

Rulemaking Comments

From: lelandroge@aol.com
Sent: Tuesday, October 28, 2008 5:25 PM
To: Rulemaking Comments
Subject: Proposed Modifications to 10 CFR 35.40 and 35.3045

DOCKETED
IISNRC

October 29, 2008 (12:45pm)

VIA E-Mail to: rulemaking.comments@nrc.gov

OFFICE OF SECRETARY
RUI FMAKINGS AND
ADJUDICATIONS STAFF

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 Leland Rogers, a radiation oncologist in Utah, based in Salt Lake City. My practice, and indeed that of my 6-physician single specialty group, is brachytherapy. We have a very busy brachytherapy schedule, and treat over 500 patients each year with a variety of brachytherapy procedures. The majority of these are for our patients with prostate cancer, followed by breast cancer, head and neck tumors, and gynecologic brachytherapy.

I am corresponding with you to voice my opinion regarding the NRC's proposed modifications to 10 CFR 35.40 and 35.3045. This purports to establish updated medical event criteria and written directive requirements for permanent brachytherapy. In its current form, the proposed amendments would needlessly categorize some perfectly acceptable, and even excellent brachytherapy procedures as medical events (MEs).

1. TIMING OF WRITTEN DIRECTIVE AND MEDICAL EVENTS

The proposed rule language for § 35.40(b)(6) and § 35.3045(a)(2) does not sufficiently take into account some important results of good clinical practice, nor some of its critical practical realities. Many physician authorized users (AUs) perform real-time, adaptive, interactive planning, whereby the written directive (WD) and the source strength to be implanted are based on the volume dynamically determined in real time in the operating room, during the brachytherapy procedure itself. Owing to a variety of reasons, it is not odd for this to differ from the findings of pre-implant imaging.

Such real-time planning is a more accurate method of implantation. It allows the physician to take into account alterations in the organ volume and contour that occur between the time of the pre-plan and the implant procedure and therefore represents the actual organ volume and implant situation. For those performing real-time adaptive planning implantation, the total source strength to be implanted is determined intraoperatively during the implantation procedure and not pre-implant. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the preplan.

I support ASTRO's suggested revisions to the proposed regulations, and believe this modification will clarify that the source strength implanted as stated in the WD 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 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.

The proposed regulations improperly 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.

I 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.

I 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. On occasion this is purposeful and intended to improve the dose distribution to a particular site, and on other occasions occurs as a result of seed migration. Such seed migrations can, for instance, occur as a vacuum phenomenon from retraction of the brachytherapy applicator. This is not a rare event, and I have yet to witness any adverse clinical event attributable to it.

Thank you for the 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. You may, of course, contact me at 801-350-8400 if you have any further questions.

With Kind Regards,

Leland Rogers MD, FACRO
GammaWest Brachytherapy
1050 E. South Temple
Salt Lake City, UT 84102
phone: (801) 350-8400

fax: (801) 350-4021

email: Leland@GammaWest.com

Received: from mail1.nrc.gov (148.184.176.41) by OWMS01.nrc.gov
(148.184.100.43) with Microsoft SMTP Server id 8.1.291.1; Tue, 28 Oct 2008
17:25:24 -0400

X-Ironport-ID: mail1

X-SBRS: 3.8

X-MID: 32093670

X-IronPort-Anti-Spam-Filtered: true

X-IronPort-Anti-Spam-Result:

Au0AAGkfb01ADI9jimdsb2JhbACBYGsuj18igQgBAQEKCQwHDwVAq0UHAQikYwGCTQ
cBeg

X-IronPort-AV: E=Sophos;i="4.33,501,1220241600";

d="scan'208";a="32093670"

Received: from imo-m11.mx.aol.com (HELO imo-m11.mail.aol.com) ([64.12.143.99])

by mail1.nrc.gov with ESMTP; 28 Oct 2008 17:24:49 -0400

Received: from LelandRoge@aol.com by imo-m11.mx.aol.com (mail_out_v39.1.) id

f.bfd.45bc6ed4 (34904) for <rulemaking.comments@nrc.gov>; Tue, 28 Oct 2008

17:24:35 -0400 (EDT)

Received: from MBLK-M21 (mblk-m21.mblk.aol.com [64.12.136.54]) by

cia-da02.mx.aol.com (v121_r3.13) with ESMTP id MAILCIADA021-8858490783131ea;

Tue, 28 Oct 2008 17:24:35 -0400

To: rulemaking.comments@nrc.gov

Subject: Proposed Modifications to 10 CFR 35.40 and 35.3045

Date: Tue, 28 Oct 2008 17:24:35 -0400

X-MB-Message-Source: WebUI

X-AOL-IP: 70.56.104.1

X-MB-Message-Type: User

MIME-Version: 1.0

From: <lelandroge@aol.com>

Content-Type: multipart/alternative;

boundary="-----MB_8CB075AB5AA6D65_D48_2054_MBLK-M21.sysops.aol.com"

X-Mailer: AOL Webmail 39598-STANDARD

Received: from 70.56.104.1 by MBLK-M21.sysops.aol.com (64.12.136.54) with HTTP

(WebMailUI); Tue, 28 Oct 2008 17:24:35 -0400

Message-ID: <8CB075AB5A5A8BB-D48-FB1@MBLK-M21.sysops.aol.com>

X-Spam-Flag: NO

Return-Path: LelandRoge@aol.com