

December 24, 2003

This event is not available for public disclosure per Agreement State request until December 29, 2003.

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-03-045

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

Southwest General Health Center/Ireland
Cancer Center
Middleburg Heights, OH
License No: 02120180001
(Agreement State licensee)

Licensee Emergency Classification

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

SUBJECT: MEDICAL EVENT INVOLVING AN INTRAVASCULAR BRACHYTHERAPY
PROCEDURE

DESCRIPTION:

On December 24, 2003, the Ohio Department of Health, Bureau of Radiation Protection (ODH/BRP), notified the NRC Operations Center of a medical event involving a Novoste Beta-Cath intravascular brachytherapy system, Model No. A-1767, using a 3.5 mm French catheter. The event occurred at Southwest General Health Center/Ireland Cancer Center in Middleburg Heights, Ohio. The Novoste Beta Cath system source train contained a sealed source of approximately 53.8 millicuries of strontium-90.

On December 23, 2003, at 1600 hours EST, the licensee notified ODH/BRP, that the source traveled to a location approximately 3 centimeters short of the intended treatment site. The dose to the unintended site was approximately 1840 rad (18.4 Gy). The immediate cause of the event was a kink in the delivery catheter which kept the source train from traveling to the correct site. The kink was not, however, substantial enough to affect the flow of sterile water used to send/retrieve the source. The error was discovered the next day during medical physics quality checks and reported to ODH/BRP. The attending physician has been notified. An investigation will be performed by ODH/BRP the week of December 29, 2003.

The NRC's Office of State and Tribal Programs and Office of Nuclear Materials Safety and Safeguards have been notified. The NRC's Region III (Chicago) Office will monitor the State's investigation. The information in this Preliminary Notification was reviewed with the State. This information is current as of 12:15 p.m. CST on December 24, 2003.

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