Date: August 4, 1980

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURENCE--PNO-III-80- 145 Page 1 of 2

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information presented is as initially received without verification or evaluation and is basically all that is known by IE staff as of this date.

Facility: Lakeview Hospital
Milwaukee, WI
License No. 48-04585-01

Subject: ADMINISTRATION OF RADIOPHARMACEUTICALS IN EXCESS OF ESTABLISHED LIMITS

Region III received allegations that the licensee's nuclear medicine personnel were routinely administering at least twice the amount of radiopharmaceuticals required by their procedures for various diagnostic scans. In one instance, a 19 year old male was to have received 38 millicuries of technetium-99m DTPA for a brain scan instead of the routinely administered 15 millicuries. It was alleged that these increased administrations were promoted by the chief nuclear medicine technician without the consent of the authorized user. It was also alleged that all patient dispensary logs had been falsified so as not to reflect the doubling of doses.

On August 1, 1980, an investigator and two materials inspectors conducted a special inspection of the licensee's facilities. Interviews with the three technicians involved in the nuclear medicine program, as well as the authorized user, revealed that the allegations were substantially correct, although the stated frequency at which these misadministrations occurred varied depending on who was being interviewed. A review of records revealed that none of the doses in excess of the prescribed dose were recorded as such in the patient dispensary log. These practices have been occurring since 1976 with only occasional consultation with the authorized user. The current authorized user has been at this facility only one month and was unaware of these practices. The reason given for the dose doubling was that it decreased scanning time from 30-45 minutes to 15-20 minutes. The chief technician instructed those working under her to falsify the dispensary records. Four items of noncompliance were identified during the investigation.

Region III is issuing an immediate action letter requiring the licensee to:

1) institute some method of control such that the patient doses being administered are known to conform to the written protocols; and

2) immediately have the dose calibrator calibrated. Other enforcement options are also being considered.

No press release has been made. The State of Wisconsin is being informed.

Region III received initial notification by telephone from one of the nuclear medicine technicians at 2:30 p.m. July 31, 1980. This information is current as of 9:30 a.m. August 4, 1980. The investigation is being continued.

Contact: W. Adam, RIII, 384-2528; C. Paperiello, RIII, 384-2511.

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