and as of 1600 on March 22, efforts were underway to contact the affected patient.

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The above noted misadministration was identified during a review of patient cases conducted after an error in a treatment plan was found on March 16, 1994. NRCC staff explained that during a routine treatment setup, a new staff member identified errors in a dose table (a "sievert integral" table) generated by the Theratronics Theraplan L treatment planning system. Following considerable review of treatment plans and data generated using the treatment planning system, the physics staff at NRCC, with assistance from Theratronics, concluded that the linear attenuation coefficient used to calculate dose tables for treatments using cesium-137 sources was in error after October 1992. Specifically, the attenuation coefficient used for cesium-137 after October 1992 appeared to correspond to that of a platinum-iridium source capsule rather than the steel capsule used for the cesium-137 brachytherapy sources used by this group of licensees. By review of historical treatment data, NRCC was able to confirm that dose tables generated prior to July 1992 appeared to be correct for treatment plans developed for use of cesium-137 sources.

Although the licensees are as of yet unable to determine the reason for a change in treatment parameters used by the Theratronics treatment planning system after October 1992, further review of data entry and discussions with the manufacturer appear to have revealed two potential problems with data entry that were previously unknown to the licensees. NRCC representatives have reported that the Theratronics Theraplan L system software requires that the user respond to a prompt to enter a linear attenuation coefficient during treatment parameter data entry. The user may elect to strike the "enter" key, which results in use of a default value equivalent to that of platinum-iridium, or may enter a numeric value. However, based upon testing conducted in response to NRCC's initial findings, it appears that if the user enters a value of "0.0" (which NRCC noted it would commonly do for cesium-137 sources encapsulated in steel), the system does not accept that value and instead uses the default value for platinum-iridium. NRCC also reported that this error, use of an attenuation coefficient other than what the user entered, is not apparent to the user because the system does not display the attenuation coefficient used to generate dose tables.

In addition to the patient involved in the misadministration noted above, the physics staff of NRCC has reviewed treatment records for patients who were treated at DMC and SVHHC since October 1992 and has identified eight patients who received brachytherapy treatments developed using the Theratronics Theraplan L treatment planning system. NRCC has identified one patient who received a treatment dose that was approximately 6 percent greater than the prescribed treatment dose, but has not yet identified any other misadministrations in this group of patients. NRCC, DMV, and SVHHC are continuing their review of these cases and plan to contact each patient for followup.

NRCC also reported that it was informed on March 22, 1994, that Theratronics issued a Product Device Alert for the Theratronics Theraplan L treatment planning system to inform users of the data entry problems described above.

Region IV plans to conduct a special inspection during the week of March 28, 1994, to review the circumstances associated with the misadministration as well as potential problems with software used in this particular treatment planning system. NMSS has contacted the manufacturer and the Food and Drug Administration to obtain copies of the Product Device Alert report.

The state of Montana will be informed. Region IV received notification of this occurrence by telephone from Mr. David Switzer, Radiation Safety Officer for NRCC, and other licensee representatives at approximately 10:00 a.m. Subsequent discussions were held with various licensee representatives to clarify aspects of the licensee's report. Region IV has informed NMSS.

This information has been confirmed with a licensee representative.

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