

June 3, 2008

EA-08-049

Ms. Jacqueline DeSouza, Chief Operating Officer
Research Medical Center
Midwest Gamma Knife Center
2316 E. Meyer Blvd.
Kansas City, MO 64132

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$3250 – NRC INSPECTION REPORT 030-33507/2007-002(DNMS) AND
INVESTIGATION REPORT 3-2007-020 – RESEARCH MEDICAL CENTER

Dear Ms. DeSouza:

This refers to the NRC inspection conducted on April 24, 26, and 27, 2007, at the Research Medical Center facility in Kansas City, Missouri, documented in Inspection Report 030-33507/2007-002(DNMS) dated May 24, 2007, and our letter dated March 3, 2008, which provided a summary of the results of an investigation conducted by the NRC Office of Investigations (OI). As stated in our letter dated March 3, 2008, OI conducted an investigation of an Open Item from the inspection report and an apparent violation of NRC requirements was identified. The details were discussed with you and members of your staff during a final exit telephone conference on March 3, 2008. During that telephone conference, we informed you of the apparent violation. The Open Item that was referenced in the inspection report is considered closed.

In our letter dated March 3, 2008, we provided you with the opportunity to address the apparent violation by attending a predecisional enforcement conference, by participating in an alternate dispute resolution session, or by providing a written response before we made our final enforcement decision. On March 13, 2008, your Radiation Safety Officer notified us that you would be providing a written response to the apparent violation and would not be requesting a predecisional enforcement conference or alternate dispute resolution. In a letter dated April 1, 2008, you provided a response to the apparent violation.

Based on the information developed during the inspection and OI investigation, and the information that you provided in your letter dated April 1, 2008, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed non-publicly available Notice of Violation (Notice) and the circumstances surrounding that violation were described in our letter dated March 3, 2008.

The violation was caused by the Radiation Safety Officer's willful failure to: (1) ensure that NRC requirements were implemented; and (2) fully inform those within the licensee's management structure who could implement the requirements so that actions could be taken to ensure the licensee was in compliance by the required date. The NRC is also concerned that licensee management did not implement the proper oversight to identify the willful violation prior to the NRC inspection on April 24, 2007, nearly one year after the NRC requirement was to be implemented. Willful violations are, by definition, of particular concern to the Commission because its regulatory program is based on licensees and their contractors, employees, and agents acting with integrity and communicating with candor. Willful violations cannot be tolerated by either the Commission or a licensee.

Because there were willful aspects to the violation, the NRC considered whether credit was warranted for both *Identification* and *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 not warranted for *Identification* because the violation was identified by the NRC during an inspection. Credit was warranted for *Corrective Action* based on your corrective actions, which included installing a system and developing a program that complied with the requirements within a day of being informed of the failure to meet those requirements. Furthermore, your staff committed to heightened management oversight of the radiation safety program, including enhanced participation in Radiation Safety Committee meetings.

Therefore, to emphasize the importance of complying with NRC regulations as well as to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the base amount of \$3250. In addition, issuance of this Notice 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. 030-33507/2007-001(DNMS), our letter dated March 3, 2008, and your letter dated April 1, 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.

This letter will be made publicly available and will be accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. However, the enclosure to this letter and your response, if you provide one, are exempt from public disclosure in accordance with 10 CFR 2.390. Therefore, the enclosure and your response, if any, will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS).

J. DeSouza

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Should you have any questions, please contact Mr. Patrick Loudon, Chief, Materials Inspection Branch, at (630) 829-9627.

Sincerely,

/RA by Mark A. Satorius Acting for/

James L. Caldwell
Regional Administrator

Docket No. 030-33507
License No. 24-17998-02

Enclosures:

1. Notice of Violation and Proposed
Imposition of Civil Penalty (Non-Public)
2. NUREG/BR-0254 Payment Methods
(Licensee only)

cc w/encl 1: State of Missouri

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Letter to J. DeSouza from James L. Caldwell dated June 03, 2008

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