

Rulemaking Comments

From: John Sylvester [JohnSylvester@seattleprostate.com]
Sent: Monday, October 27, 2008 1:23 PM
To: Rulemaking Comments
Subject: new regulations regarding brachytherapy

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Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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 a radiation oncologist that specializes in prostate cancer treatment. I perform approximately 240 prostate brachytherapy procedures a year. I helped with the ASTRO comment letter that recommended changes to the new proposed NCI regulations. I perform pre-planned implants with RAPID strand, Source-link and other connected sources. I have published extensively in the medical literature on prostate brachytherapy and outcomes. I am the Chief Medical Officer of Proqura, the largest quality assurance program in the USA that deals with prostate seed implants-brachytherapy.

There are several problems with the wording of the new proposed U.S. Nuclear Regulatory Commission's (NRC's) proposed modifications to 10 CFR 35.40 and 35.304. I believe that the new proposed regulations would inappropriately classify many excellent implants as "medical events".

The ASTRO subcommittee I participated in spent many hours going over the exact wording

1. TIMING OF WRITTEN DIRECTIVE AND MEDICAL EVENTS

The proposed rule language for § 35.40(b)(6) and § 35.3045(a)(2) does not take into account clinical practice realities. Many authorized users (AUs) perform real-time, adaptive, interactive planning, whereby the written directive and the source strength to be implanted are based on the actual volume dynamically determined during the procedure rather than based on the pre-implant volume.

Real-time planning is a more accurate method of implantation. It allows the physician to take into account any alterations in the organ volume and shape 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. I 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.

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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.

I believe that the proposed regulations 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 **many** 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.

Thank you for giving me this 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. Please contact me at 206 215 2480 or johnsyvester@seattleprostate.com if you have any questions.

Sincerely,

John Sylvester M.D.

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From: John Sylvester <JohnSylvester@seattleprostate.com>
To: <rulemaking.comments@nrc.gov>
Return-Path: JohnSylvester@seattleprostate.com