DCS No.: 03003013030616
Date: July 24, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE PNO-I-03-020A

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 I staff on this date.

Facility
Guthrie Healthcare System and Guthrie Clinic
Guthrie Square
Sayre, Pennsylvania 18840

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

Docket No.: 03003013
License No.: 37-01893-01

SUBJECT: UPDATE ON POTENTIAL MEDICAL EVENT AT GUTHRIE HEALTHCARE SYSTEM AND GUTHRIE CLINIC

On June 16, 2003, Guthrie Healthcare System and Guthrie Clinic (the licensee) made a report to the NRC Operations Center concerning a prostate seed implant performed in May of 2001. The patient returned to the licensee in June of 2003 for reevaluation after a diagnostic test revealed that his prostate cancer may have recurred. The radiation oncologist reviewed a new CT scan that showed the array of iodine-125 seeds to be approximately 3 centimeters from the prostate. The radiation oncologist then reviewed imaging studies performed shortly after the implant in 2001. The old CT scan indicated that the array of iodine-125 seeds was in the same location as the new CT scan. The licensee notified the patient and referring physician.

NRC Region I sent an inspector to the licensee's site on June 19, 2003 to evaluate the circumstances surrounding this treatment. The licensee performed dose calculations and determined that the dose received by the prostate was only a small fraction of the prescribed dose. The dose to the unintended area was significantly higher than would have been expected from the prescribed treatment. The licensee agreed to audit other prostate seed implants performed in 2001 by former licensee staff.

On July 18, 2003, the licensee made a report to the NRC Operations Center concerning a second prostate seed implant that was performed in July of 2001. As part of the audit of implants performed in 2001, the licensee reviewed the second patient's CT scan performed shortly after the implant. The array of iodine-125 seeds was found to be approximately 3 centimeters from the prostate. Post-implant dose calculations performed last week showed that the dose received by the prostate was only a small fraction of the prescribed dose. The dose to the unintended area was significantly higher than would have been expected from the prescribed treatment. The licensee is attempting to contact the affected patient. The licensee is continuing its investigation and will provide a written report to NRC within 15 days.

NRC Region I plans to further evaluate the circumstances surrounding these treatments. Region I has contracted with a medical consultant to review any medical implications that may arise from these events. The licensee will continue to audit the remaining prostate seed implants performed in 2001 and additional medical events may be identified. In addition, the licensee revised their prostate seed implant procedures when new staff were hired in 2002.

The Commonwealth of Pennsylvania has been notified. Region I continues to monitor the situation. Region I is prepared to respond to media inquiries.

This information is current as of 2:00 p.m. on July 24, 2003.

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Region I Form 83
(Rev. July 2, 2003)