

May 21, 2010

EA-10-063
NMED No. 090659

Arthur P. Lemay, R.Ph.
Executive Director, Oncology Services
Yale-New Haven Hospital
Radiosurgery Center
40 Temple Street
New Haven, CT 06510

SUBJECT: NOTICE OF VIOLATION – NRC INSPECTION REPORT NO.
03034705/2009001

Dear Mr. Lemay:

This letter refers to the reactive inspection conducted between August 13 - August 14, 2009, at the Yale-New Haven Hospital's Radiosurgery Center (YNHH) in New Haven, Connecticut. The purpose of the inspection was to review the circumstances surrounding a medical event involving a patient who received a dose that was different from the prescribed dose during a gamma stereotactic radiosurgery (GSR) treatment. The event was reported to the NRC Operations Center by your staff on August 6, 2009. In addition to the on-site review, the inspection also involved consideration of: (1) additional information provided by YNHH in correspondence dated August 21, 2009, March 8 and 24, 2010; and, (2) the findings of a medical consultant retained by the NRC to review this event, as documented in the consultant's report, dated March 8, 2010. The NRC presented the results of the inspection to you and members of your staff during a telephonic exit meeting on April 7, 2010. Subsequently, in a letter dated April 16, 2010, the NRC transmitted the results of the inspection in NRC Inspection Report No. 03034705/2009001 (non-publicly available).

In a telephone conversation on April 23, 2010, Mr. Marc Ferdas of my staff informed you that the NRC was considering escalated enforcement for an apparent violation identified during the inspection, and that the NRC had sufficient information regarding the apparent violation and YNHH's corrective actions to make an enforcement decision without the need for a predecisional enforcement conference or a written response from YNHH. In response, you indicated that additional written information would be provided to the NRC. The NRC received the additional information in YNHH's letter, dated April 23, 2010.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in Inspection Report No. 03034705/2009001. The violation involves the failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive, as required by 10 CFR 35.41(a)(2). Specifically, YNHH's written

procedures: (1) did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to initiation of GSR treatment; and, (2) did not specify how hospital personnel should respond to unexpected GSR treatment console errors. These procedural inadequacies represented a programmatic weakness that resulted in a medical event on August 5, 2009, when several unexpected GSR treatment console errors were received and YNHH personnel did not subsequently verify that the automatic position system coordinates were in accordance with the written directive.

The NRC medical consultant reviewed this event, its effect on the patient, and YNHH's corrective actions. The medical consultant agreed with YNHH's assessment that the untreated area could be retreated, if appropriate, and that no clinically significant side-effects from radiation damage to the unintended areas would be expected to the patient. The NRC medical consultant did note a small risk of weakness or numbness for the patient due to dose to unintended areas. During the exit meeting with the NRC, YNHH personnel stated that no additional weakness or numbness has been exhibited by the patient and that the patient's dexterity has improved following treatment. Nevertheless, the violation involved a programmatic weakness in the implementation of written directives or procedures for administrations requiring a written directive, and a medical event occurred as a result. Therefore, the NRC has categorized this violation in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. 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. YNHH's corrective actions, completed by April 2010, include the following: (1) issuing a memorandum to all personnel involved in radiosurgery treatments to require visual verification of the physical coordinates against the electronic coordinates before the start and at the end of each treatment run; (2) retraining all GSR personnel on the importance of fully understanding error conditions and reviewing unexpected errors with other staff involved in the treatment (e.g, Radiation Oncologist, Authorized Medical Physicist, etc.) prior to clearing any unexpected error; and (3) issuing a document entitled, "Gamma Knife APS Errors Policy and Procedure," which provides instructions for responding to equipment error indications. Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SL III violation constitutes escalated enforcement action that may subject YNHH 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 the NRC's inspection report dated April 16, 2010 and in the YNHH letter dated April 23, 2010. 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

Docket No. 03034705
License No. 06-30445-01

Enclosure: Notice of Violation

cc:
Michael J. Bohan, Radiation Safety Officer
State of Connecticut

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Samuel J. Collins
Regional Administrator

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Enclosure: Notice of Violation
cc:
Michael J. Bohan, Radiation Safety Officer
State of Connecticut

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NOTICE OF VIOLATION

Yale-New Haven Hospital
New Haven, Connecticut

Docket No. 03034705
License No: 06-30445-01
EA-10-063

During an NRC reactive inspection conducted between August 13 - August 14, 2009, for which a telephonic exit meeting was held on April 7, 2010, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, as of August 5, 2009, the licensee did not develop and maintain written procedures to provide high confidence that each administration requiring a written directive was performed in accordance with the written directive. Specifically, Yale-New Haven Hospital's written procedures: (1) did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to initiation of gamma stereotactic radiosurgery (GSR) treatment; and, (2) did not specify how hospital personnel should respond to unexpected GSR treatment console errors. These procedural inadequacies resulted in a medical event on August 5, 2009, when Yale-New Haven Hospital personnel did not verify that the automatic position system coordinates were in accordance with the written directive, during the treatment of a patient undergoing GSR.

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 be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the NRC inspection report sent to YNHH by letter dated April 16, 2010, and in the YNHH letter dated April 23, 2010. 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-10-063," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 475 Allendale Rd., King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. 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 may be required to post this Notice within two working days.

Dated this 21st day of May 2010