

PR 35  
(73FR08830)

NRC-2008-0071-0006song.txt

February 27, 2008 (4:30pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Comment Info: =====

General Comment: The following comments are submitted in response to NRC's Part 35 Draft Preliminary Language, dated February 7, 2008, and Revision 1, dated February 21, 2008. They represent the preliminary review of the review of Walter Furr and Haijun Song, Ph.D.

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1. 35.3045 (a)

a. We oppose this new definition of a medical event, which would now include the failure to prepare a written directive as a medical event. We believe that existing regulations, under which failure to prepare a written directive is a violation, but not a medical event, provide adequate protection. Another issue we have with this addition is the word "prepared". It is not defined. If the written directive is not with the chart but the AU scratched something on a scratch paper, put it in a drawer and had forgot to put it in the chart, does that qualify as "prepared"?

2. 30.3045 (a) (2) (i)

a. We oppose the provision of 35.3045 (a) (2) (i) that defines as a medical event "The total source strength implanted in the treatment site differing from the preimplantation written directive by 20 percent or more." In permanent implant brachytherapy, the authorized user physician is typically present and either performing the implantation or directing it. It may be medically necessary for planned seeds to be left out, or for additional seeds to be implanted, per the judgment of the authorized user physician. The clinical goal is to obtain an optimal dose distribution, not a total source strength matching the preimplantation written directive. Instead, the criteria for a medical event should be based on the total source strength differing from the postimplantation written directive.

3. 30.3045 (a) (2) (ii)

There are several problems with this addition. The term "treatment site" is confusing. "3 cm" is arbitrary. Sometimes it is necessary to place activity outside the tumor in order to ensure dose coverage. How would "treatment site" be defined in this instance? If a radiation source is placed on body surface to reach a target at 3.5 cm depth, how does this regulation apply? In our opinion this addition should be removed as a whole. It is too specific to be applicable as regulation.

If the regulation does go this direction, we suggest language such as "If the achieved dwell positions of the radiation sources deviate from the expected positions by more than the tolerance. The tolerance should be established for a particular procedure by the medical community."

4. 30.3045 (a) (2) (iii) Requires that a single seed outside the boundary (an insignificant activity/dose) would be defined as a medical event.

5. We believe that the response date of February 26, 2007, does not provide sufficient time for response, particularly in view that Revision 1 to the draft preliminary language was released by NRC on February 22, 2007. We request that the response date for comments be extended so we may distribute to VA impacted parties in order that they may provide comments on this important issue for provision of veteran patient care.

Template = SECY-067

SECY-02

**Secy**

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**From:** Carol Gallagher  
**Sent:** Wednesday, February 27, 2008 8:27 AM  
**To:** Secy  
**Subject:** Comment letter n Draft Rule Language AI-26  
**Attachments:** NRC-2008-0071-0006song.txt

Van,

Attached for docketing is a comment letter on the above noted draft rule language from Haijun Song and Walter Furr that I received via the regulations.gov website on 2/26/08.

Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by TWMS01.nrc.gov  
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To: Secy <SECY@nrc.gov>  
Date: Wed, 27 Feb 2008 08:27:19 -0500  
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Thread-Topic: Comment letter n Draft Rule Language AI-26  
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