July 14, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-03-031

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
Washington University in St. Louis
St. Louis, Missouri
License No.: 24-00167-11
Docket No.: 030-02271

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

SUBJECT: Reported Medical Event Involving Samarium-153 (Underdose)

On July 11, 2003, the licensee reported that a medical event occurred involving a samarium-153 (Sm-153) palliative treatment which resulted in an administered dose approximately 96 percent under the prescribed dose. The Sm-153, known as Quadramet, was being injected into the patient in liquid form.

According to the licensee, a prescribed dose of [redacted] was prepared for administration on July 9, 2003, in accordance with the written directive. The authorized user physician and radiation oncology technologist experienced difficulties with the intravenous port and syringe during the administration. The staff did not believe this affected the treatment and released the patient.

Radiation safety was consulted on July 9, 2003, and performed confirmatory radiation surveys. The injection room and adjacent area did not contain any residual activity. However, the absorbent material used during the delivery was assayed on July 10, 2003, in a dose calibrator to evaluate residual activity. Radiation safety staff determined that approximately [redacted] remained. Therefore, of the original [redacted] of Sm-153 in the syringe, approximately [redacted] was administered to the patient.

The licensee planned to notify the patient's physician on July 14, 2003, and to notify the patient, as appropriate, and complete the palliative treatment at a later date. The licensee does not anticipate any adverse effects due to this medical event.

NRC Region III plans to conduct a follow-up inspection to review the circumstances surrounding the reported medical event during the week of July 21, 2003.

The NRC's Office of Nuclear Material Safety and Safeguards and the State of Missouri have been notified. The NRC's Operations Center was notified of the medical event at 4:58 p.m., EDT on July 11, 2003. The information in this preliminary notification has been reviewed with licensee management. This information is current as of 1:00 p.m. CDT on July 14, 2003.

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