July 10, 2006

EA-06-095
NMED No. 060216
NMED No. 060219

John W. Talbott, Chief Operating Officer
IUPUI/Indiana University Medical Center
541 Clinical Drive
Indianapolis, IN 46202

SUBJECT: NOTICE OF VIOLATION [NRC SPECIAL INSPECTION REPORT NO. 030-01609/06-001(DNMS)] IUPUI/INDIANA UNIVERSITY MEDICAL CENTER

Dear Mr. Talbott:

This refers to the special inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on April 3 and 4, 2006, at IUPUI/Indiana University Medical Center, Indianapolis, Indiana, to review the circumstances related to medical events that occurred on January 17, 2005, and March 15, 2006. Your staff reported the medical events to the NRC on March 30, and April 3, 2006. One apparent violation was identified during the inspection. The apparent violation pertained to the failure to develop, implement, and maintain written procedures to provide high confidence that each administration of NRC-licensed material is in accordance with the written directive of an authorized user physician. The inspection report was provided to you on May 4, 2006.

In the letter transmitting the inspection report, we provided you 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 May 15, 2006, you declined to attend a PEC and on June 2, 2006, you provided a written response to the apparent violation. 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 June 2, 2006, letters, 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, IUPUI/Indiana University Medical Center failed to develop, implement, and maintain written procedures to provide high confidence that each administration of NRC-licensed material was in accordance with the written directive of an authorized user physician, as required by 10 CFR 35.41, “Procedures for Administrations Requiring a Written Directive.” Specifically, the licensee’s written procedures did not require its staff to verify the correct position of the source carrier or the actual location of the radioactive sources to provide high

confidence that each administration of NRC-licensed material was in accordance with the written directive of an authorized user physician. A low-dose-rate (LDR) gynecologic brachytherapy treatment, using cesium-137, NRC-licensed material, was administered on March 15, 2006. The authorized user physician prepared a written directive prescribing a dose of 1600 centigray (cGy) be administered to a patient using an intracavity applicator. On March 29, 2006, a physicist discovered the source carriers for the intracavity applicator used on March 15, 2006, were shorter than the applicator handle and would not allow the radioactive sources to drop completely into the applicator ovoids. As a result of using a shorter source carrier, the patient received a dose of 612 cGy, 62 percent less than the prescribed dose of 1,600 cGy. The licensee reviewed documents and x-rays associated with other brachytherapy treatments involving the use of intracavity applicators in LDR gynecologic brachytherapy treatments from 2003 to 2006, and identified six treatments which included use of the short source carriers. A subsequent dose assessment of these treatments determined that on January 17, 2005, a patient received a dose of 1,203 cGy instead of 2,500 cGy, a dose of 52 percent less than that prescribed by the authorized user physician. The five other treatments were determined to be 10 to 19.3 percent less than the treatment dose prescribed.

The treatments conducted on January 17, 2005, and March 15, 2006, were medical events in accordance with 10 CFR 35.2 and 10 CFR 35.3045(a) since the dose differed from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent or by 0.5 Sv (50 rem) shallow dose equivalent to the skin and the total dose delivered differed from the prescribed dose by 20 percent or more. The authorized user physician did not expect any adverse medical effects to the patients as a result of the medical events. The failure to develop, implement, and maintain written procedures to provide high confidence that each administration of NRC-licensed material is in accordance with the written directive of an authorized user physician is a significant safety concern. Therefore, this violation has been 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 2 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 your corrective actions which consisted of: (1) removing the short length source carriers from service and ordering new ovoid applicators; (2) modifying the Brachytherapy Implant Checklist to include dual verification of the source position prior to each brachytherapy treatment; (3) marking ovoid applicator kits with unique identifications to match the applicator with the associated source carrier; and (4) assigning a staff physicist with the responsibility for ensuring all applicator parts are compatible and unmatched parts are removed from service.

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 Report No. 030-01609/06-001(DNMS), and letters from the licensee dated April 13, and June 2, 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. 030-01609
License No. 13-02752-03

Enclosure: Notice of Violation

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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

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. 030-01609/06-001(DNMS), and letters from the licensee dated April 13, and June 2, 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.

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Sincerely,

/RA by Geoffrey E. Grant Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-01609
License No. 13-02752-03

Enclosure: Notice of Violation

Letter to J. Talbott from J. Caldwell dated July 10, 2006

SUBJECT: NOTICE OF VIOLATION

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NOTICE OF VIOLATION

IUPUI/Indiana University Medical Center
Indianapolis, Indiana

Docket No. 030-01609
License No. 13-02752-03
EA-06-095

During an NRC inspection conducted on April 3, and 4, 2006, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.40(a) requires, in part, 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, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with a written directive. Procedures must meet the requirements described in 10 CFR 35.41(b) to verify that the administration is in accordance with the treatment plan and the written directive.
>
> Contrary to the above, as of April 4, 2006, the licensee did not develop written procedures to provide high confidence that each administration was in accordance with a written directive. Specifically, the licensee's written procedures did not require its staff to determine or verify the correct position of each radioactive source in a Fletcher-Suit-Delclos ovoid brachytherapy applicator prior to patient treatments. As a result, the licensee's use of shorter length source carriers, containing cesium-137, caused the sources to be displaced from the correct position in the ovoid applicators during brachytherapy treatments, resulting in medical events that occurred on January 17, 2005, and March 15, 2006.
>
> 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 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. 030-01609/06-001(DNMS), and letters from the licensee dated April 13, and June 2, 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-06-095," 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