From: Donna S Wimberley [wimbe004@mc.duke.edu]
Sent: Thursday, October 30, 2008 3:08 PM
To: Rulemaking Comments
Subject: Comments on Permanent Implant Brachytherapy Proposed Rules
Attachments: 20081030140831057.pdf

Please see the attached letter for Comments on Permanent Implant Brachytherapy Proposed Rules from Dr. W. Robert Lee.

Thanks

DOCKETED
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October 30, 2008 (4:00pm)

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RULEMAKINGS AND
ADJUDICATIONS STAFF

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SECY-02

DUKE UNIVERSITY MEDICAL CENTER
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October 30, 2008

VIA E-Mail to: rulemaking.comments@nrc.gov

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 who practices at Duke University Medical Center in Durham, NC. My practice focuses on treating patients with prostate cancer. In the last decade I have performed approximately 800 permanent implant brachytherapy procedures. I am also a past president of the American Brachytherapy Society (ABS) and have worked with CMS and other government agencies to ensure that brachytherapy is available to as many patients as possible.

I am quite 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 have unintended consequences and result in inappropriately categorizing some perfectly 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) 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. Although I do not use this method and rely on preplanning technique I am concerned that the changes may produce problems.

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. For someone like myself that performs permanent brachytherapy using

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preplanned techniques, I will occasionally modify the plan intraoperatively if discrepancies in the gland or organ volume are observed.

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 (GTV), 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 (CTV)," 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 (PTV)."

These expansion margins should change depending on the clinical context. Radiation oncologists may use a larger margin if there is high degree of uncertainty and/or if there are no adjacent critical structures. Conversely, the margins may be 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 (CTV) or those in the planning target volume (PTV).

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 brachytherapy implant procedures, several sources may be placed beyond 3 cm (1.2 in) from the outside boundary of the treatment site. In some cases this placement is anticipated and planned. In other cases, one or two sources will

come to rest slightly outside of the intended volume. In the vast majority of cases the "misplacement" of 1-2 seeds will have no clinical consequences.

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 if you have any specific questions.

Sincerely,

W. Robert Lee, MD, MS, MEd
Professor of Radiation Oncology
Duke University School of Medicine

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