August 21, 2013

James Bower, M.D.
Chief Medical Officer
Midwest Division – RMC, LLC
d/b/a Research Medical Center
2316 East Meyer Blvd.
Kansas City, MO 61432

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03013959/2013001(DNMS) – MIDWEST DIVISION – RMC, LLC

Dear Dr. Bower:

On July 25 and 26, 2013, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your facility in Kansas City, Missouri, with continued in-office review through August 6, 2013. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included a review of written directives and post-treatment plans for several prostate implant procedures and review of a memorandum addressing actions to be taken. A final exit meeting was held between Mr. Geoffrey Warren of my staff and Dr. Stephen T. Slack, your facility's Radiation Safety Officer, by telephone on August 7, 2013.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. No violations were identified as a result of this inspection.

The inspector identified a concern with prostate implant procedures. As of July 25, 2013, hospital staff had completed post-treatment plans for only three of thirty-five prostate implant procedures performed since February 4, 2013. The cause of this situation was that the authorized user had not contoured the scans taken following each procedure. Contributing factors included (1) the physicist did not notify management personnel about the situation and (2) the written procedure did not specify a time frame for contouring the scans. The authorized user has now contoured the scans, excluding those procedures that are still in process, and the physics staff has completed the post-treatment plans. Review of these plans indicated that no medical events occurred during this period. The NRC's concern is that if any medical events had occurred during the period, you would have been unable to follow up on them in a reasonable amount of time to determine the cause. In that case, the cause of the medical event could recur and cause additional medical events. This issue does not constitute a violation of NRC requirements because no medical event occurred and your written procedure addresses each point required by Title 10 of the *Code of Federal Regulations* (CFR), Section 35.41.

Based on a memorandum that Dr. Slack provided to the NRC on August 6, 2013, you have committed to taking additional actions for future prostate implant procedures to prevent recurrence of this issue. These actions include: (1) the dosimetrist notifying hospital management if the post-treatment plan has not been completed within 30 days after an implant and once the plan is completed, (2) the Medical Staff Office providing penalties to the authorized user for continued failure to complete required medical records, and (3) the Chief of Clinical Operations of Radiation Oncology compiling a written report of completion of seed implant cases each month for review by the Radiation Safety Committee.

The NRC has concluded that information regarding the reason for the issue and the actions taken and planned to address the concern and prevent recurrence is already adequately addressed on the docket in the memorandum received from Dr. Slack on August 6, 2013, and in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, clearly mark your response as a “Reply to Inspection Report No. 03013959/2013001(DNMS),” 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, Region III, within 30 days of the date of this letter.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC’s Public Document Room or from the NRC’s Agencywide Documents Access and Management System (ADAMS), accessible from the NRC’s website 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 publicly available without redaction.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-13959
License No. 24-18625-01

cc: Stephen T. Slack, Ph.D., Radiation Safety Officer
Matt Sogard, Chief Operating Officer
State of Missouri

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Aaron T. McCraw, Chief
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cc: Stephen T. Slack, Ph.D., Radiation Safety Officer
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Letter to James Bower, M.D. from Patrick L. Louden dated August 21, 2013

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