May 21, 2001

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-01-016

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	**Licensee Emergency Classification**
Ohio State University Medical Center	___Notification of Unusual Event
Columbus, Ohio	___ Alert
(Agreement State Licensee)	___ Site Area Emergency
Ohio License: 02110-250037	___ General Emergency
	_x_ Not Applicable

SUBJECT: MEDICAL MISADMINISTRATION CAUSED BY EQUIPMENT MALFUNCTION

DESCRIPTION:

On May 11, 2001, a patient was to receive a 1,800 rad (1,800 centiGray) radiation dose to a coronary artery using an intravascular brachytherapy device with a 547 millicurie (20.3 Gbq) iridium-192 source. The device was an investigational device called the AngioRad, manufactured by Interventional Therapies, LLC, of Westport, Connecticut.

In the procedure, a catheter is placed into the coronary artery and then the source, connected to a cable, is moved through the catheter to the treatment location.

After the source was inserted, the Medical Center treatment team determined that it was not in the intended location. An x-ray image later showed that it was about 4.5 to 5 millimeters short of the target area of the artery. The treatment was terminated after about 2 minutes, and the source withdrawn.

After troubleshooting and consultation with the device manufacturer, the treatment team cleaned the source cable and resumed the treatment. The procedure was successfully completed without incident.

The initial problem apparently occurred when a lubricant was squeezed out of the cable as it was tensioned. This lubricant affected the clutch mechanism of the device, causing the source to be positioned incorrectly.

The manufacturer is continuing to investigate the problem to determine if it may affect other similar devices.

While the treatment procedure was successfully completed, it was determined to be a misadministration because of the radiation dose to an unintended area during the initial treatment. The licensee calculated a 246 rad (246 centiGray) dose to the unintended portion of the coronary artery.

The Ohio Bureau of Radiation Protection is reviewing the misadministration. The NRC Office of Nuclear Material Safety and Safeguards and the NRC Office of State and Tribal Programs have been informed.

The Ohio Bureau of Radiation Protection reported the misadministration to the NRC Operations Center at 3:20 p.m. EDT on May 18, 2001. This information is current as of 9 a.m. on May 21, 2001.

CONTACTS:

James Lynch	Monte Phillips
630/829-9661	630/829-9806