June 20, 2007

EA-07-071
NMED No. 070024

Ms. Charla Higbee, Director of Cancer Services
Hackley Hospital
1700 Clinton Street
Muskegon, MI 49443-3302

SUBJECT: NOTICE OF VIOLATION [NRC SPECIAL INSPECTION REPORT NO. 03002044/2007-001(DNMS)] HACKLEY HOSPITAL

Dear Ms. Higbee:

This letter refers to information that your staff provided to the U.S. Nuclear Regulatory Commission (NRC) on January 8, 2007, concerning a medical event which involved a prostate implant procedure that occurred at Hackley Hospital on January 8, 2007. The NRC conducted a special onsite inspection on January 11 and 12, 2007, with continued NRC in-office review through March 16, 2007. The NRC in-office review included a review of the March 15, 2007, report of an NRC medical consultant. One apparent violation of NRC requirements was identified and involved the failure to develop adequate written procedures to ensure that each administration of licensed material is in accordance with the written directive as required by 10 CFR 35.41. The special inspection report was issued on April 4, 2007.

In the letter transmitting the special inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference (PEC) or by providing a written response before we made our final enforcement decision. On April 16, 2007, you declined a PEC and on May 4, 2007, we received your undated written response to the apparent violation. Additional information was provided in a January 18, 2007, letter from your medical physicist.

Based on the information developed during the inspection and the information provided by Hackley Hospital, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. In summary, your procedure did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the authorized user physician's written directive and treatment plan. On January 8, 2007, the physician prescribed the administration of 120 Gray (Gy) to a patient's prostate using 41 iodine-125 seeds. After implantation of seven iodine-125 seeds, the patient apparently moved on the operating room table. The implant procedure was suspended and additional anesthesia was administered to stabilize the patient. The surgeon's field of view was apparently occluded following the patient's movement and the remaining 34 seeds were then

inadvertently inserted into the patient's penile bulb instead of the patient's prostate. A radiograph was taken at the conclusion of the procedure and revealed that 34 seeds were inserted approximately 4 centimeters inferior to the prostate. This resulted in the patient's prostate receiving only 13 Gy of the 120 Gy prescribed in the written directive and the penile bulb, which was an unintended treatment site, received 110 Gy. Additionally, the patient's skin, also an unintended treatment site, received approximately 2.4 Gy. 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, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. The current edition of the Enforcement Policy can be found at the NRC Web site www.nrc.gov.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3,250 is considered for a 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. Credit was warranted for corrective actions because you immediately canceled all scheduled prostate seed implants and revised the written procedure to require imaging the treatment area at the beginning, the middle and the end of the implant procedure, placing a marker around the ultrasound probe to verify probe insertion distance into the rectum, alerting the anesthesiologist prior to beginning needle insertions, loading the base plane of the prostate with needles first, and performing specific steps of the "Prostate Seed Implant Procedure" prior to resuming treatment incident to patient movement.

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 Severity Level III violation 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 Inspection Report No. 03002044/2007-001(DNMS) and an undated letter received from the licensee on May 4, 2007. 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, Decommissioning Branch, with any questions. Mr. Louden can be reached at telephone number (630) 829-9627.

Sincerely,

/RA by Geoffrey E. Grant Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-02044
License No. 21-04125-01

Enclosure:
Notice of Violation

cc w/encl: A. Scott Lachniet, MD
Chairman, Board of Trustees

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James L. Caldwell
Regional Administrator

Docket No. 030-02044
License No. 21-04125-01

Enclosure: Notice of Violation

cc w/encl: A. Scott Lachniet, MD
Chairman, Board of Trustees

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DATE	06/18/07		06/18/07		06/05/07	06/08/07		06/19/07		06/20/07		06/20/07

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[1] FSME concurrence received via e-mail from Leelavathi Sreenivas, OE, on 06/12/2007.

[2] OE concurrence received via e-mail from Leelavathi Sreenivas, OE, on 06/12/2007.

Letter from J. Caldwell to C. Higbee dated June 20, 2007

SUBJECT: NOTICE OF VIOLATION [NRC SPECIAL INSPECTION REPORT NO. 03002044/2007-001(DNMS)] HACKLEY HOSPITAL

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NOTICE OF VIOLATION

Hackley Hospital
Muskegon, Michigan

Docket No. 030-02044
License No. 21-04125-01
EA-07-071

During an NRC inspection conducted from January 11 to March 16, 2007, 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) provides, in part, that for any administration requiring a written directive, the licensee is required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).
>
> 10 CFR 35.41(b), provides, in part, that the procedures required by 10 CFR 35.41(a) must address methods for verifying that the administration of byproduct material is in accordance with the treatment plan, if applicable, and the written directive.
>
> Contrary to the above, as of January 8, 2007, Hackley Hospital failed to develop adequate written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the "Prostate Seed Implant Procedure" did not include appropriate steps or guidance to ensure that radioactive sources were positioned in the patient in accordance with the written directive and treatment plan. The written directive for the treatment performed on January 8, 2007, prescribed a radiation dose of 120 Gray (Gy) to the patient's prostate, using 41 iodine-125 seeds. However, 7 seeds were implanted in the patient's prostate providing a dose of 13 Gy to the prostate. The remaining 34 seeds were mistakenly implanted into the patient's penile bulb, an unintended treatment site causing an unintended dose of approximately 110 Gy to the penile bulb and a dose of approximately 2.4 Gy to the skin.
>
> 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 Inspection Report No. 03002044/2007-001(DNMS) and an undated letter received from Hackley Hospital on May 4, 2007. 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-07-071," 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.

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

Dated this 20th day of June 2007.