

PR 35  
Secy (73FR08830)

March 4, 2008 (3:35pm)

**From:** Cynthia Flannery [CMF@nrc.gov]  
**Sent:** Thursday, February 28, 2008 10:10 AM  
**To:** Edward Lohr; Ronald Zelac; Sandra Gabriel  
**Cc:** Ashley Tull  
**Subject:** Fwd: Re: Part 35 Preliminary Draft Rule Language Rev 1  
**Attachments:** Comments-Part 35 Preliminary Draft-PermlImplantBrachy022608.doc

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Attached are Ralph's comments for consideration by the Working Group. I don't know who else is on the WG so please forward to the other members.

Thanks,  
Cindy

>>> "Ralph Lieto" <LietoR@trinity-health.org> 2/27/2008 11:12 AM >>>

Cindy & Ashley,  
FYI -

I wanted to inform you of my comments on this draft language.

Also, several people/organizations are AND WILL BE responding late because of the short notice & major concerns with this draft.

I have significant concerns not all of which I was able to put into comments. Whether intended or not, this goes way beyond what the ACMUI Subcomm suggested both in scope and complexity. I guess it is a work in progress, & this is Phase I.

Regards, Ralph

>>> "medical generic communications" <medical-gc@nrc.gov> 2/22/2008  
10:39 AM >>>

This is an automated mailing from NRC's medical list server.

1. On February 8, 2008, via this list server NRC sent preliminary draft rule language with proposed changes to 10 CFR 35.40 and 35.3045.

This preliminary draft rule language, dated February 7, 2008, was related to medical events in brachytherapy.

2. In this message, NRC is sending out Revision 1 of the draft preliminary rule language (dated February 21, 2008). Revision 1 is the

first attachment to this message. The preliminary draft language that was sent out on February 8, 2008 is also attached, for reference.

[Note: The Revision 1 draft and the draft sent on February 8, 2008 can also be accessed through the NRC's Agencywide Documents Access and Management System (ADAMS) under accession numbers ML080520359 and ML080350090, respectively. For more information on accessing documents through ADAMS, see Paragraph 8 below].

3. The goal of this rulemaking is to better define medical events arising from permanent implant brachytherapy procedures. The proposed amendments will change the criteria for defining a medical event for permanent implant brachytherapy from dose based to activity based; will add a requirement to report as a medical event any administration requiring a written directive if a written directive was not prepared; and will make certain administrative and clarification changes. This rulemaking is based on recommendations from the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). The availability of the preliminary draft rule language is intended to inform stakeholders of the current status of the NRC's activities and solicit early input from the public. Redline strikeout is used to delineate between original rule language and the proposed changes.

Template = SECY-067

SECY-02

4. This preliminary draft rule language may be subject to significant revisions during the rulemaking process. NRC is informing stakeholders, via the NRC's Medical List Server as well as the notice published in the Federal Register, of this opportunity to provide input on the draft revisions. The NRC may post updates to the draft proposed rule language on the Federal eRulemaking Portal. Stakeholders will also have an opportunity to comment on the rule language when it is published as a proposed rule.

5. The public is invited to submit comments by February 26, 2008 . Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

6. Please include the following number in the subject line of your comments: RIN 3150-AI26. Comments on rulemakings submitted in writing

or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information, such as your name, address, telephone number, e-mail address, etc., will not be removed from your submission. You may submit comments by any one of the

following methods listed in items a through e.

a. Electronically: Via the Federal eRulemaking Portal <http://www.regulations.gov> (Docket # NRC-2008-0071) and follow instructions for submitting comments. Address questions about the docket to Carol Gallagher 301-415-5905; e-mail [cag@nrc.gov](mailto:cag@nrc.gov) .

b. Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

c. E-mail

comments to: [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov) . If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at 301-415-1966.

d. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone 301-415-1966).

e. Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.

7. Publicly available documents related to this rulemaking may be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. The PDR reproduction contractor will copy documents for a fee.

8. Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/adams.html> <http://www.nrc.gov/reading-rm/adams.html> . From this site, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the PDR Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to [pdr@nrc.gov](mailto:pdr@nrc.gov) .

8. Point of contact for further information is Edward M. Lohr , Office of Federal and State Materials and Environmental Management Programs, telephone (301) 415-0253, e-mail, [eml1@nrc.gov](mailto:eml1@nrc.gov) .

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If you have further questions about the medical list server, please email: [Med-Listserverquestions@nrc.gov](mailto:Med-Listserverquestions@nrc.gov)

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## Secy

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**From:** Edward Lohr [EML1@nrc.gov]  
**Sent:** Monday, March 03, 2008 2:40 PM  
**To:** Secy  
**Subject:** Fwd: Re: Part 35 Preliminary Draft Rule Language Rev 1  
**Attachments:** Fwd: Re: Part 35 Preliminary Draft Rule Language Rev 1

This comment was submitted to our medical team. Please add it to ADAMS under 73FR08830, Medical Use of Byp.

Thanks for the assistance!

Received: from NRNWMS05.NRC.GOV (148.184.200.215) by OWMS01.nrc.gov  
(148.184.100.43) with Microsoft SMTP Server id 8.0.751.0; Mon, 3 Mar 2008  
14:40:25 -0500

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Mon, 03  
Mar 2008 14:40:25 -0500

Message-ID: <s7cc0dd9.090@NRNWMS05.NRC.GOV>

X-Mailer: Novell GroupWise Internet Agent 6.5.7

Date: Mon, 3 Mar 2008 14:39:55 -0500

From: Edward Lohr <EML1@nrc.gov>

To: <SECY@extest.nrc.gov>

Subject: Fwd: Re: Part 35 Preliminary Draft Rule Language Rev 1

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