PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-V-94-003

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 V staff on this date.

Facility
Kaiser Foundation Hospital
Honolulu,Hawaii
License No: 53-05379-01

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

Subject: MISADMINISTRATION

On February 10, 1994, the licensee informed the Headquarters Operations Officer of 4 medical therapeutic misadministrations involving phosphorus 32 doses administered to 4 patients for treatment of polycythemia vera on March 9, August 19, September 8 and September 16, 1992. The written directives specified doses ranging from 1.5 to 4.0 millicuries. The licensee used a dose calibrator to verify the radiopharmacy's assay (millicuries per milliliter) on each phosphorus 32 dose and found discrepancies in each one. Based on its dose calibrator reading, which it believed to be accurate, the licensee adjusted the volume of each phosphorus 32 dose and administered the doses to the 4 patients. Following the dose administrations, the licensee's consultant discovered during a routine audit that the dose calibrator readings were inaccurate due to inherent variations in volume and geometry which are significant when assaying beta radiation emitters like phosphorus 32. Given the phosphorus 32 assay by the radiopharmacy was correct, adjustment of the volumes in the 4 vials caused misadministrations ranging from a 25% underdose to a 28% overdose when compared to the written directives. Following discovery of the assay discrepancies in early December 1992, the licensee informed Region V and requested guidance to determine if misadministrations had occurred based on 10 CFR 35.2. The licensee elected not to notify the referring physicians or patients until it received a response from Region V.

In January 1993, Region V requested guidance from NMSS to determine if misadministrations had occurred and the recommended method to use in assaying phosphorus 32 doses. In November 1993, after consultation with OGC, NMSS informed Region V that the 4 cases were reportable misadministrations and to notify the licensee to comply with all notification and reporting requirements pursuant to 10 CFR 35.33. In December 1993, Region V notified the licensee to complete its evaluation of the 4 cases, and comply with 10 CFR 35.2 and 35.33 as appropriate. Following its February 10, 1994, notification to the NRC Headquarters Operations Officer, the licensee has informed 3 of the 4 referring physicians and patients. The fourth patient is in a terminal cancer situation and the referring physician has decided not to inform.

Region V will review the licensee's final report of the 4 misadministrations which must be submitted by February 25, 1994 in accordance with 10 CFR 35.33.

The licensee does not intend to make any public information releases and Region V has not received any inquiries concerning the misadministrations.

Region V received initial notification of this occurrence by telephone from the Headquarters Operations Officer at 10:45 a.m. on February 10, 1994. The information presented herein has been discussed with the licensee, and is current as of 10:00 a.m. PST, February 11, 1994.

Contact: GREG YUHAS
(510)975-0226