

November 13, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-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 III staff on this date.

Facility

Facility Name: Lakeland Medical Center
Licensee: Lakeland Medical Center
City, State: St. Joseph, MI
Docket: 03002049
License: 21-04177-01

Licensee Emergency Classification

☐ Notification of Unusual Event
☐ Alert
☐ Site Area Emergency
☐ General Emergency
☒ Not Applicable

SUBJECT: Medical Event Involving Samarium-153

DESCRIPTION:

On November 11, 2003, Lakeland Medical Center (licensee) reported to the NRC that a medical event occurred earlier that day when a patient received a dosage of samarium-153 that was 10 percent of the prescribed [REDACTED] dosage. The licensee received a unit dosage from Cardinal Health Pharmacy in Jenison, Michigan, with the label indicating that it contained [REDACTED] of samarium-153. The licensee measured the dosage and identified that the activity displayed on the dose calibrator was 10 percent of that prescribed. Therefore, the licensee notified the pharmacy about the discrepancy. The pharmacy informed the licensee that a correction factor of 10 should be used to convert the displayed activity to the actual activity. The licensee applied the correction factor, calculated that the actual activity was as prescribed, and administered the dosage to the patient. The licensee identified the medical event approximately one hour later when the pharmacy informed the licensee that the administered dosage was [REDACTED] rather than the prescribed [REDACTED], due to a pharmacy dosage assay error. The licensee plans to administer more samarium-153 to the patient and complete the treatment.

The licensee is reviewing the medical event causes, potential corrective actions, and the health effects (if any) to the patient as a result of the medical event. In addition, the pharmacy is reviewing the event to determine the appropriate corrective actions necessary to preclude a similar event. The licensee notified the referring physician on November 10, 2003, and the physician notified the patient. The NRC Region III notified the Michigan Department of Health of the medical event.

The NRC Region III will dispatch an inspector to the pharmacy and the licensee next week to review the event and the pharmacy's and the licensee's responses.

The information contained in this Preliminary Notification was reviewed with licensee management.

The NRC's Office of Nuclear Materials Safety and Safeguards have been notified. The above information is current as of 9:00 a.m. (CST) on November 13, 2003.

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