



MERCY HEALTH PARTNERS

16 May 2011

Mark Satorius
Regional Administrator
US Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Response to an Apparent Violation in Inspection Report No. 030-02016/2011-001 (DNMS); EA-11-094

Dear Mr. Satorius:

With regards to the apparent violation identified in the Inspection of 24-25 February 2011, we agree the former policy labeled as HDR treatment procedures did not address specifically and in detail the steps necessary to safely and effectively deliver the written directive for an HDR treatment. As the inspector confirmed, no medical events arose as a consequence of this apparent violation. We believe many factors contributed to this lack of appropriate documented procedures, including initial rapid growth of the radiation oncology treatment practice. In addition, relevant documented procedures were stored in a widely available location, but outside of the accepted policies and procedures folders and as a result had not been formally recognized.

When the inspector pointed out the apparent error, I immediately updated our available procedures to fully reflect our current robust practice. Our HDR team, including our authorized users, authorized medical physicists, dosimetrists, therapists and nurses carefully reviewed the revised documents for accuracy. Further, following subsequent telephone conversations with the same inspector, I continued to refine the procedures to clarify the treatment planning and delivery timeline. Once satisfied the procedures were complete, I placed them in the appropriate folder for policy formatting. The clinic staff and HDR team recognizes and adheres to these procedures.

We are committed to reviewing, updating as necessary and practicing all pertinent procedures related to the safe and effective delivery of the written directive of an HDR treatment. The review period shall not exceed a year.

We achieved full compliance 08 April 2011.

I certainly appreciate your prompt attention to this response. If you have any questions, please call me a 231-672-2011.

Sincerely,

Jennifer Hann Fisher, MS, DABR
Radiation Safety Officer

✓ cc: Tamara E. Bloomer, Chief
Materials Inspection Branch
Anne Boland, Director
Division of Nuclear Materials Safety

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