March 23, 2004

EA-04-025
NMED No. 030502
Docket No. 03003013 License No. 37-01893-01

William Vanaskie
President and Chief Executive Officer
Robert Packer Hospital
Guthrie Healthcare System
One Guthrie Square
Sayre, PA 18840

SUBJECT: CORRECTED COPY OF FIRST PAGE OF NRC LETTER DATED, MARCH 19, 2004

Dear Mr. Vanaskie:

On March 19, 2004, the NRC sent you a letter indicating that the NRC was issuing a Notice of Violation for events which occurred at your Robert Packer Hospital facility located in Sayre, Pennsylvania. On the original copy of the letter mailed to you, the last line of the first page of the letter was inadvertently missing. All other copies and electronic versions of the letter did not contain this error. A corrected copy of the first page of that letter is enclosed.

In accordance with 10 CFR 2.390, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

We apologize for any inconvenience.

Sincerely,

/RA/ James T. Wiggins ***Acting For/***

Hubert J. Miller
Regional Administrator

Enclosure:
As Stated

Distribution:
ADAMS (PARS)
D. Holody, RI
J. Nick, RI
C. Bixler, RI

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DATE	3/23/04		3/23/04		3/23/04			

OFFICIAL RECORD COPY

March 19, 2004

EA-04-025
NMED No. 030502

William Vanaskie
President and Chief Executive Officer
Robert Packer Hospital
Guthrie Healthcare System
One Guthrie Square
Sayre, PA 18840

SUBJECT: NOTICE OF VIOLATION (NRC Inspection Report No. 03003013/2003002), NOTICE OF ENFORCEMENT DISCRETION, AND CLOSURE OF CONFIRMATORY ACTION LETTER AND ITS SUPPLEMENTS

Dear Mr. Vanaskie:

This letter refers to an NRC inspection conducted on June 19, 2003, and August 21, 2003, at the Guthrie Healthcare System (Guthrie) facility, Robert Packer Hospital, located in Sayre, Pennsylvania. During the inspection, the NRC reviewed the circumstances associated with numerous misadministrations (now called medical events) that you reported had occurred at your facility between May 24, 2001, and January 2002. The potential misadministrations involved the unintended location of iodine (I-125) seeds implanted in a patient's prostate during treatment. The inspection was continued in the NRC Region I office until January 30, 2004, to review additional information submitted by Guthrie between September 8, 2003, and January 6, 2004, regarding other potential patient misadministrations. During the inspection, two apparent violations were identified. The findings from the inspection were sent to you on February 13, 2004.

In the February 13, 2004 letter transmitting the inspection report, the NRC provided you the opportunity to address one apparent violation identified (for which escalated enforcement action was being considered) by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a telephone conversation on February 19, 2004, Ms. Mary Mannix, of your staff, informed Dr. Sandy Gabriel, of my staff, that Guthrie did not believe a predecisional enforcement conference or written response was needed.

As noted in your letter dated September 15, 2003, after further evaluation and review, using CT scans (3-dimensional imaging), of 49 treatments performed between January 2001 and August 2003, your staff concluded that 21 misadministrations occurred between January 2001 and January 2002. Your staff also contended that you were unable to determine whether misadministrations had occurred before that time (between June 1993 and November 2000), because only localization radiographs (not CT scans) were required at the time by your QMP. This contention was based on the uncertainty involved with the use of localization radiographs because a patient's prostate gland is not visible on radiographs and calculation of the dose to