Avera
Medical Group
Radiation Oncology

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8 February 2012

To: U.S. Nuclear Regulatory Commission, Region IV
Attn: Roy Caniano, Division Director, Nuclear Materials Safety
1600 E Lamar Blvd
Arlington, TX 76011-4511

From: Licensee-Avera McKennan Hospital 40-16571-01 (Docket #030-11252)
Department-- Avera Medical Group- Radiation Oncology

Subject: Action plan following report of Medical Event #47599

Dear Mr. Caniano-

At the conclusion of the exit interview last week a number of requests were made regarding our long and short term plan of corrective action. This letter sets out our actions to date, and also outlines both our short and long term corrective action plans. In addition to the task list, we remain committed to monitoring the patient following this incident. The physician continues with regular follow-up visits with the patient and has discussed with her the need for this due to the increased risk of skin reaction.

Our incident response group has continued to review the incident and clinic practices in light of the NRC comments during the inspection and exit interview. As a result, the following actions have been, or will be taken.

Completed Immediate Corrective Actions

- Kris Gaster, Assistant Vice President of Outpatient Cancer Clinics, has been added to the radiation safety committee meeting roster.
- The institutional and departmental organizational charts have been revised to add the Radiation Safety Officer as attached.
- On February 7, 2012, educated all Avera Radiation Oncology (ARO) staff on the Radiation Safety Officer duties and responsibilities.
- Standard Operating Procedures (SOP) revision, development, implementation and training.
    - Developed and implemented a master standard operating procedure (SOP) on writing, reviewing, revising, training and auditing to maintain standard operating procedures (SOP) within ARO.

- An SOP has been developed and implemented for treatment plan review by an alternate physicist or a trained dosimetrist prior to first treatment. This procedure is to prevent recurrence of the first erroneous treatment fraction in the Medical Event. Training completed February 8, 2012.
- An SOP has been developed and implemented for End of treatment (EOTs) chart reviews by the alternate physicist. The medical physicists have reviewed and approved the SOP. This procedure is intended for timely discovery of potential errors, both near misses and Medical Events.
- The SOP for data transfer from the Oncentra Treatment Planning System (TPS) to the Treatment Control System (TCS) has been revised. This SOP will be used exclusively by the medical physicists. The medical physicists have reviewed and approved the policy. This procedure is to prevent recurrence of the second erroneous treatment fraction in the Medical Event.
- A Time Out policy used exclusively for HDR has been developed. Training and implementation of the HDR Time Out policy was completed for physicians on February 7, 2012. Training and implementation of the HDR Time Out policy will be completed for CT and brachytherapy staff on February 9, 2012. Training included a "demo back" by the trainees to confirm the understanding of the policy. This procedure is intended to prevent recurrence of the errors made in this Medical Event.

- Human Resource Department has been contacted to obtain a locum medical physicist for coverage until third staff physicist is on site.

Culture of Safety development, implementation and training

- Initial conversations have been made for contracting an external consultant to assist with the development of a safety culture initiative in ARO.
- Dr. Kapaska, Regional President, to speak with ARO staff about the importance of a culture of safety.
- Develop a Safety Committee to focus on safety culture initiatives. Regular monthly safety meetings will be held. Communication with ARO staff will be done monthly with the first staff meeting scheduled for February 15, 2012.

Short Term Corrective Actions in Process

- The Radiation Safety Officer is continuing to work on refining the patient skin dose calculation. It is anticipated that this will be completed on or before the end of February.
- The Radiation Safety Officer's initial sampling audit of HDR catheter lengths for January 2011 through January 2012 is completed. A 100% audit of all HDR treatments will be completed by February 29, 2012. A written report will be prepared following the 100% audit. This report will be kept on file for inspection.
- An HDR variance log will be implemented as a separate variance log from the linear accelerators. Completion date February 29, 2012.
- We will define and educate staff on conditions which would constitute a "near miss" for HDR treatments. This will include items to be documented in the HDR variance log. An SOP defining what constitutes an HDR variance will be developed and implemented. Training on the HDR variance SOP will take place at an ARO March 2012 staff meeting.

- A contractual agreement will be put in place for locum medical physicist coverage until a third staff medical physicist is hired.
- An independent consultant will be retained to review the overall structure and function of ARO.

Intermediate Corrective Action Plan

- A variance log review and trend analysis will be conducted on a periodic basis. The results will be communicated at appropriate staff meetings.
- Overall annual variance log review will be conducted by the Radiation Safety Officer and Department Manager as part of the RSO's annual audit of the Radiation Safety Program. A written annual review for 2011 will be prepared as soon as possible. Routine annual reviews will commence in January 2013.
- Planned changes to include, among other things, a 100% audit of HDR patients/procedures on a quarterly basis beginning April 2012.
- Hire an additional Medical Physicist.

Respectfully Submitted,

R. J. Massoth, Ph.D.

Richard J. Massoth, Ph.D.
Radiation Safety Officer

Reviewed and Approved:

Kris Gaster

Kris Gaster
Assistant Vice President
Outpatient Cancer Clinics

With concurrence of:

Judy Blauwet, RN
Senior Vice President
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