

May 25, 2010

NMED 100063

Mr. Timothy Applegate, RN
Radiation Safety Officer
DMC Sinai-Grace Hospital
6071 Outer Drive
Detroit, Michigan 48235

SUBJECT: NRC ROUTINE INSPECTION REPORT 030-01992/10-01(DNMS) AND
NOTICE OF VIOLATION – DMC SINAI-GRACE HOSPITAL

Dear Mr. Applegate:

On April 26 and 27, 2010, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection at the DMC Sinai-Grace Hospital in Detroit, Michigan. At the conclusion of the inspection an exit meeting was held between yourself and the NRC inspector to discuss the inspection findings.

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

Based on the results of the inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations involved failure to include required information in a number of written directives between January 1, 2009, and April 1, 2010. The violations are cited in the enclosed Notice of Violation (Notice). The violations are being cited in the Notice because they were identified by the NRC inspector.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The

T. Applegate

-2-

NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC 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 available to the public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No.: 030-01992
License No.:21-00299-04

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

T. Applegate

-2-

NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC 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 available to the public without redaction.

Sincerely,

/RA/

Tamara E. Bloomer, Chief
Materials Inspection Branch

Docket No.: 030-01992
License No.:21-00299-04

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

DISTRIBUTION:
Cynthia Pederson
Steven Reynolds
Patrick Loudon
Steven Orth
Carole Ariano
Paul Pelke
Patricia Buckley
Tammy Tomczak
MIB Inspectors

*See previous concurrence

DOCUMENT NAME: G:\Work in progress\IR - DMC Sinai-Grace Hospital NOV.docx

☒ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ☒ Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS	E	RIII DNMS	E	RIII		RIII	
NAME	GO Parker: jm TEB for		TEBloomer					
DATE	05/25/10		05/25/10					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

**DMC Sinai-Grace Hospital
Detroit, Michigan**

**Docket No. 03001992
License No. 21-00299-04**

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 26 and 27, 2010, 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.

Contrary to the above, on several occasions between January 1, 2009, and April 1, 2010, the licensee failed to ensure that an authorized user dated and signed written directives before the administration of therapeutic doses of radiation from byproduct material.

This is a Severity Level IV violation (Supplement VI)

- B. 10 CFR 35.40(b)(6)(i) requires, in part that, for all brachytherapy including low, medium and pulsed dose rate remote afterloaders the written directive contain before implantation: treatment site, the radionuclide, and dose.

Contrary to the above, on three occasions between January 1, 2009, and April 1, 2010, the licensee failed to ensure that written directives for applicable brachytherapy contained the treatment site before implantation.

This is a Severity Level IV violation (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, DMC Sinai-Grace Hospital is hereby required to submit a written statement or explanation 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 the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified suspended, or revoked, or why such other action as may be proper should not be taken. Where

good cause is shown, consideration will be given to extending the response time. 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, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agency Document Access and management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the basis for your claim of withholding (e.g., explain why disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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

Dated this 25TH day of May 2010.