March 26, 2001

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-01- 013

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 IV staff on this date.

Facility
Alton Ochsner Medical Foundation
New Orleans, Louisiana
License No.: LA-0002-L01
Louisiana Licensee

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

SUBJECT: MISADMINISTRATION INVOLVING AN INTRAVASCULAR BRACHYTHERAPY PROCEDURE

DESCRIPTION: On March 21, 2001, Region IV was notified by the Louisiana Department of Environmental Quality, Radiation Surveillance Section (LDEQ) of a misadministration that occurred during an intravascular brachytherapy procedure for the treatment of in-stent restenosis of coronary arteries. This event occurred at the Alton Ochsner Medical Foundation (Ochsner) located in New Orleans, Louisiana.

Ochsner, a broad scope medical licensee, is participating in the Radiance Medical Systems research protocol using phosphorus-32 (P-32) in the Model RDX series radiation delivery catheter. The P-32 is incorporated into a thin film that is secured between two layers of the balloon catheter. The Ochsner RSO reported to LDEQ that during the procedure the balloon wall tore and released P-32 into the patient's bloodstream. From urine analysis, it was determined that the patient received 0.6 megabequerel (15 microcuries) of P-32. The licensee has estimated a radiation dose of 0.6 rads to the bone marrow. The licensee has ceased performing procedures and is waiting for the manufacturer's determination of the cause of the balloon wall tear. The licensee is also planning to report this event to the FDA.

Region IV received initial notification of this occurrence by facsimile from the State on March 21, 2001. Region IV has informed NMSS, OEDO, OSTP, and the Region's SLO and PA.

This information has been discussed with the State and is current as of 10:30 a.m. on March 26, 2001.

CONTACTS: Vivian Campbell 817-860-8143
Linda Howell 817-860-8213