July 11, 2008

EA-08-136
EA-08-137
NMED No. 080132

Mr. Craig C. Kinyon
Vice President/Chief Financial Officer
Reid Hospital and Health Care Services
1401 Chester Boulevard
Richmond, IN 47374

SUBJECT: NOTICE OF VIOLATION [NRC REACTIVE INSPECTION REPORT NO. 03001614/2008-001(DNMS)] REID HOSPITAL AND HEALTH CARE SERVICES

Dear Mr. Kinyon:

This refers to information that your staff provided to the U.S. Nuclear Regulatory Commission (NRC) on February 29, 2008, concerning a medical event which had occurred during a brachytherapy seed implant procedure to treat prostate cancer at Reid Hospital and Health Care Services on
February 27, 2008. The NRC conducted an onsite inspection on March 5 and 6, 2008. An exit meeting was conducted on April 17, 2008. The inspection report was issued on April 28, 2008. Two apparent violations of NRC requirements were identified: (1) failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive for I-125 seed prostate implants as required by 10 CFR 35.41; and
(2) failure to report a medical event to the NRC Operations Center no later than the next calendar day after discovery as required by 10 CFR 35.3045(c).

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. On May 27, 2008, we received your written response dated May 23, 2008.

Based on the information developed during the inspection, your written response, and the report from our medical consultant, the NRC has determined that 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. An authorized user's written directive prescribed a total dose of 110 Gray, equivalent to 110 Sieverts (Sv), to a patient's prostate through the placement of 62 seeds containing I-125. Even though the urologist and authorized user physician did not see the needles in one view of the ultrasound image as clearly as they had expected, they began positioning the needles and seeds in the patient. After positioning 37 seeds, the physicians used an x-ray machine to verify the
location of the seeds. The radiograph indicated that the seeds had been placed outside of the

treatment site, approximately 1 to 2 centimeters below the prostate in the perineum. The physicians determined that positioning the remainder of the seeds in the prostate would not deliver the prescribed dose, so they terminated the procedure.

As a result, the region of the perineum, an unintended site, received a dose of approximately 55 Sv. In addition, the prostate received a dose of 3-15 Sv rather then the prescribed dose of 110 Sv. This was considered a medical event because: (1) the perineal tissue received a dose above 0.50 Sv and 50 percent more than the expected dose; and (2) the prostate received a dose that differed from the prescribed dose by more than 0.50 Sv and the total dose delivered differed from the prescribed dose by more than 20 percent. Your staff indicated that the 55 Sv dose to the perineal tissue could lead to fibrosis or necrosis in that tissue.

Violation A involves your failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive for I-125 seed prostate implants as required by 10 CFR 35.41. Your written policy for prostate implant procedures did not require that the position of the prostate be verified with certainty before placement of the seeds. The failure to include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan is a significant regulatory concern. Therefore, Violation A has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

Violation B involves your failure to report the medical event to the NRC Operations Center no later than the next calendar day after discovery as required by 10 CFR 35.3045(c). The Radiation Safety Officer, a medical physicist, assisted during the implant procedure. While he had adequate knowledge of the procedure to recognize that a medical event had occurred, he did not report the medical event to the NRC Operations Center until February 29, 2008, because he was unaware of the NRC definition of a medical event and the reporting requirements for medical events. The failure to report the medical event no later than the next calendar day after discovery is significant. Delays in reporting events can impact the NRC's response. Additionally, the Radiation Safety Officer should have been particularly knowledgeable of, and sensitive to, the NRC regulatory requirements. The oversight function of the Radiation Safety Officer is vital to public health and safety. Therefore, Violation B has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for each Severity Level III violation. Because your facility has not been the subject of escalated enforcement actions 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.

For Violation A, credit was warranted for corrective actions which included: (1) halting prostate seed implant procedures until all corrective actions were completed; (2) revising the prostate seed implant procedure policy to require that the location of the needle in the prostate be verified with certainty by x-ray and ultrasound imaging prior to any seeds being deposited, and to require that the procedure be stopped before any seeds are implanted if the location of the needle in the prostate cannot be verified with certainty; and (3) providing education and training on the

ultrasound machine and stepper for physicians and other personnel.

