March 31, 2008

EA-07-313
NMED No. 070641

Mr. Dan Goodwin
Administrator, Division of Medical Specialties
Oncology Institute of Greater Lafayette
420 North 26th Street
Lafayette, IN 47904

SUBJECT: NOTICE OF VIOLATION – ONCOLOGY INSTITUTE OF GREATER LAFAYETTE; NRC ROUTINE INSPECTION REPORT 030-34812/ 2007-001(DNMS)

Dear Mr. Goodwin:

This refers to the inspection conducted on October 16, 2007, at your Lafayette, Indiana facility, with continued in-office review through November 20, 2007. The purpose of the inspection was to examine routine activities at your facility. During the inspection, two apparent violations of NRC requirements were identified by the inspector. Details regarding the apparent violations were provided in NRC Routine Inspection Report No. 030-34812/2007-001(DNMS), dated January 7, 2008.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated February 5, 2008, you provided a response to the apparent violations. In your response, you noted two corrections to our inspection report: (1) You stated that, instead of incorrectly entering the step size, the authorized medical physicist neglected to verify the step size. The NRC acknowledges this correction and has determined that it does not change the overall conclusion, in that the actual step size between dwell positions did not agree with the written directive. (2) You stated that you disagreed with the description of the effect on the patient as a result of the medical event. The NRC discussed your comments with our medical consultant and his position remained unchanged. Therefore, while we considered the additional information you provided, it did not alter the fact that a medical event occurred and did not change our final enforcement decision.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated February 5, 2008, the NRC has determined that two violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report dated January 7, 2008. On October 16, 2007, the NRC identified that a high dose rate (HDR) remote afterloader unit brachytherapy medical event occurred during the licensee's administration of three treatment fractions to a patient on August 14, 2007, August 28, 2007, and September 11, 2007. As a result, portions of the treatment site received a dose that differed from the prescribed dose by more than 50 rem to tissue and a total dose that differed from the prescribed dose by more than 20 percent. Your staff did not identify any

adverse effects to the patient as a result of the medical event. An NRC Medical Consultant concluded that the medical event resulted in: (1) an overdose to the vaginal vault that was unlikely to cause vaginal necrosis; and (2) an underdose to the inferior-posterior vaginal wall (which contained cancer) that increased the risk of cancer recurrence.

The root cause of the violations was an error in verifying the step size in the HDR unit. Contributing factors to the violations included: (1) the failure by your staff to instruct an Authorized Medical Physicist (AMP) in its written directive (WD) procedures; (2) the AMP's failure to read your WD procedures until the inspection; (3) inability to transfer the treatment data electronically to the HDR unit for the treatment; and (4) the AMP's perceived sense of urgency to complete the treatment because of the patient's discomfort.

The NRC considers these violations to be significant as they resulted in an actual medical event and indicate the potential for future medical events. Therefore, the violations have been categorized in accordance with the NRC Enforcement Policy as a Severity Level III problem.

Because your facility has not been the subject of escalated enforcement action within the last 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. The NRC determined that credit was warranted for your corrective actions which included: (1) having the AMP review and implement the WD procedures; (2) revising the WD procedures to include dual verification that the parameters in the treatment console used for patient treatments are the same as those developed in the treatment planning computer, including step size, dwell times, and number of dwell positions, regardless of the means of transferring the treatment parameters from the treatment planning computer to the HDR; (3) discussing the licensee's WD procedures with all applicable licensee staff and licensee management to ensure that they are aware of the WD procedures; (4) ensuring that new staff understand the WD procedures prior to participation in licensed activities; and (5) working with the HDR unit manufacturer to resolve the difficulty in transferring the data electronically to the HDR unit. In addition, your staff changed the HDR unit's default step size setting from 2.5 millimeters to 5 millimeters, as that is the step size normally used in your medical administrations.

Therefore, to encourage prompt identification 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 Severity Level III problem constitutes escalated enforcement action, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason 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 Inspection Report 030-34812/2007-001(DNMS), dated January 7, 2008, and in your response dated February 5, 2008. 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, its enclosure and your response, if you choose to make one, 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 www.nrc.gov/reading-rm/ adams.html. 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. 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 www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Mark A. Satorius Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-34812
License No. 13-32087-01

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

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 make one, 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 www.nrc.gov/reading-rm/ adams.html.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. 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 www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,
/RA by Mark A. Satorius Acting for/
James L. Caldwell
Regional Administrator

Docket No. 030-34812
License No. 13-32087-01

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

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See next page

*See previous concurrence
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1 FSME concurrence received via E-mail from G. Morell on March 11, 2008

2 OE concurrence received via E-mail from L. Sreenivas on March 12, 2008

Letter to D. Goodwin from James Caldwell dated March 31, 2008

SUBJECT: NOTICE OF VIOLATION – ONCOLOGY INSTITUTE OF GREATER LAFAYETTE; NRC ROUTINE INSPECTION REPORT 030-34812/ 2007-001 (DNMS)

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NOTICE OF VIOLATION

Oncology Institute of Greater Lafayette
Lafayette, Indiana

Docket No. 030-34812
License No. 13-32087-01
EA-07-313

During an NRC inspection conducted on October 16, 2007, at your Lafayette, Indiana facility, with continued in-office review through November 20, 2007, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. 10 CFR 35.27(a)(1) requires, in part, a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material.

   Contrary to the above, from August 14, 2007 to October 16, 2007, the licensee did not instruct an Authorized Medical Physicist, a supervised individual, in the licensee's written directive procedures with respect to the use of byproduct material.

2. 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).

   Contrary to the above, from August 14, 2007 to October 16, 2007, the licensee failed to develop, implement, and maintain written directive procedures to provide high confidence that each administration was in accordance with the written directive. Specifically:

   a. The licensee's written directive procedures required checks to ensure that the treatment plan data was properly transferred by program card to the high dose rate remote afterloader unit before treatment, including a check of the step size (dwell position). However, the licensee did not use a program card to transfer the information and, therefore, did not verify before treatment that the treatment plan was properly input into the high dose rate remote afterloader unit. This resulted in a patient being given three treatments with an incorrect step size (dwell position). As a result, a medical event occurred.

   b. The licensee's written directive procedures required that, after treatment, printouts of the actual treatment parameters be checked for agreement with the treatment plan; however, licensee staff did not verify, after treatment, that the step size (a treatment parameter) that was used for the treatments of four patients was in agreement with the treatment plan. As a result, a medical event occurred.

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

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-34812/2007-001(DNMS) and in a letter from the licensee dated February 5, 2008. 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-07-313," 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 III, 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 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 31st day of March 2008