PR 35
(73FR08830)

American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
Fax (301) 209-0862
http://www.aapm.org

DOCKETED
USNRC

(9)

March 5, 2008 (11:26am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

February 28, 2008

U.S. Nuclear Regulatory Commission
ATTN: Rulemakings and Adjudications Staff
Washington, DC 20555-0001

Re: RIN 3150-AI26

The American Association of Physicists in Medicine (AAPM)[1] appreciates the opportunity to provide comments on RIN 3150-AI26 draft rule language for proposed changes to 10 CFR §35.40 and §35.3045 related to medical events in brachytherapy. The first notification of the proposed changes was issued February 7, 2008 and revision 1 February 21, 2008. AAPM requested an extension of the comment period to allow for a more expansive review of the proposed changes in a separate comment.

Representatives of the AAPM were present during the Advisory Committee on Medical Uses of Isotopes (ACMUI) meeting in which the proposed changes were discussed and presented. Our review of revision 1, dated February 21, 2008 indicates that the proposed changes do not appear consistent with the changes recommended by the ACMUI.

AAPM offers the following specific comments:

1. RIN 3150-AI26 states: "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." However, the proposed changes go beyond permanent implant brachytherapy procedures.

   Specifically, we feel that the language in §35.3045(a) places an unnecessary burden on both licensees and NRC. Draft language classifies the failure to complete a written

[1] The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

Template = SECY-067

SECY-02

directive as a medical event. We support the concept of written directives and understand their importance. However, the mere fact of not completing a written directive does not elevate to the severity of a medical event. NRC should recognize that a summary of medical events must be periodically reported to Congress. Inclusion of such minor violations would add unneeded bulk to this summary, potentially rendering it useless, as significant medical errors could easily be lost in the mix.

2. For permanent implant brachytherapy, it is indeed vital that the Authorized User record the information required in §35.40(b)(6)(i) and (ii). However, as written, no flexibility is given to the Authorized User to modify the written directive as need during the procedure. It is not uncommon for a prostate to be significantly larger or smaller than measured pre-operatively. In such cases, the total implanted source strength would necessarily be different from that indicated in the pre-treatment written directive.

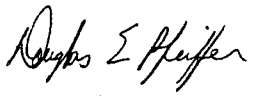
3. The limitation of §35.40(b)(6) is exemplified by §35.3045(a)(2)(i), wherein total source strength implanted in the treatment site differing from the *pre-implantation* written directive by 20 percent or more is defined as a medical event. Again, clinical realities may dictate an appropriate deviation by 20% or more from the pre-implantation written directive. AAPM recommends adding language explicitly allowing for the modification of the pre-implantation written directive as required by the authorized user.

4. Section 35.3045 titled: "Report and notification of a medical event" should be explicitly divided into separate sections. Section 1 should address medical event definition as it applies to unsealed material and section 2 should be limited to permanent implant brachytherapy. As drafted, it appears that the two are intermixed. For example, §35.3045 (a) (1) states that this does not apply to permanent implant brachytherapy, however §35.3045 (a) (1) (ii) (A) states ". . . or the wrong radionuclide for a brachytherapy procedure" and §35.3045 (a) (1) (ii) (B) both include ". . . or by use of the wrong applicator in a brachytherapy procedure".

   This section should be rewritten and provided for comment.

AAPM is prepared to discuss these comments with NRC staff. If you have questions, please contact Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at lynne@aapm.org or 301-209-3364.

Sincerely,



Douglas E. Pfeiffer, MS, DABR
Chair
AAPM's Government and Regulatory Affairs Committee

Review Comment

Docket Information

Docket ID NRC-2008-0071

Long Title Medical Use of Byproduct Material - Amendments/Medical Event Definitions

Document Information

Document ID NRC-2008-0071-0002

Document Title Medical Use of Byproduct Material--Amendments/Medical Event Definitions

How to Comment Please include the following number RIN 3150-AI26 in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC"s Web site in the Agencywide Documents Access and Management System (ADAMS) and on regulations.gov. 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. Electronically: Via the Federal eRulemaking Portal (Docket NRC-2008-0071) and follow instructions for submitting comments. Address questions about this docket to Carol Gallagher 301- 415-5905; e-mail cag@nrc.gov. Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff. E-mail comments to: Rulemaking.Comments@nrc.gov. If you do not receive a reply e-mail confirming thatwe have received your comments, contact us directly at 301-415-1966. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone 301-415-1966). Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101. 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. 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. 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.

Submitter Information

First Name

Last Name

Mailing Address One Physics Ellipse

Mailing Address 2

City College Park

Country United States

State or Province MD

Postal Code 20740

Organization Name American Association of Physicists in Medicine

Submitter's Representative Lynne Fairobent

Government Agency Type Federal

Government Agency NRC

Comments

re: RIN 3150-AI26
The American Association of Physicists in Medicine (AAPM) appreciates the opportunity to comment on RIN 3150-AI26 draft rule language for proposed changes to 10 CFR §35.40 and §35.3045 related to medical events in brachytherapy. The first notification of the proposed changes was issued February 7, 2008 and revision 1 February 21, 2008. However, AAPM feels that five days to review proposed rule language, even at a preliminary stage, is unacceptable and an extension should be provided.

AAPM intends to file detailed comments in the next week regardless whether an extension is granted.

Attachments

Action

Note: If you wish to print your comment, please click the "Print" button.

Cancel/Exit | Edit | Print | Submit

Secy

From: Carol Gallagher
Sent: Wednesday, March 05, 2008 8:52 AM
To: Secy
Subject: FW: AAPM comments on permanent implant brachytherapy
Attachments: request extension brachytherapy comments.pdf; permanent_implants_comments_2-28-08.pdf

Van,

Please docket the second attachment to this e-mail.

Carol

From: Lynne Fairobent [mailto:lynne@aapm.org]
Sent: Tuesday, March 04, 2008 5:43 PM
To: Carol Gallagher; Cynthia Flannery; Edward Lohr
Subject: AAPM comments on permanent implant brachytherapy

Dear All:

Cindy Flannery said the attached comments were not received due to a glitch in the system.
Lynne

Lynne A. Fairobent
Legislative and Regulatory Affairs Manager
AAPM
One Physics Ellipse, College Park, MD 20740-3846
phone: 301-209-3364 fax: 301-209-0862
email: lynne@aapm.org

AAPM - Celebrating 50 years | 1958 - 2008
Honoring the Past...Celebrating the present...
Preparing for the future

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by OWMS01.nrc.gov
([148.184.100.43]) with mapi; Wed, 5 Mar 2008 08:52:15 -0500
Content-Type: application/ms-tnef; name="winmail.dat"
Content-Transfer-Encoding: binary
From: Carol Gallagher <Carol.Gallagher@nrc.gov>
To: Secy <SECY@nrc.gov>
Date: Wed, 5 Mar 2008 08:52:15 -0500
Subject: FW: AAPM comments on permanent implant brachytherapy
Thread-Topic: AAPM comments on permanent implant brachytherapy
Thread-Index: Ach+SSdWhC2XiixHRSW80eQy4ImNIQAfttCQ
Message-ID:
<83F82891AF9D774FBBB39974B6CB134F18FBA4E929@HQCLSTR01.nrc.gov>
Accept-Language: en-US
Content-Language: en-US
X-MS-Has-Attach: yes
X-MS-Exchange-Organization-SCL: -1
X-MS-TNEF-Correlator:
<83F82891AF9D774FBBB39974B6CB134F18FBA4E929@HQCLSTR01.nrc.gov>
MIME-Version: 1.0