March 29, 2005

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-05-006

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 III staff on this date.

Facility	Licensee Emergency Classification
St. Joseph's Regional Medical Center	___ Notification of Unusual Event
South Bend, Indiana	___ Alert
License: 13-02650-02	___ Site Area Emergency
	___ General Emergency
	_X_ Not Applicable

SUBJECT: TWO MEDICAL EVENTS INVOLVING UNINTENDED DOSES TO THE SKIN

DESCRIPTION:

On March 28, 2005, the licensee's Radiation Safety Officer notified the NRC Operations Center of two medical events involving unintended doses to the patients' skin at St. Joseph's Regional Medical Center, South Bend, Indiana, which occurred in 2004

Both medical events involved the use of a new model, manual low-dose-rate cylindrical brachytherapy device. The device utilizes an open spring to hold the sources in place. The manufacturer's instructions for the use of the device advised that only a source from a specified vendor be used with the device. The licensee failed to use sources manufactured by the recommended vendor and instead used sources manufactured by a different vendor which had a smaller source diameter. The smaller diameter sources could shift position within the device when the patient would sit in an upright position. This shift in source position could result in the sources traveling through the spring to a position within the device causing an unintended radiation dose to the patient's inner thigh.

Both patients exhibited skin ulcerations following the treatments; however, the licensee's initial calculations estimated the doses to be below the reporting limit of 50 rem to the skin. In January 2005, one of the patients exhibited a recurring skin ulceration prompting the licensee to reevaluate these doses. The first patient, treated February 23 through 24, 2004, received an unintended dose to a small area of the skin on the upper thigh of approximately 2,000 centigray (2,000 rads). The second patient, treated March 1 through 2, 2004, received an unintended dose to a similar area of the thigh of about 1,500 to 2,000 centigray (1,500 - 2,000 rads). Based on clinical observations, the licensee believed both patients received the respective prescribed doses to the treatment areas.

The patients and their referring physicians have been notified of the medical events. The licensee does not believe the medical events will have any additional adverse effect to either patient. The licensee will continue to followup the unintended doses to the patients.

An NRC Region III inspector will be at the licensee's facility in South Bend, Indiana, on March 30, 2005, to review the circumstances surrounding this event. An NRC medical consultant will provide an independent medical evaluation of the probable deterministic effects of the radiation exposures.

The Office of Nuclear Materials Safety and Safeguards and the State of Indiana have been notified. The information in this preliminary notification has been reviewed with licensee management.

The licensee reported this event to the NRC Operations Center at 10:13 a.m. (CST) on March 28, 2005. This information is current as of 8:00 a.m. (EDT) on March 29, 2005.

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