For Violation B, credit was warranted for corrective actions which included: (1) discussing NRC regulations requiring reporting of a medical event with physicians, authorized users, the Radiation Safety Officer, physicists, and other personnel; (2) reviewing on an annual basis NRC reporting requirements regarding medical events with authorized users, the Radiation Safety Officer, physicists, and other Radiology/Radiation Oncology/Nuclear Medicine personnel involved in procedures using NRC-licensed materials; and (3) revising your administrative policy to state that the requirement is to report medical events to the NRC no later than the next calendar day.

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 these Severity Level III violations constitutes escalated enforcement action that 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 No. 03001614/2008-001(DNMS) and your written response dated May 23, 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, should you choose to respond, 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 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.

Please contact Patrick Louden, Chief, Materials Inspection Branch, with any questions. Mr. Louden can be reached at telephone number (630) 829-9627.

Sincerely,

/RA by Mark A. Satorius Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-01614
License No. 13-03284-02

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

For Violation B, credit was warranted for corrective actions which included: (1) discussing NRC regulations requiring reporting of a medical event with physicians, authorized users, the radiation safety officer, physicists, and other personnel; (2) reviewing on an annual basis NRC reporting requirements regarding medical events with authorized users, the radiation safety officer, physicists, and other Radiology/Radiation Oncology/Nuclear Medicine personnel involved in procedures using NRC-licensed materials; and (3) revising your administrative policy to state that the requirement is to report medical events to the NRC no later than the next calendar day.

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James L. Caldwell
Regional Administrator

Docket No. 030-01614
License No. 13-03284-02

Enclosure: Notice of Violation
cc w/encl: State of Indiana

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DATE	07/09/08	07/09/08	07/10/08	07/08/08	07/10/08	07/11/08

1 OE concurrence received via E-mail from S. Woods on July 08, 2008

Letter to Craig C. Kinyon from James L. Caldwell dated July 11, 2008

SUBJECT: NOTICE OF VIOLATION [NRC SPECIAL INSPECTION REPORT NO. 03001614/2008-001(DNMS)] REID HOSPITAL AND HEALTHCARE SERVICES

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NOTICE OF VIOLATION

Reid Hospital and Healthcare Services
Richmond, Indiana

Docket No. 030-01614
License No. 13-03284-02
EA-08-136; EA-08-137

During an NRC inspection conducted on March 5 and 6, 2008, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

10 CFR 35.41(b)(2), requires, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, as of February 27, 2008, the licensee's procedure for prostate seed implants did not provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee's procedure did not require that the licensee verify the position of the patient's prostate before placing the seeds into the prostate. This resulted in an overdose of 55 Gy to a portion of the patient's perineum, more than 0.5 Sv and 50 percent above the minimal dose it was expected to receive, and a dose of 3-15 Gy to the patient's prostate, more than 20 percent below the prescribed dose of 110 Gy. (EA-08-136)

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

B. 10 CFR 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.

Contrary to the above, on February 27, 2008, the licensee became aware that a medical event had occurred, and the licensee did not notify the NRC until February 29, 2008, which was later than the next calendar day. Specifically, the Radiation Safety Officer was aware of the administration of byproduct material which resulted in an overdose of 55 Gy to a portion of the patient's perineum, more than 0.5 Sv and 50 percent above the minimal dose it was expected to receive, and a dose of 3-15 Gy to the patient's prostate, more than 20 percent below the prescribed dose of 110 Gy and did not take action to notify the NRC until after the Radiology Director was briefed two days later (EA-08-137).

This is a Severity Level III violation (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. 030-01614/2008-001(DNMS) and a written response received from Reid Hospital and Health Services dated May 23, 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-08-136; EA-08-137)", 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 and the Enforcement Officer, 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. 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 11th day of July 2008