September 26, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-II-03-020

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 Region II staff (Atlanta, Georgia) on this date.

Facility	**Licensee Emergency Classification**
I. Gonzalez Martinez Oncologic Hospital	Notification of Unusual Event
P. O. Box 191811	Alert
Hato Rey, Puerto Rico 00919	Site Area Emergency
Docket/License: 030-03532/52-13471-01	General Emergency
	X Not Applicable

Subject: TWO REPORTED APPARENT BRACHYTHERAPHY MEDICAL EVENTS

On September 25, 2003, the licensee discovered and reported that up to two medical events may have occurred at its facility, one likely on August 21 and the other likely on August 27, 2003. The licensee indicated they received a letter from their iodine-125 brachytherapy seed vendor (the vendor), a State of Georgia licensee, that an error was made in the preparation of up to two orders totaling 190 seeds received by the licensee for implants on August 21 and 27, 2003. The vendor stated that the error may have resulted in the patients receiving radiation doses as much as 24% in excess of the prescribed dose. The prescribed dose for both patients was 14,400 centigrays (14,400 rads) each. The licensee is in the process of determining the actual doses delivered.

The error was discovered by the vendor's parent company, its supplier (the supplier), the week of September 18, 2003. The vendor reported that they received a requested inventory of 500 seeds from the supplier that contained 89 seeds with approximately twice the activity requested. All seeds were identical in appearance. The vendor further reported that a random assay of 5% of the seeds received did not identify any of the higher-activity seeds. Upon notification from the supplier, the vendor assayed the remaining 310 seeds of that lot and identified 52 of the 89 seeds of higher activity. This meant that 37 of the higher activity seeds were dispersed between the two orders received by the licensee and that no other licensee received a defective order. The licensee relied on the vendor's certification of activity contents.

The vendor based its 24% overdose estimate on statistical models of the distribution of the seeds in the two orders. Vendor representatives will be at the licensee's facility today to help the licensee reconstruct the treatment plans based on the new information.

Region II relayed this information to the State of Georgia for follow up with the licensee's vendor. State personnel indicated they were notified of the error by the vendor on September 17, 2003. The State plans to review the 30-day vendor's report due October 16, 2003, to determine whether an inspection of the vendor is warranted.

The licensee indicated they intend to notify the patients today. This information is current as of 9.00 a.m. on September 26, 2003. The Commonwealth of Puerto Rico has been notified.

Contact: Hector Bermudez
404-562-4734