March 12, 2001

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-01-009

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
Loyola University Medical Center
Loyola University Medical Center
Maywood, Illinois
Docket:
License: IL-01131-02 (Agreement State)

Licensee Emergency Classification
___Notification of Unusual Event
___ Alert
___ Site Area Emergency
___ General Emergency
_X_ Not Applicable

SUBJECT: INTRAVASCULAR BRACHYTHERAPY MISADMINISTRATION

DESCRIPTION:

On March 9, 2001, the Illinois Department of Nuclear Safety (IDNS) notified Region III (Chicago) that the licensee reported misadministrations occurring on March 8, 2001, involving two patients during Cordis intravascular brachytherapy system treatments.

During the course of cardiac therapy, the two patients were treated with iridium-192 seeds to prevent restenosis in a stent. The prescribed doses were 8 gray (800 rads) to the tunica media layer of the heart. However, the calculated dose to one of the patients was 12.5 gray (1250 rads) and 14.3 gray (1430 rads) to the second patient.

The licensee has determined that the cause of the problem appears to be the use of a new method for determining the actual dose of radiation to an intended organ. The new procedure requires the use of an intravascular ultrasound device which takes measurements from the intended treatment area and the radiation sources. These measurements then determine the dwell time for the sources to be in a designated area and provide the prescribed dose.

The licensee believes that the new measurement method, combined with possible communication problems while taking and using the measurements, contributed to the problem.

IDNS is conducting an investigation into the incident. The licensee committed to no further use of this system until these problems are resolved and the licensee's Radiation Safety Committee and IDNS are satisfied that there will not be a recurrence.

The NRC Office of Nuclear Material Safety and Safeguards and the NRC Office of State and Tribal Programs have been notified. The information in this preliminary notification has been

reviewed with IDNS management and is current as of 10:00 a.m. (CST).

CONTACTS:

James Lynch
(630) 829-9661

Geoffrey Wright
(630) 829-9602