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3/9/2012

U.S. Nuclear Regulatory Commission
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Washington, DC 20555-0001

Brachytherapy Response to Notice of Violation, License #40-00238-04

A. 10 CFR 35.41(a)(2) states, in part, that for any administration requiring a written directive, the licensees shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
B. 10 CFR 35.41(b)(2) states, in part, that at a minimum, the procedures required by Paragraph (a) of this section must address verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive.

Contrary to the above, on September 1, 2011, the licensee's procedures did not meet the requirements described in 10 CFR 35.41(b), in that the procedures did not require verifying that the administration was in accordance with the treatment plan and the written directive. Specifically, the licensee's prostate permanent implant brachytherapy procedure did not require explicit verification that the administration was in accordance with the treatment plan and the written directive.

This is a Severity Level IV violation (Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, Rapid City Regional Hospital, Inc. is hereby Required to submit a written statement or explanation within 30 days of the date of the letter

Response

At the time of the inspection, the inspector and the radiation safety officer performed a routine review of the prostate implant program. During this review it was noted that a formal policy was not in place, regarding the evaluation of the post implant CT. Since the inspection a new policy has been written.

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Following a prostate seed implant, each patient will have a one month post implant CT performed. Following the CT, dosimetry or physics staff will identify the seeds and the physician will contour the relevant anatomy. This will be used by the planning system to provide a post implant dose rendering. The post plan will be evaluated, and results will follow these criteria.

The target D90 of the one month post plan will be 90%. Following NRC 10 CFR 35.3045 Report and notification of a medical event, these results will not vary from this by more than 20%. There are 2 exceptions to these criteria:

1) If the D90 of the approved preplan falls outside of these boundaries.

   Due to the difference in gland shape and size, there are times when the approved preplan falls outside these boundaries. In these situations, we will expect the post implant D90 to be within 20% of the preplan dose.

2) If there is a significant change in the volume of the prostate gland, between the planning and post plan images.

   Some patients receive pre-implant hormonal therapy, pre-implant radiation therapy, or both. These therapies, individually or combined, can have a continuing effect on the volume of the prostate gland. The traumatic nature of the implant procedure also has an impact on volume of the gland. In these cases the D90 will be normalized to the size of the original planning image.

Failure to meet these criteria will constitute a medical event. Medical events will be handled according to NRC: 10 CFR 35.3045 Report and Notification of a Medical Event.

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