From: White, Matt
To: RulemakingComments Resource
Subject: FW: nrc rule change
Date: Monday, October 20, 2014 11:55:53 AM
Attachments: Response to Rule Change for Medical Event.doc

To Whom it May Concern:

Please consider our attached response to the proposed amendment to 10 CFR 35 for Medical Event Reporting for permanent implant brachytherapy.

Sincerely,
Matthew White

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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemakings and Adjudications Staff

To Whom it May Concern:

The members of our permanent implant brachytherapy program respectfully submit the following response to the proposed rule changes outlined in Vol. 79, No. 139 of the Federal Register (July 21, 2014). Our response specifically addresses the newly proposed definitions of a medical event in permanent implant brachytherapy.

Section 35.3045, paragraph (a)(2) criterion (2) indicates that greater than 20 percent of the source strength outside of the treatment site defined in the post-implantation portion of the WD would result in a medical event. Our program performs prostate seed implants. We implant I-125 seeds into the prostate, but we also implant seeds into normal tissue surrounding the prostate so that the prescription dose will cover a treatment margin (Planning Target Volume or PTV) in addition to the prostate. This treatment margin is meant to treat extra-capsular extension of prostate cancer. The American Association of Physicists in Medicine Task Group Report 137 and the American Brachytherapy Society Prostate Low-Dose Rate Task Group Report recommend treating a margin of tissue outside of the prostate. Because of the rapid dose fall-off in prostate seed brachytherapy, many of the seeds are even implanted just outside of the PTV to ensure adequate dose coverage to the PTV. This results in a high quality implant with excellent dose statistics, but at the same time it would be viewed as a Medical Event under the NRC proposed rule change. A secondary concern with this criterion is that our vendor's software does not currently have a satisfactory method of determining whether 20 percent of the source strength is outside of the treatment site.

Section 35.3045, paragraph (a)(2) criterion (3) indicates that a medical event would occur if 5 contiguous cubic centimeters of normal tissue located outside of the treatment site receives an absorbed dose that exceeds the prescription dose by 50 percent or more. Currently our vendor's software does not have an automated method for determining the volume of normal tissue outside of the treatment site that exceeds the prescription dose by 50 percent. A manual workaround solution of contouring the tissue outside the treatment site must be employed, and this workaround will likely lead to differing results, depending on the one doing the contouring. Furthermore, the definition of the term "contiguous normal tissue" is not clear. Does this mean "connected" to the treatment volume or a continuous 5 cc volume all over 150

percent of the prescription value connected or not. Our software does not differentiate "contiguous volume" in its DVH values of dose vs volume. It calculates total integrated volume at a given dose level.

Section 35.3045, paragraph (a)(2) criterion (4) indicates that a medical event would occur if 5 contiguous cubic centimeters of normal tissue located within the treatment site receives an absorbed dose that exceeds the prescription dose by 50 percent or more. In the case of prostate brachytherapy, it is common to have 50 percent or more of the prostate covered by an absorbed dose that exceeds the prescription dose by 50 percent (the V150 is routinely 50 percent by design). The brachy therapist may perform a quality implant that would be deemed to be a Medical Event by the NRC. A secondary concern is that our vendor's current software does not provide a method to evaluate dose coverage to contiguous volumes of tissue within the treatment site.

Our first suggestion is that a medical event should be defined by the dose coverage to the intended target. This is a much more meaningful indicator of the quality of an implant. We suggest that the D90, which is probably the single most important parameter in assessing implant quality, be greater than 80%. The D90 is defined in AAPM Task Group 137 as the minimum dose in the hottest 90 percent of the target volume.

Our second suggestion is that a medical event is defined by dose to the organs at risk. In prostate seed brachytherapy, the primary organs at risk outside the prostate are the bladder and rectum. This would hold the brachy therapist accountable for protecting the organs at risk but would not penalize the brachy therapist for implanting sources in the normal tissue surrounding the target to intentionally treat a PTV. Another benefit of both of these suggestions is that current brachytherapy software offers a method of evaluating the dose coverage to the target and organs at risk.

Thank you for considering our responses to the proposed rule changes. If any questions arise, we may be reached by telephone or email.

Sincerely,

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