

DMC
Sinai-Grace
Hospital

6071 W. Outer Drive
Detroit, MI 48235
www.sinaigrace.org

June 18, 2010

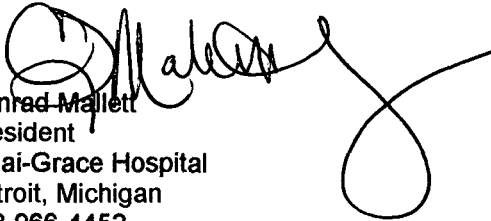
U.S. Nuclear Regulatory Commission
Regional Administrator, Region III
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352

Re: License No. 21-00299-04, DMC Sinai-Grace Hospital

In accordance with the NRC Routine Inspection Report 030-01992/10-01(DNMS) and Notice of Violation dated May 25, 2010, we are providing a written reply as required.

Thank you for your cooperation with this matter. If you have any questions or require additional information please contact Timothy Applegate, Radiation Safety Officer at 966-4391 or TApplega@dmc.org

Sincerely,



Conrad Mallett
President
Sinai-Grace Hospital
Detroit, Michigan
313 966-4452
CLMallett@dmc.org

A better way to get better.

JE07

Reply to a Notice of Violation

Docket Number: 03001992
License Number: 21-00299-04

Violations Identified:

- A. The authorized user did not sign and date the written directive before the administration of therapeutic doses of radiation from byproduct material on several occasions.
- B. The authorized user did not document the treatment site on the written directive prior to implantation of I-125 seeds for LDR brachytherapy on three occasions.

Investigation:

An investigation and review was conducted by representatives from senior administration, radiation oncology administration, radiation safety, and the radiation oncology medical and technical staff. The written directive requirements, procedures, forms, and personnel responsibilities were reviewed.

Root Cause:

There was a lack of compliance in the completion of the required elements on the existing written directive forms and the current record reviewing process was not effective. The investigation revealed that the written directive forms and procedures required revision. The pre-implant and post-implant elements of the written directive were recorded inconsistently in separate locations on several different forms. The completion and reviewing of the written directives was challenging due to the multiple forms. The required elements of the written directive and the responsibilities of the staff were not clearly defined in the existing procedure. The written directive review process was not clearly defined.

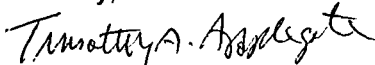
Corrective Action:

The written directive requirements as specified in NRC Regulation 10 CFR 35.40 were reviewed by the Radiation Safety Officer with the authorized user, medical physicist, technical and administrative staff of the Radiation Oncology Center. A new written directive form has been developed and implemented by the Radiation Safety Officer and the Administrative Director of the Radiation Oncology Center. All of the required elements of the written directive are contained on a single page, including signature of the authorized user, date, and treatment site documentation. A management operating policy directive has been written by the Administrative Director of the Radiation Oncology Center and the Lead Dosimetrist to specify the written directive requirements, personnel responsibilities, and review process and has been reviewed with the staff of the Radiation Oncology Center. The written directive regulations were reviewed with the authorized user by the Radiation Safety Officer to assure knowledge of the regulatory requirements and compliance with the requirements.

Date of full compliance:

The corrective actions will be completed and implemented by June 25, 2010.

Sincerely,



Timothy A. Applegate RT (N)
Radiation Safety Officer
DMC/Sinai-Grace Hospital
Detroit, Michigan
313 966-4391
TApplega@dmc.org