

March 21, 2007

Julie MacDonald, MS, RN  
Senior Vice President  
Patient Care Services/COO  
Saint Joseph Mercy Health Systems  
St. Joseph Mercy Hospital  
P.O. Box 995  
Ann Arbor, MI 48106-0995

SUBJECT: NRC INSPECTION 030-01997/07-01(DNMS) AND NOTICE OF VIOLATION -  
ST. JOSEPH MERCY HOSPITAL

Dear Ms. MacDonald:

This refers to the inspection conducted on February 26 through 27, 2007, at the St. Joseph Mercy Hospital. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with you and members of your staff.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations, and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov>. The violation is cited in the enclosed Notice of Violation (Notice). The violation involves the failure to perform required monthly spot checks on your high dose rate (HDR) remote afterloading unit.

During your Radiation Safety Officer's (RSO's) quarterly audits, he identified that monthly HDR safety checks during January, July, November and December 2005 were not performed as required. The monthly safety checks included performing a source output check in accordance with historical licensing requirements although a monthly source calibration/output check is not required by 10 CFR Part 35. Discussions with your staff revealed that during 2005, the department was staffed with one authorized medical physicist who was also involved with the commissioning of a new LINAC unit at a satellite clinic. Other medical physicists at the hospital failed to recognize the regulatory requirements for performing the monthly safety checks. Your chief physicist provided training to your staff medical physicists on the requirements to perform monthly safety checks with emphasis on regulatory requirements.

Unfortunately, your RSO again identified that the staff failed to conduct monthly safety checks on the HDR unit in September 2006. Discussions with the physics staff revealed that the September 2006 safety check was not performed because the dosimetry equipment had been

sent out for calibration. Since the department performed a source output check concurrently with the monthly safety checks and the dosimetry equipment was unavailable in September 2006, the staff failed to perform the required safety checks. According to your staff, when the dosimetry equipment was sent out for calibration in late August 2006, the electrometer was damaged in shipment and required additional repairs resulting in unexpected delays in its return. In light of this delay, the department purchased an additional electrometer so that sufficient dosimetry equipment is available. However, the commitments in your license for performing monthly safety checks do not include source calibration/output checks and it was unnecessary to delay conducting HDR unit safety checks due to unavailable dosimetry equipment.

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 is already adequately addressed on the docket 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, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

Based on the results of this inspection, the NRC has also determined that an additional violation of NRC requirements occurred. The violation involves failure to perform semi-annual inventories of your brachytherapy sources. This matter was also identified by your Radiation Safety Officer during his June 2006, audit. Your prompt and effective corrective actions included adding a notice to the radiation oncology department calendar to remind the staff to conduct semi-annual inventories of your brachytherapy sources. This non-repetitive, licensee-identified and corrected violation is being treated as a Non-Cited Violation, consistent with Section VI.A.8 of the NRC Enforcement Policy.

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 provide one, 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/readingrm/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.

Sincerely,

***/RA by D. Wiedeman Acting for/***

John R. Madera, Chief  
Materials Inspection Branch

Docket No. 030-01997  
License No. 21-00943-03

Enclosure:  
Notice of Violation

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Sincerely,  
**/RA by D. Wiedeman Acting for/**  
 John R. Madera, Chief  
 Materials Inspection Branch

Docket No. 030-01997  
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DATE	03/16/07	03/21/07		

Letter to Julie MacDonald from John R. Madera dated xxx

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ST. JOSEPH MERCY HOSPITAL

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G. Grant, RIII

S. Reynolds, RIII

G. Shear, RIII

K. O'Brien, RIII

## NOTICE OF VIOLATION

Saint Joseph Mercy Health System  
St. Joseph Mercy Hospital  
Ann Arbor, Michigan

Docket No. 030-01997  
License No. 21-00943-03

During an NRC inspection conducted from February 26 through 27, 2007, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," the violation is listed below:

Condition 21.A. of License No. 21-00943-03 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in a letter, dated August 24, 2005, with attachments.

Item 8.18 - "Therapy Unit - Calibration and Use" of the letter, dated August 24, 2005, states that the licensee has developed procedures for performing periodic spot checks of the high dose rate (HDR) machine as required by 10 CFR 35.643.

Item B.2., "Safety Checks" of Appendix II, "High Dose Rate (HDR) Remote Afterloader Program," requires, in part, that the following safety checks be performed in a period not to exceed one month prior to any patient treatment: (1) Source position; (2) Timer accuracy and linearity; (3) Source guide tubes lengths confirmed; and (4) Back up battery test.

Contrary to the above, during January, July, November and December 2005, and September 2006, the licensee did not perform any of the required safety checks on its HDR unit and patients were treated during these months.

This is a Severity Level IV 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 will be achieved is already adequately addressed on the docket in the letter transmitting this Notice. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, 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, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

Enclosure

If you choose to respond your response will be placed in the NRC Public Document Room (PDR), therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

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

Dated this 21st day of March 2007

Enclosure

