

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

the gland from the implanted seeds cannot be precise. The localization radiographs can show only extreme deviations of the seeds from the intended location.

The NRC staff agrees that (1) 21 misadministrations occurred at your facility during the period from January 2001 to January 2002; and (2) it was difficult for your staff to determine, by using the localization radiographs after the implants, if any of the treatments performed from June 1993 through November 2000 resulted in a misadministration. In addition, the NRC's medical consultants provided no information that changed the characterization of the violation.

Notwithstanding the above, the NRC has determined that two violations of NRC requirements occurred based on the information developed during the inspection. The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The first violation involved the failure to follow the requirement of your written Quality Management Plan (QMP) to develop a second radiation dosimetry plan based on actual distribution of prostate implant sources relative to the prostate gland as seen by localization radiographs. Specifically, a second radiation plan was not developed after implantation of iodine-125 seeds to assess the actual dose to the patients' prostates (as shown by localization films) for 26 out of 30 patients treated with prostate implants between January 2001 and January 2002. The NRC has concluded that this failure to follow the QMP did not directly result in any of the misadministrations. Further, the NRC has concluded that this failure did not cause a delay in identifying these misadministrations because the use of localization radiographs would only identify extreme deviations from the intended distribution, and in these cases, any deviation from the intended distribution would have been difficult to identify.

This violation was of concern to the NRC because this programmatic failure to follow the written QMP could have resulted in the failure to identify other potential problems during the implant treatments. This failure was considered programmatic because your staff failed to follow the QMP for nearly all the treatments performed between January 2001 and January 2002. Therefore, the first violation has been categorized at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit for corrective action is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) re-evaluating seed implants performed at Guthrie; (2) performing a root cause analysis for the identified misadministrations; (3) verifying that the current seed implant program was not resulting in misadministrations; and (4) increased management oversight of the prostate seed implant program.

Therefore, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation with no civil penalty for this Severity Level III violation. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and Inspection Report No. 03003013/2003002 (dated February 13, 2004). Therefore, you are not required to respond to this letter unless that description does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

With respect to the second violation, your staff failed to perform a QMP review in 2002 for prostate seed implants performed during 2001 as required by 10 CFR 35.32 (revised in October 2002, the regulation was in effect at that time). The NRC has decided to exercise enforcement discretion, as provided for in section VII.B.6 of the Enforcement Policy, and not cite this violation. Discretion is warranted in this case because the revised 10 CFR Part 35 no longer requires this review.

In addition to the above, the NRC issued Confirmatory Action Letter (CAL) No. 1-03-003 to Guthrie on July 28, 2003, because the NRC was concerned that other misadministrations may have occurred during prostate seed implants. The CAL confirmed that Guthrie would re-evaluate all other prostate implants performed since 2001, and all implants prior to 2001 that were performed by the Radiation Oncology staff members involved in the reported misadministration. The CAL was revised on July 30, 2003, to address new information that Guthrie had provided on July 28 and 29, 2003. The first revision to the CAL confirmed that Guthrie would evaluate the adequacy of 25% of the implants performed prior to 2001. The CAL was revised again on October 15, 2003, to extend the deadline for the response to the original CAL. Guthrie responded to the CAL and its revisions in letters to the NRC dated September 8, 2003, September 15, 2003, November 24, 2003, and January 6, 2004, providing information regarding the results of the re-evaluations. The re-evaluations for the treatments between January 2001 and January 2002 were made using information from CT scans performed soon after the implant or as part of the recent review. Guthrie identified, through the use of the CT scans, 21 misadministrations out of a total of 30 procedures performed between January 2001 and January 2002. However, in the January 6, 2004 letter, Guthrie state that it was difficult to determine if misadministrations had occurred during the period from June 1993 through November 2000, based on the use of the localization radiographs that were required at that time. CT scans were not used for these cases. Guthrie identified that the likely root causes for the misadministrations were (1) the "medical direction of the program;" and (2) the "technique used for needle retraction" which may have resulted in placement of the iodine seeds outside the target area. The NRC has concluded that a contributing cause was inadequate medical oversight of the implant program. The current prostate seed implant program (from January 2002 to the present) utilizes real-time treatment planning and post-implant treatment planning, based on CT scans, to confirm the accuracy of seed placement. No misadministrations or medical events were identified for the 19 implant procedures performed between October 2002 and July 2003. Therefore, since the current licensee's program has corrected the inadequacies of the former program and has not resulted in any misadministrations or medical events, the NRC has determined that no further response is required regarding these issues and the CAL is closed.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be made available

electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

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

Hubert J. Miller
Regional Administrator

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

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Notice of Violation

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Commonwealth of Pennsylvania

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*Concurrence from OE and NMSS obtained per e-mail from S. Merchant and L. Gersey to J. Nick on 3/18/04

ENCLOSURE

NOTICE OF VIOLATION

Guthrie Healthcare System
Sayre, PA

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

During an NRC inspection conducted at the licensee's facility on June 19, 2003, and August 21, 2003, and subsequently continued in the NRC Region I office until January 30, 2004, one violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is set forth below:

10 CFR 35.25 required, in part, that a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of the authorized user as allowed by 10 CFR 35.11(b)(1), shall require the supervised individual to follow the licensee's written radiation protection procedures with respect to the medical use of byproduct material.

The licensee's written Quality Management Plan (QMP), the written radiation protection procedures that addressed the medical use of byproduct material (iodine-125 seeds used for prostate implant treatments), required that a second radiation dosimetry plan be made, after implantation of the seeds in the patient's prostate, to determine the actual distribution of the sources as shown by localization films.

Contrary to the above, between January 2001 and January 2002, an individual under the supervision of the authorized user did not make a second radiation dosimetry plan for 26 out of 30 patients treated with prostate implants during that time.

This is a Severity Level III violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and Inspection Report No. 03003013/2003002 (dated February 13, 2004). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, you should clearly mark your response as a "Reply to a Notice of Violation, EA-04-025" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you are required to post this Notice within two working days.

Dated this 19th day of March 2004.