October 28, 2005

EA-05-124

Kathleen Harrison
Vice President for Operations
Lancaster General Hospital
555 North Duke Street
P. O. Box 3555
Lancaster, PA 17604-3555

SUBJECT: NOTICE OF VIOLATION

Dear Ms. Harrison:

This letter refers to the routine unannounced NRC inspection conducted at your Lancaster General Hospital's Cancer Center facility in Lancaster, Pennsylvania on October 21, 2004, as well as subsequent in-office NRC reviews of (1) additional information you provided to the NRC regarding a medical event which occurred at the facility in September 2003, and was not reported to the NRC as required, and (2) the report by a medical consultant retained by the NRC to review this medical event. The results of the inspection were discussed with you and members of your staff during an exit meeting following the inspection on October 21, 2004, as well as additional exits conducted on April 4 and 5, 2005, and July 13, 2005, following the additional in-office reviews. Based on the inspection, three apparent violations of NRC requirements were identified.

On August 23, 2005, we sent you a letter which contained the inspection report and described the apparent violations. The apparent violations were associated with a program weakness in your gamma knife stereotactic radiosurgery (GSR) program which resulted in radiation exposure to an unintended area of a patient's brain during a GSR treatment and the failure to report this medical event to the NRC. The violations occurred when, following a GSR treatment on September 30, 2003, it was discovered that the stereotactic frame moved seven centimeters from its initial setting, causing a dose of approximately 3500 rems to an unintended area of the patient's brain. During gamma knife treatments, a stereotactic frame is fixed to the patients head by screws to ensure proper positioning of the head in the gamma knife unit. The z-bar of the stereotactic frame sets the z-coordinate on the x-y-z coordinate definition of the treatment site and can slip if sufficient pressure is applied to the frame. During the procedure conducted on September 30, 2003, the medical physicist authorized the patient to move his head "a little" because the patient was uncomfortable. However, you indicated that the patient "vigorously" moved and that this vigorous movement resulted in the slippage of the z-bar and the exposure to an unintended portion of the patient's brain. The treatment was not suspended to verify that the setting coordinates required by the treatment plan and written directive remained unchanged after viewing the patient's vigorous movement.

Our August 23, 2005, letter also informed you that the NRC was considering escalated enforcement action in accordance with its enforcement policy and you were provided an opportunity to address our concerns at a predecisional enforcement conference (PEC). On September 16, 2005, a PEC, open for public observation, was conducted with you and your

staff to discuss the apparent violations, their causes, and your corrective actions. At this PEC, you (1) acknowledged the facts surrounding the medical event as presented in the inspection report, (2) stated that Lancaster General Hospital was very concerned about this incident, and (3) described your corrective actions to preclude recurrence of the violations. In addition, you stated that at the time of the incident, your staff concluded that the medical event was not reportable because medical events are not reportable if they are caused by patient intervention, and at the time, your staff concluded that the patient caused the medical event by moving vigorously. However, you acknowledged that, in retrospect, the conclusion to not report the event to the NRC was made in error because vigorous movement by the patient was not the sole reason the medical event occurred. Further, your decision to replace the z-bar, indicates that the event may not have been solely the result of patient intervention. Specifically, your removal of the z bar on the stereotactic frame for return to the manufacturer for analysis indicates that you questioned the role the equipment failure may have played in the event. In addition, you stated that you regretted that the incident was not managed better.

Based on the information developed during the inspection, and the information provided by you during the conference, the NRC has determined that three violations of NRC requirements occurred. 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 failure to have adequate procedures to require the immediate re-verification that treatment parameters remain in accordance with the written directive following vigorous patient movement during treatment, contrary to 10 CFR 35.41(b), constituted the first violation. The failure to report this medical event to the NRC, contrary to 10 CFR 35.3045, constituted the second violation. The failure to report an equipment failure involving the slippage of z-bar, contrary to 10 CFR 21.21(d), constituted the third violation.

