

January 19, 2007

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

Re: Response to An Apparent Violation in Inspection Report 030-02286/2006-01
(DNMS); EA-06-315

In response to the NRC Special Inspection Report dated December 29, 2006, Saint Luke's Hospital of Kansas City (SLH) accepts the findings of one violation of 10 CFR 35.41(a) associated with failure to have adequate written procedures.

As described in our initial notification report of this event (dated November 8, 2006), the violation resulted due to a typographical error during treatment planning. Written procedures did not require that the specific item (catheter length) be checked to ensure that the length entered into the computer agreed with the measured length.

Immediately following the identification of the medical event, the SLH Radiation Safety Committee (RSC) initiated the following corrective actions:

1. Under recommendation of the Authorized Users (AUs) for Radiation Oncology, the High Dose Rate afterloader (HDR) program was continued for non-MammoSite patients. The AUs determined that halting the program would have negative clinical effects on a number of patients that are currently in the middle of treatment or would suffer from delay of treatment. The RSC did halt further Mammosite treatments until the program could be completely reviewed.
2. A subcommittee was formed to review the entire HDR program prior to resumption of MammoSite treatments. The subcommittee reviewed the current policies, procedures and checklists. They also reviewed other institutions procedures and checklists and incorporated best practices into the program. The full RSC approved these changes and authorized the resumption of Mammosite treatments on December 20, 2006.
3. A review of all previous HDR cases was performed to ensure that this error has not occurred previously. All previous HDR cases have been reviewed and no errors were detected.

4. A radiation safety inservice was performed by the physicists and included the additional precautions described below. Additionally, the HDR manufacturer (Varian) performed the annual refresher training for the radiation therapy staff.
5. The HDR procedure and checklists were modified so that two individuals make independent measurements of the catheter length, and one of the individuals must be a physicist. Additionally, two individuals independently verify the numbers entered into the planning computer. These revised written procedures and checklists were provided to the inspector previously.

Full compliance with the requirements was achieved by December 20, 2006. We believe that the corrective actions we have taken will allow us to verify that HDR therapy administrations are in accordance with the treatment plan and written directive.

If you have any questions or require additional information, please feel free to contact me at (816) 932-6296 or gsackett@saint-lukes.org.

Regards,



Greg Sackett, CHP
Radiation Safety Officer

Cc: NRC Region III, Enforcement Officer