July 11, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-03-030

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
University of Wisconsin-Madison
Madison, Wisconsin
License No.: 48-09843-18
Docket No.: 030-03465

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

SUBJECT: *Reported Medical Event Involving Yttrium-90 Microspheres (Underdose)*

On July 9, 2003, the licensee reported that a medical event occurred involving a yttrium-90 (Y-90) liver treatment which resulted in an administered dose approximately 60.0 percent under the prescribed dose. The Y-90 was in the form of insoluble resin microspheres, and was being injected into the patient's liver utilizing a Sirtex delivery device.

According to the licensee, a prescribed dose of [redacted] was to be administered from a delivery vial containing [redacted] of Y-90. The microspheres are delivered to the treatment area in pulsated quantities. Contrast media is then used to flouroscopically evaluate the saturation of the tumor volume with the microspheres. Based on the x-ray fluoroscopy of the tumor volume, the administering physician with concurrence from the authorized user, indicated that the tumor volume was saturated with the microspheres. In addition, the physician visually inspected the delivery vial and did not see any residual volume of licensed material. Based on these observations, the physician believed the entire prescribed dose had been administered and the procedure was terminated. However, when the delivery vial, stop-cock apparatus, and tubing used during delivery were placed in a dose calibrator to evaluate residual activity, approximately [redacted] remained in the aforementioned delivery components. Therefore, of the original [redacted] of Y-90 in the delivery vial, approximately [redacted] had been administered to the treatment site representing an underdose of approximately 60.0 percent.

NRC Region III plans to conduct a follow-up inspection to review the circumstances surrounding the reported medical event during the week of July 14, 2003.

The NRC's Office of Nuclear Materials Safety and Safeguards and the State of Wisconsin have been notified. The NRC's Operations Center was notified of the medical event at 6:07 p.m., EDT on July 9, 2003. The information in this preliminary notification has been reviewed with licensee management. This information is current as of 10:00 a.m. CDT on July 11, 2003.

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