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11/17/2011

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

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formal policy was not in place, regarding the evaluation of the post implant CT. Since the inspection a new policy has been written. This policy is attached for review.

Approximately one month following a prostate seed implant, each patient will have a 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 post implant information. Following NRC 10 CFR 35.3045 Report and notification of a medical event results will not vary more than 20%.

In the journal Practical Radiation Oncology: October-December 2011, page 220, "ASTRO recommends a source strength-based criterion of >20% of source strength prescribed in the post-procedure written directive being implanted outside the planning target volume for defining a medical event in permanent prostate brachytherapy"

Following these recommendations, a medical event will be defined as:

The total activity of the seeds implanted, into the treatment volume, will not vary more than 20% from the post implant written directive.

Failure to meet 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.

James S. Mckee Jr.
Radiation Safety Officer
Rapid City Regional Hospital
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