This Event is not for public disclosure per Agreement State request until 4/18/05

April 14, 2005

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-05-008

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
University of Wisconsin	___ Notification of Unusual Event
Madison, WI	___ Alert
License No.: 25-1323-01	___ Site Area Emergency
(Agreement State licensee)	___ General Emergency
	_X_ Not Applicable

SUBJECT: MEDICAL EVENT INVOLVING YTTRIUM-90 ZEVALIN

DESCRIPTION:

On April 8, 2005, the Wisconsin Department of Health and Family Services (DHFS) notified the NRC Operations Center of a medical event involving Yttrium-90 (Y-90) at the University of Wisconsin Hospital, in Madison, Wisconsin. The licensee notified DHFS of the event on April 8, 2005.

The medical event occurred on April 5, 2005, when a 48 millicurie dose of Y-90 Zevalin was administered to a patient. Based on patient weight and blood platelet count, the intended dose should have been 28 millicuries. The dose was dispensed as ordered from a nuclear pharmacy and administered without modification. A written directive, required by Wisconsin regulations, was not prepared for this therapy.

DHFS inspectors initiated an investigation at the licensee facility on April 11, 2005. That investigation is continuing. A Confirmatory Action Letter, signed by DHFS and the licensee, was issued on April 12, 2005. The letter confirms that: 1) Y-90 Zevalin therapeutic use is suspended; 2) the licensee will conduct a root cause investigation of the event and determine if a larger problem exists with the therapeutic use of radioactive materials; 3) the licensee will develop and implement corrective actions based on the results of the investigation; and 4) the licensee will submit a report to DHFS by May 4, 2005, and will receive written approval prior to resuming use of Y-90 Zevalin.

A medical consultant is being contracted by DHFS to provide the State with a medical analysis of the consequences of the medical event. The patient and referring physician were notified of the event.

The NRC's Office of State and Tribal Programs and Office of Nuclear Materials Safety and Safeguards have been notified. The NRC's Region III (Chicago) Office is monitoring the State's investigation. The information in this Preliminary Notification was reviewed with the State. This information is current as of 3:00 p.m. CDT on April 14, 2005.

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