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Rulemaking Comments

From: Subir.Nag@kp.org
Sent: Thursday, October 23, 2008 8:42 PM
To: Rulemaking Comments
Subject: Comments on Proposed Rule for Medical Use of Byproduct Mat
Attachments: 1nrc perm brachy response NAG102308.pdf

ATTN: Rulemakings and Adjudications Staff
My comments on Proposed Rule for Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150-AI26, NRC-2008-0071) are attached in pdf format.
Thanks.

DOCKETED
USNRC

October 29, 2008 (12:45pm)

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RULEMAKINGS AND
ADJUDICATIONS STAFF

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October 23, 2008

Annette L. Vietti-Cook
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Washington, DC 20555-0001

ATTN: Rulemakings and Adjudications Staff

Re: Comments on Proposed Rule for Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150-AI26, NRC-2008-0071) [*See* 73 FR 45635 (August 6, 2008)]

Dear Ms. Vietti-Cook:
I am a brachytherapist currently practicing at Kaiser Permanente, Santa Clara, CA. I have performed over 2000 permanent implant brachytherapy procedures on prostate and other cancer patients over the past 30 years. I am also a member of the Advisory Committee for the Medical Use of Isotopes. I am making these comments as a member of the radiation oncology community and will make my comments as a member of the ACMUI separately, at the ACMUI meeting. I am concerned that the U.S. Nuclear Regulatory Commission's (NRC's) proposed modifications to 10 CFR 35.40 and 35.3045 to establish separate medical event criteria and written directive requirements for permanent implant brachytherapy would result in inappropriately categorizing some properly executed, medically acceptable implants as "medical events" (ME's).

1. TIMING OF WRITTEN DIRECTIVE AND MEDICAL EVENTS

The proposed rule language for § 35.40(b)(6) and § 35.3045(a)(2) does not take into account clinical practice realities. Many authorized users (AUs), including myself, perform real-time, adaptive, interactive planning, whereby the written directive and the source strength to be implanted are based on the actual volume dynamically determined during the procedure rather than based on the pre-implant volume. Real-time planning is a more accurate method of implantation. It allows the physician to take into account any alterations in the organ volume and shape that occur between the time of the pre-plan and the implant procedure and therefore represents the actual organ volume and implant situation. For those performing real-time adaptive planning implantation, the total source strength to be implanted is determined intraoperatively during the implantation procedure and not pre-implant. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the preplan. Hence the basis for medical event should be the total source strength implanted after administration but before the patient leaves the post-treatment recovery area. Therefore, § 35.3045 (a)(2)(i) should be modified to read "The administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in the total source strength administered differing by 20 percent or more from the total source strength documented in the written directive." {ie delete "preimplantation I believe this modification will clarify that the source strength implanted as stated in the WD refers to the source strength implanted after administration but before the patient leaves the post-treatment recovery area. Similarly, the word "preimplantation" should be deleted from "preimplantation written directive" in sections § 35.3045 (a)(2)(ii), (iii) and (iv).

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2. DEFINITION OF TREATMENT SITE

The definition of "treatment site" described in § 35.2 as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to some ambiguity regarding the exact volume that "treatment site" refers to in § 35.3045(a)(2)(ii). There are various standard volumes already defined in radiation oncology, including the gross tumor volume, which is the volume that contains tumor. Two other margins are added to the gross tumor volume during the brachytherapy planning process. One margin is added to account for the subclinical spread of tumor, which is termed the "clinical target volume," and a second margin is added to account for uncertainties in source positioning, tumor boundaries, isodose constrictions, etc., which is termed the "planning target volume." These expansion margins are not constant but change for different clinical situations. Radiation oncologists use a larger margin if there is high degree of uncertainty and/or if there are no adjacent critical structures. Conversely, the margins are smaller if the boundary is distinct and/or if there are adjacent critical structures. Using the definition found at § 35.2 of "treatment site" as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" raises ambiguities in terms of the proposed medical event reports and notifications as it is unclear whether the "treatment site" refers to the gross tumor volume or includes the margins in the clinical target volume or those in the planning target volume. Further, the NRC will be interfering into medical judgment if it dictates the amount of source strength the authorized user can place in the margin which is a clinical decision. I therefore suggest that the definition of "treatment site" in § 35.2 and § 35.3045(a)(2)(ii) be clarified to reflect that it includes the gross tumor, the clinical target volume, plus a variable planning target volume. By following this suggested alternative language, section § 35.3045 (a)(2)(iii) of the proposed rule would become superfluous and therefore could be eliminated.

In summary, I believe that these suggested modifications to the proposed rule language are necessary because in the normal course of some properly executed, medically acceptable, brachytherapy implant procedures, a few seeds may come to rest beyond 3 cm (1.2 in) from the outside boundary of the treatment site due to situations that are beyond the control of the AU.

Thank you for giving me this opportunity to provide comments on the NRC's proposed rule changes to 10 CFR 35.40 and 35.3045 related to medical events in permanent implant brachytherapy. Please contact me at subir.nag@kp.org or 408-851-8085 if you have any questions.

Sincerely,

Subir Nag, MD
Director of Brachytherapy Services

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