

November 6, 2008 (4:30pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

IN REPLY REFER TO



PR 35  
(73FR45635)

DEPARTMENT OF THE NAVY  
OFFICE OF THE CHIEF OF NAVAL OPERATIONS  
2000 NAVY PENTAGON  
WASHINGTON, DC 20350-2000

5104  
Ser N456S/8U158337  
06 November 2008

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Secretary  
U.S. Nuclear Regulatory Commission (NRC)  
Washington, D.C. 20555-0001  
ATTN: Rulemakings and Adjudications Staff

Subj: RIN 3150-AI26 Medical Use of Byproduct Material -  
Amendments/Medical Event Definitions

Ladies and Gentlemen:

The Naval Radiation Safety Committee (NRSC) has collected comments from Navy physicians on the subject ruling and are hereby forwarded for your consideration.

1. In 35.3045 (a)(2)(ii) "The total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site being more than 20 percent of the total source strength documented in the preimplantation written directive." The concern is the possibility of defining the "treatment site" strictly as the prostate itself, which would limit loading methods (i.e. peripheral loading). We propose the addition of "or treatment planning volume" to allow for prostate treatment volume expansion and coverage.

2. In 35.3045 (a)(2)(iv) "A dose to the skin or an organ or tissue other than the treatment site exceeding by 0.5 Sv (50 rem) and by 50 percent or more of the dose expected to that site from the administration if carried out as specified in the written directive." Skin dose is not an issue with brachytherapy. As for other normal tissues, there is not a clinically accepted parameter used to describe an acceptable vs. an unacceptable dose to the two main normal organs at risk, the urethra and rectum. We use parameters such as D30 (dose to 30% of the organ) to the other organs as a guide, but this would not preclude a rather high dose to a very small percent of the organ, which, if a seed is just a few mm "too close" might be quite high indeed (for example D1). Therefore, we recommend this sentence be deleted in its entirety.

Template=SECY-067

SECY-02

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3. For clarity, the expectations of "treatment site" should be provided in 35.40(b)(6)(i). Because the new medical event criteria for permanent implant brachytherapy includes a discussion of incorrect implantation of sources outside the boundaries of the treatment site, there needs to be a expectation of how specific the written directive needs to be when defining the treatment site. For example, for permanent implant brachytherapy treatment of glioblastoma in the brain, would it be sufficient to state "left temporal lobe" on the written directive or would the AU have to specify the exact location in the temporal lobe? This quandary has not been a problem before for brachytherapy because there was no distance criterion in the medical event criteria.

4. For consistency with the previous paragraph, 35.40(b)(6)(ii) should be revised to read, "...the number of sources and the strength of each source implanted, the date..."

5. For clarity, 35.3045(a)(1)(iii) should be revised to read, "A dose to the skin or an organ or tissue other than the treatment site that is exceeded by..."

6. For clarity, 30.3045(a)(3) should be revised to read, "...preimplantation written directive results in a total source strength delivering a dose that differs by more..."

Sincerely,



L. L. FRAGOSO  
Captain, MSC, U.S. Navy  
Executive Secretary  
Naval Radiation Safety Committee

Copy to: Region I, Atlanta Office  
BUMED M342  
NMCPHC (Radiation Health)

## Rulemaking Comments

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**From:** Carol Gallagher  
**Sent:** Thursday, November 06, 2008 2:31 PM  
**To:** Rulemaking Comments  
**Subject:** Comment on medical Use of Byproduct Material Proposed Rule  
**Attachments:** fragoso.pdf

Attached for docketing is a comment letter from Lino Fragoso on the above noted proposed rule (73 FR 45635) that I received on 11/6/08.

Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by TWMS01.nrc.gov  
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From: Carol Gallagher <Carol.Gallagher@nrc.gov>  
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>  
Date: Thu, 6 Nov 2008 14:30:35 -0500  
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