PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-97-011

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 Region I staff in King of Prussia, Pennsylvania on this date.

Facility
Monsour Medical Center
Monsour Medical Center
70 Lincoln Way East
Jeanette, Pennsylvania 15644
Dockets: 03008184 License No: 37-14870-01

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

Subject: MISADMINISTRATION INVOLVING A DIAGNOSTIC DOSE OF IODINE-131

At 3:40 p.m. on February 14, 1997, the licensee notified the NRC Operations Center that, on February 12, 1997, a misadministration occurred at their facility when a patient received an 88 microcurie (uCi) dose of iodine-131 (I-131) and only 12 uCi of I-131 was prescribed. This event resulted in a misadministration because: (1) it involved the administration of a radiopharmaceutical dosage of greater than 30 uCi of sodium iodide I-131; (2) the administered dosage differed from the prescribed dosage by more than 20 percent of the prescribed dosage; and (3) the difference between the administered dosage and the prescribed dosage exceeded 30 uCi.

The licensee reported that their staff technologist ordered a 12 uCi dose of I-131 from a commercial radiopharmacy on February 11 but that on February 12, the radiopharmacy delivered an 88 uCi dose. The licensee stated that the 88 uCi dose was properly labeled by the radiopharmacy and was assayed in the dose calibrator by a temporary technologist prior to patient administration, but that the temporary technologist did not question the lack of a written directive for a dose exceeding 30 uCi of sodium iodide I-131. The licensee said that no written directive was prepared by the physician because their Quality Management Program and NRC regulations do not require a written directive when the prescribed dosage of sodium iodide I-131 is less than 30 uCi. The misadministration was identified by the staff technologist on February 14, 1997.

The licensee stated that the patient's referring physician was informed of the misadministration by the prescribing physician. The referring physician reportedly decided not to inform the patient because of the patient's advanced age and medical condition. The licensee will submit a report of misadministration to NRC within the required 15 days. Region I will perform a special inspection to review the misadministration.

The Commonwealth of Pennsylvania has been notified. The Region I Office of Public Affairs is prepared to respond to media inquiries.

This information is current as of 10:00 a.m. on February 18, 1997.

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