July 10, 2006

EA-06-101
NMED No. 060235

William R. Corley, Chief Executive Officer
Community Hospitals of Indiana, Inc.
1500 North Ritter Avenue
Indianapolis, IN 46219

SUBJECT: NOTICE OF VIOLATION [NRC INSPECTION REPORT NOS. 030-01625/06-001(DNMS) AND 030-01625/06-002 (DNMS)] COMMUNITY HOSPITALS OF INDIANA

Dear Mr. Corley:

This refers to the routine safety inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on April 3 and 4, 2006, at Community Hospitals of Indiana, Indianapolis, Indiana. Two apparent violations and a non-cited violation (NCV) were identified during the inspection. The NCV was sent to you in our May 5, 2006, letter forwarding the inspection report. The two apparent violations were associated with a medical event that occurred on November 8, 2005. The first apparent violation pertained to the failure of Community Hospitals of Indiana to develop and implement written procedures to ensure each administration of NRC-licensed material is in accordance with the written directive of the authorized user physician. The second apparent violation involved the failure of Community Hospitals of Indiana to notify the NRC that a medical event occurred by the next calender day following identification.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violations 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 May 15, 2006, you declined a PEC and on May 10, 2006, you provided a written response to the apparent violations. Additional information pertaining to this issue was contained in an April 13, 2006, letter from your Radiation Safety Officer.

Based on the information developed during the inspection and the information provided in the April 13 and May 10, 2006, letters, 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. In summary, Indiana Community Hospitals failed to develop and implement written procedures to ensure with high confidence that each administration of NRC-licensed material was in accordance with the written directive from an authorized physician user, as required by 10 CFR 35.41, “Procedures for Administrations Requiring a Written Directive.” Specifically,

Community Hospitals of Indiana's written procedures did not require its staff to verify the correct position of the source carrier or the actual location of the radioactive source to assure that the administration of NRC-licensed material was in accordance with the written directive of the authorized user physician. As a result, on November 8, 2005, a nurse, overseeing the treatment simulation process, did not install a metal interface connector to the end of the catheter. Subsequently, the proximal area of the intended treatment site received a dose of 500 rem instead of the 200 rem prescribed and the distal portion of the treatment site received 200 rem instead of 500 rem prescribed by the authorized user physician. Based on the above, this is a medical event and licensees are required to report medical events to the NRC in accordance with 10 CFR 35.3045. Your staff identified the event on November 8, 2005, but failed to notify the NRC Operations Center within the next calendar day as required. Failure to develop and implement written procedures to ensure high confidence that each administration of NRC-licensed material is in accordance with the written directive of the authorized user physician, and failure to notify the NRC of a medical event are significant safety concerns. Therefore, the violations are collectively categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the 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 years, 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 consisting of modifying the written policy to include: (1) assigning the nursing staff the responsibility for complete catheter preparation and insertion of radiographic markers; (2) requiring the therapist performing the imaging to verify the correct placement of markers prior to imaging; and (3) requiring the physics staff to oversee the localization process. Additional corrective actions included: (1) recalculating the dose to the patient; (2) notifying the NRC Operations Center on April 5, 2006, that a medical event occurred on November 8, 2005; and (3) requiring the Radiation Safety Officer to review the NRC reporting requirements and committing to review all future treatments that are not completed as planned.

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 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 Reports No. 030-01625/06-001 and 030-01625/06-002 (DNMS), and letters from the Licensee dated April 13 and May 10, 2006. 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.

Please contact John R. Madera, Chief, Materials Inspection Branch, with questions. Mr. Madera can be reached at telephone number (630) 829-9834.

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 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; select **What We Do**, **Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA by Geoffrey E. Grant Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-01625
License No. 13-06009-01

Enclosure: Notice of Violation

*See previous concurrence
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DATE	07/07/2006		07/07/2006		07/07/2006		07/07/2006		07/10/2006	

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[1] OE concurrence received on 07/07/2006 per e-mail from D. Solorio

[2] NMSS concurrence received on 7/07/2006 per e-mail from D. Solorio

Please contact John R. Madera, Chief, Materials Inspection Branch, with questions. Mr. Madera can be reached at telephone number (630) 829-9834.

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Sincerely,

/RA by Geoffrey E. Grant Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-01625
License No. 13-06009-01

Enclosure: Notice of Violation

Letter to W. Corley from J. Caldwell dated July 10, 2006

SUBJECT: NOTICE OF VIOLATION

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NOTICE OF VIOLATION

Community Hospitals of Indiana, Inc.
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-026009-01
EA-06-101

During an NRC inspection conducted on April 3 and 4, 2006, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of any therapeutic dose of radiation from byproduct material.

10 CFR 35.41(a) requires, in part, that for any administration requiring a written directive, licensee's 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 November 8, 2005, the licensee did not develop and implement written procedures to provide high confidence that each administration requiring a written directive was in accordance with the written directive. Specifically, the licensee's written procedure for high dose rate (HDR) brachytherapy did not describe that the HDR metal interface connector was to be attached during treatment simulation to determine appropriate location of the sources within the patient. As a result, on November 8, 2005, the licensee failed to ensure the HDR metal interface connector was attached, during treatment simulation, and subsequently delivered a dose of approximately 500 rem to tissue adjacent to the treatment site rather than the 200 rem anticipated by the treatment plan.

B. 10 CFR 35.3045(a) requires, in part, that the licensee report any event, except an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose to the skin or an organ or tissue that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive.

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

Contrary to the above, on November 8, 2005, the licensee administered a radiation dose from byproduct material to a patient that resulted in a dose to tissue that exceeded 50 rem to tissue and more than 50 percent of the dose expected from the administration defined in the written directive. The written directive prescribed a radiation dose of

200 rem to the primary area of treatment. However, the dose that was actually delivered was approximately 500 rem and the licensee did not notify the NRC Operations Center until April 5, 2006, a period in excess of the next calendar day following discovery of the medical event.

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

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 Reports No. 030-01625/06-001 and 030-01625/06-002 (DNMS), and letters from the licensee dated April 13 and May 10, 2006. 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-06-101," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 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 10th day of July 2006