

April 4, 2002

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-02-013

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 III staff on this date.

**Facility**

Rush-Presbyterian/St. Luke's Medical Center  
Rush-Presbyterian/St. Luke's Medical Center  
Chicago, Illinois  
License: IL-01766-01 (Agreement State)

**Licensee Emergency Classification**

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

SUBJECT: Intravascular Brachytherapy Misadministration (Underdose)

DESCRIPTION:

On March 21, 2002, the licensee performed a quality assurance record review of an intravascular brachytherapy procedure performed in October 2001. The procedure, part of an FDA study sponsored by Radiance Medical Systems, Inc., used a phosphorus-32 impregnated balloon catheter to treat a coronary artery. The treatment was designed to be a sequence of inflations and deflations of the balloon at the treatment site. Due to significant patient discomfort during balloon inflation, the physician ordered that the entire treatment be performed in the deflated mode. Mistakenly, only the deflated mode portion of the originally ordered treatment was delivered and no compensation was taken for the inflated portion of the therapy.

The delivered dose was approximately 11 Gray (55%) of the prescribed 20 Gray. The licensee notified the Illinois Department of Nuclear Safety when the misadministration was confirmed.

The patient and referring physician were notified of the misadministration. Licensee procedures are being updated to avoid similar errors.

The NRC Office of Nuclear Material Safety and Safeguards and the NRC Office of State and Tribal Programs were notified of the incident.

The Illinois Department of Nuclear Safety reported this event to the NRC Operations Center on April 3, 2002. This information was discussed with IDNS and is current as of 10:00 a.m. CST on April 4, 2002.

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