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November 5, 2008

Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
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 radiation oncologist in Durham, North Carolina, associated with Duke University Hospital. I am the medical director of radiation oncology services at Durham Regional Hospital. The majority of Duke prostate interstitial brachytherapy occurs at our facility, performed by myself or one of my partners. This totals about 35 cases a year.

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 medically acceptable implants as "medical events" (ME's). **I agree with the American Society for Therapeutic Radiology and Oncology recommendations for changes to the proposed rule language, as described below.**

I. 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) 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.

Further, even those performing permanent brachytherapy using preplanned techniques such as ourselves, will often modify their plan if intraoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the preplan.

During the implant, we commonly adjust our plan for differences in anatomy between the planning ultrasound and on day of implant. This improves the quality of the implant as we are able to adjust the coverage appropriately to cover the target prostate while limiting normal tissue irradiation. We also commonly add additional seeds if we recognize a cold spot within the prostate after the placement of all planned seeds, which can happen due to seed migration during the procedure.

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I support ASTRO's suggested revisions to the proposed regulations. 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.

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.

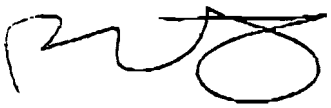
I believe that the proposed regulations cross into clinical decision-making by specifying margin parameters and the source strength to be placed in the margin. The NRC will be interfering into medical judgment if it dictates the amount of source strength the authorized user can place in the margins. 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.

I support ASTRO's recommended changes to the definition of "treatment site" at § 35.2 be revised to reflect the distinct clinical areas - gross tumor, the clinical target volume, plus a variable planning target volume. Further, by following ASTRO's suggested alternative language, section § 35.3045 (a)(2)(iii) of the proposed rule would become superfluous and therefore could be eliminated.

I believe that these suggested modifications to the proposed rule language are necessary because in the normal course of some 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. **In permanent prostate brachytherapy, seed migration is a known event often beyond the control of the practitioner. Migration is one of the reasons post-implant dosimetry is performed to evaluate the degree of migration and if additional seed placement would be required to optimize the prostate coverage. The quality of an implant is based upon the overall coverage of the target, rather than the location of individual seeds.**

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 919-470-8600 or bridget.koontz@duke.edu if you have any questions.

Sincerely,



Bridget Koontz, MD

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TO: Annette L. Vietti-Cook
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VIA FACSIMILE TRANSMISSSION
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FROM: Bridget Koontz, MD
Medical Director of DRH Radiation Oncology Services
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