Allegiance
HEALTH

December 10, 2009

United States Nuclear Regulatory Commission
Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

Re: Response to an Apparent Violation in Inspection Report No. 030-01990/2009-001(DNMS); EA-09-266

Dear Ms. Tamara Bloomer:

(1) The reason for the apparent violation:

For medical event #1 the relative positions of the implanted I-125 seeds did not produce sufficient dose coverage of the prostate volume as specified by the written directive and the pre-plan. A slight cold-spot in the anterior superior portion of the prostate was found.

For medical event #2 the relative positions of the implanted I-125 seeds did not produce sufficient dose coverage of the prostate volume as specified by the written directive and the pre-plan. A cold spot in the superior/base portion of the prostate was found.

(2) The corrective steps that have been taken and the results achieved:

Temporary suspension of patient implant procedures from 8/25/2009 to 9/27/2009.

For medical event #1, the patient continues to undergo close surveillance with no further implant planned.

For medical event #2, the patient underwent a corrective implant on 9/28/2009. Post implant dosimetry utilizing CT and MR imaging modalities was completed on 11/5/2009 and showed that the corrective implant was successful.

(3) The corrective steps that have been taken to avoid further violations:

The department policies and procedures, as well as the brachytherapy policies and procedures have been updated to reflect the following corrective actions:

1. Scheduling for pre-planned cases: The OR date for the implant will be scheduled first. Once the OR date is scheduled, the pre-plan volume study will be scheduled within three weeks prior to the OR implant date, in order to minimize the potential changes to the prostate volume.
2. Prior to implanting the patient with radioactive material the Authorized User must verify the prostate volume.

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3. During the implant procedure, the Authorized User will use appropriate imaging modalities (including bi-planar ultrasound and/or fluoroscopy) to ensure that the patient's prostate is still localized correctly and the seeds are placed in the intended positions in the prostate.
4. The Authorized User performing seed implants must have documented experience in successfully performing prostate seed implants within the past 18 months, or have documented training in the performance of the prostate seed implants within the past 18 months.

(4) Compliance of action plans was achieved December 1, 2009:

1. 9/8/2009 - Scheduling guidelines and procedure was written defining priority and timing of scheduling brachytherapy procedures and treatment. Manager of Radiation Oncology provided education and training to the scheduling staff.
2. 10/20/09 – Documented that Dr. Feng successfully completed 9 brachytherapy cases including using appropriate imaging modalities at Providence Hospital under the supervision of Dr. McLaughlin prior to resuming brachytherapy at Allegiance Health.
3. 12/01/2009 – Written Directive Administration Procedure was updated and approved by the Department Manager and Authorized User to include the following:
    i. Scheduling for pre-planned cases: The OR date for the implant will be scheduled first. Once the OR date is scheduled, the pre-plan volume study will be scheduled within three weeks prior to the OR implant date, in order to minimize the potential changes to the prostate volume.
    ii. The Authorized User performing seed implants must have documented experience in successfully performing prostate seed implants within the past 18 months, or have documented training in the performance of prostate seed implants within the past 18 months.
    iii. Prior to implanting the patient with radioactive material a treatment plan must be generated that provides sufficient information and direction to meet the objectives of the written directive.
    iv. Prior to implanting the patient with radioactive material the Authorized User must verify the volume of the prostate.

Very truly yours,

ALLEGIANCE HEALTH

Karen D. Yacobucci

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