These violations are a concern to the NRC because the incident resulted in a significant dose to an unintended portion of the patient's brain. Therefore, these violations are categorized collectively as a Severity Level III problem in accordance with the NRC Enforcement Policy.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a Severity Level III violation for medical licensees. Because your facility has not been the subject of escalated enforcement action within the last two years or two inspections, 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 actions is warranted because your corrective actions were considered prompt and comprehensive. These corrective actions included, but were not limited to: (1) replacing the z-bars on the stereotactic frame with new ones to ensure proper operations; (2) returning the z-bar to the manufacturer for analysis; (3) revising treatment procedures to state that any movement by a patient during a treatment will require the treatment to be stopped and restarted after verifying proper treatment settings; (4) training appropriate staff members on the revised procedures; and, (5) retraining Senior Management personnel on the reporting requirements in 10 CFR 21.21 and 10 CFR 35.3045.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation without a civil penalty for this Severity Level III problem. However, you should be aware that significant violations in the future could result in a civil penalty. 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 reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter and in the inspection report issued on August 23, 2005. Therefore, you are not required to respond to this letter unless the description therein 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. We appreciate your cooperation with us in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, 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 http://www.nrc.gov; select **What We Do, Enforcement,** then **Significant Enforcement Actions.**

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Enclosure: Notice of Violation

cc:
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Commonwealth of Pennsylvania

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NOTICE OF VIOLATION

Lancaster General Hospital
Lancaster, Pennsylvania

Docket No. 030-35003
License No. 37-11866-04
EA-05-124

Based on an NRC inspection conducted at your Lancaster General Hospital's Cancer Center facility in Lancaster, Pennsylvania, on October 21, 2004, as well as an in-office review of additional information you provided to the NRC subsequent to the onsite inspection, the results of which were discussed at exit meetings on October 21, 2004, April 4 and 5, 2005, and July 13, 2005, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(b)(2) requires, in part, that the licensee's procedures for administration of licensed material requiring a written directive include verification that the administration is in accordance with the written directive.

Contrary to the above, on September 30, 2003, a written directive was prepared for a stereotactic radiosurgery treatment and required specific treatment parameters for the stereotactic head frame to ensure that the authorized dose was delivered to the proper treatment site. On that date, the licensee observed the patient move vigorously during treatment and the licensee's procedures did not require the immediate re-verification that treatment parameters were in accordance with the written directive following vigorous patient movement during treatment. At the conclusion of the treatment, it was discovered that the stereotactic frame moved seven centimeters from its initial setting, causing a dose of approximately 3500 rems to an unintended area of a patient's brain.

B. 10 CFR 21.21(d)(1) requires, in part, that the licensee notify the Commission when it obtains information reasonably indicating a failure to comply or a defect affecting a basic component supplied for an activity that is subject to the licensing requirements under 10 CFR Part 30.

10 CFR 21.21(d)(3) requires, in part, that initial notification be made by facsimile or telephone within two days following receipt of the information, and in writing within 30 days of receipt of the information providing the information specified in 10 CFR 21.21(d)(4).

Contrary to the above, as of October 21, 2004, the licensee had not notified the NRC, either by facsimile, telephone, or in writing, with the information specified in 10 CFR 21.21(d)(4), regarding a failure affecting a basic component supplied for an activity subject to the licensing requirements in 10 CFR Part 30. Specifically, as of October 21, 2004, the licensee had failed to notify the NRC that, on September 30, 2003, the frame of the licensee's gamma knife unit, a basic component designed to prevent movement of the head during treatment, did not prevent the change of the treatment site coordinates during a patient treatment. Verbal notification to the NRC was not made until April 5, 2005. The required written notification to the NRC was not made until April 11, 2005.

C. 10 CFR 35.3045(a)(3) requires, in part, that the licensee report any event, except for an event that results from patient intervention, in which the administration of radiation from byproduct material results in a dose to tissue other than the treatment site that exceeds by 50 rems to the tissue and 50 per cent or more of the dose expected from the administration defined in the written directive.

10 CFR 35.3045(c) requires that the licensee notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a medical event. 10 CFR 35.3045(d) requires, in part, that the licensee submit a written report within 15 days after the discovery of a medical event.

Contrary to the above, as of October 21, 2004, the licensee had not reported, either by telephone or in writing, an event that occurred on September 30, 2003, in which the reporting criteria specified in 10 CFR 30.3045(a)(3) were met and the event did not result solely from patient intervention. Specifically, on September 30, 2003, 3,500 rem was administered to an unintended area of the patient's brain during a gamma stereotactic radiosurgery treatment, and as of October 21, 2004, the licensee had not notified the NRC by telephone or in writing. Verbal notification to the NRC was not made until April 5, 2005. The required written notification to the NRC was not made until April 11, 2005.

These three violations represent a Severity Level III problem (Supplement VI).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken 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 in the inspection report issued on August 23, 2005. Therefore, no response to this Notice is required. 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, clearly mark your response as a "Reply to a Notice of Violation, EA-05-124" 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 the violation, 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.

Because any 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), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room). If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the

information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 28th day of October 2005