

PR 35  
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*In alliance with  
The University of Vermont*

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OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

November 7, 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 writing as the Medical Director of the Radiation Oncology Department at Fletcher Allen Health Care in Burlington, Vermont, and speak for our practice which includes six Radiation Oncologists. Our practice includes treatments utilizing brachytherapy procedures, including prostate seed implants. We perform approximately 40 of these procedures per year.

We are 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).

**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.

We perform permanent brachytherapy using preplanned techniques. However, we will often modify the plan if intraoperatively a discrepancy in the gland or organ size is observed.

We support ASTRO's suggested revisions to the proposed regulations. We believe this modification will clarify that the source strength implanted as stated in the written directive 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 usually 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.

We 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.

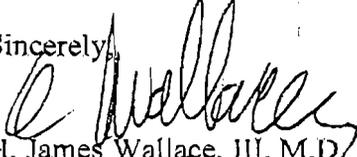
We support ASTRO's recommended changes to the definition of "treatment site" at § 35.2 be revised to reflect the distinct clinical areas - gross tumor, the clinical target volume, plus a variable planning target volume. Further, by following ASTRO's suggested alternative language, section § 35.3045 (a)(2)(iii)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

We 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. For example, in withdrawing a needle in a prostate implant which may utilize thirty needles, it is not unusual for one or two seeds to be dragged, and thus be placed at greater than 3 cm from the apex of the gland.

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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 802 847-3506 if you have any questions.

Sincerely,



H. James Wallace, III, M.D.  
Medical Director  
Radiation Oncology  
Fletcher Allen Health Care  
Burlington, VT 05401



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The University of Vermont

FAX COVER SHEET

DEPARTMENT OF RADIATION ONCOLOGY  
SHEPARDSON 2S MCHV - FAHC  
111 COLCHESTER AVENUE  
BURLINGTON, VT 05401

FAX: (802) 847-2386

PHONE: (802) 847-3506



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FAX Number: 301 415 1101

TO: U.S.N.R.C. Rulemaking Staff

Company Name:

FROM: Marlean Moore, RSO

Radiation Oncology

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Comments: Comment for Proposed Rule

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Thank You.