THIS EVENT IS NOT FOR PUBLIC DISCLOSURE PER AGREEMENT STATE REQUEST UNTIL 10/18/2003.

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-03-043

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 IV staff on this date.

Facility Sacred Heart Medical Center Spokane, Washington License No.: WN-M031-1 Washington Agreement State Licensee

Licensee Emergency Classification

- ____ Notification of Unusual Event ____ Alert
- ____ Site Area Emergency
- General Emergency
- X Not Applicable

SUBJECT: POTENTIAL BRACHYTHERAPY MISADMINISTRATION

DESCRIPTION:

On October 9, 2003, the Washington Department of Health, Office of Radiation Protection (the Office) notified NRC of a potential brachytherapy misadministration that had occurred on October 8, 2003, involving a potential leaking iodine-125 seed.

On October 8, 2003, a patient had a source train containing thirty-one I-125 seeds implanted into his lung for cancer treatment. During the implant process, the licensee determined that the source train was longer than needed and decided to clip the unwanted part. However, during the clipping of the source train the licensee had inadvertently cut through two seeds that contained a total activity of 1.46 mCi (54.02 MBq). As a precaution, within one hour of breaching the seeds, the licensee administered large quantities of supersaturated potassium iodide (SSKI) to the patient. The licensee's current treatment plan is to continue the administration of SSKI in amounts of at least 0.5 ml daily for two weeks following the incident.

The individuals involved in the implant process have received thyroid bioassays. These bioassay results were determined to be negative. To determine whether the sealed sources were leaking, the licensee conducted a test which consisted of soaking the seeds in plain water. The test results showed significant leakage. The licensee's assessment for the amount of material released is based on assuming a worst-case scenario where the entire contents of one seed and one-half of the second seed has leaked into the patient.

The licensee has monitored the pleural fluids from the patient for I-125 contamination and a "small amount" of contamination was found. Also, a urinalysis of the patient was performed and a "significant amount" of contamination was discovered in the urine. Additionally, the licensee performed a thyroid bioassay of the patient on October 10, 2003. This involved counting directly over the implant site using a NeoProbe calibrated with a I-125 source. Counting over the implant site resulted in 1800 counts per minute (cpm); whereas, counting over the thyroid resulted in 2-3 cpm. This comparison count indicated that the SSKI had blocked any I-125 uptake. The licensee indicated that the patient and his physician were notified of the incident. The licensee and the Washington Department of Health are continuing to investigate this incident.

Region IV received notification of this incident by email from the State at 1:30 p.m. on October 9, 2003. Region IV has informed OEDO, NMSS, OSTP and the Region's PAO and SLO.

This information has been discussed with the State and is current as of 1:10 p.m. (CDT) on October 14, 2003.

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