September 22, 2003

THIS EVENT IS NOT FOR PUBLIC DISCLOSURE PER AGREEMENT STATE REQUEST UNTIL 9/24/03.

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-03-042

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
Arizona Oncology Services
Scottsdale, Arizona
License No.: AZ-07-161
Arizona Agreement State Licensee

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

SUBJECT: Medical Misadministration

DESCRIPTION:

On September 19, 2003, the Arizona Radiation Regulatory Agency (the Agency) notified NRC's Operations Center that a medical misadministration involving the use of an iridium-192 high-dose rate brachytherapy afterloader (HDR) unit had occurred at Arizona Oncology Services located in Scottsdale, Arizona. The event is classified as a "medical misadministration" based on Arizona's current regulation for the medical use of radioactive material.

The licensee notified the Agency on September 17, 2003, that a medical misadministration had occurred during a breast cancer treatment procedure. The patient had been prescribed a series of 10 fractional treatments beginning September 15, 2003. The licensee reported that a saline filled balloon was used in conjunction with the HDR unit for proper positioning of the 0.36 terabequerel (9.6 curie) iridium-192 source for the cancer treatment. Between each treatment, the licensee performed an ultrasound to assure continued proper placement of the source. The physician noted that the balloon was ruptured upon removal after completing the treatment plan. Based on the review of the ultrasound images, the balloon had ruptured between the sixth and seventh fraction of the treatment plan. The licensee estimates that the patient received a skin dose of 266 centigray (266 rad) rather than the 175 centigray (175 rad) originally calculated. The patient and the referring physician have been notified of the event. In addition, the licensee has informed the balloon manufacturer. The licensee plans to review any health effects during patient follow-up and is continuing to investigate this event. The Agency plans to further evaluate the circumstances of this event during an inspection.

Region IV received notification of this occurrence by facsimile from the Agency on September 19, 2003. Region IV has informed OEDO, NMSS, OSTP and the Region's SLO and PAO.

This information has been discussed with the State and is current as of 4:00 p.m. on September 22, 2003.

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