



5

February 26, 2008

VIA E-Mail to: [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov)

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

Re: Comments on RIN 3150-AI26--Nuclear Regulatory Commission's Medical Use of Byproduct Material—Amendments/Medical Event Definitions

Dear Sir or Madam:

The American Society for Therapeutic Radiology and Oncology (ASTRO) applauds the efforts of the U.S. Nuclear Regulatory Commission (NRC) in proposing changes to 10 CFR 35.40 and 35.3045 related to medical events in brachytherapy. ASTRO commends the NRC's stated goals of this preliminary draft rule to better define medical events arising from permanent implant brachytherapy procedures, and it appreciates the opportunity to participate in this rulemaking process by offering the following comments.

ASTRO is the largest radiation oncology society in the world, with more than 9,000 members who specialize in treating patients with radiation therapies. As a leading organization in radiation oncology, biology and physics, the Society is dedicated to the advancement of the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in a rapidly evolving healthcare environment.

ASTRO is concerned that the proposed language for § 35.3045(a)(2) could inappropriately include certain medically acceptable implants as "medical events." ASTRO recommends modification of the proposed language for § 35.3045(a)(2) "permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in-- (ii) The total source strength implanted outside the treatment site and within 3 cm (1.2 in) of the boundary of the treatment site exceeding 20 percent of the total source strength documented in the preimplantation written directive" to reflect that the boundary of the "treatment site" can sometimes be ambiguous, and the authorized user in administration of effective treatment may need to implant sources outside the "treatment site" to cover margins.

8280 Willow Oaks Corporate Drive # 800.962.7876  
Suite 500 703.502.1550  
Fairfax, VA 22031 703.502.7852

Targeting Cancer Care  
[www.astron.org](http://www.astron.org)  
[www.rtananswers.org](http://www.rtananswers.org)

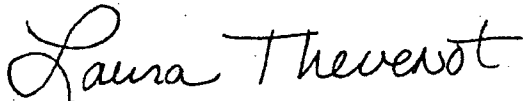
067  
Template = SELV-043

SELV-02

ASTRO further believes that the proposed language "(iii) Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the boundary of the treatment site" should be clarified to allow one or two seeds to be placed outside the treatment area without such administration being counted as a medical event. ASTRO recommends that the language be modified to "(iii) 20% or more of the brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the boundary of the treatment site."

Thank you for affording us this opportunity to provide comments on the NRC's preliminary draft rule changes to 10 CFR 35.40 and 35.3045 related to medical events in brachytherapy. Please contact Emily Wilson at 703-839-7364 or [emilyw@astro.org](mailto:emilyw@astro.org) or Richard Martin at 703-839-7366 or [richardm@astro.org](mailto:richardm@astro.org) if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Laura Thevenot". The signature is written in black ink and is positioned above the printed name and title.

Laura I. Thevenot  
Chief Executive Officer

**Secy**

---

**From:** Emile Julian  
**Sent:** Wednesday, February 27, 2008 4:06 PM  
**To:** Secy  
**Subject:** FW: NRC Comment Letter -- Attached  
**Attachments:** Letter\_NRC\_Rulemaking Comments\_02-25-08.pdf

---

**From:** Richard Martin [mailto:richardm@astro.org]  
**Sent:** Tuesday, February 26, 2008 2:12 PM  
**To:** rulemaking  
**Cc:** Emile Julian  
**Subject:** FW: NRC Comment Letter -- Attached

Richard J. Martin, Esq.  
Legislative and Regulatory Analyst  
Government Relations  
American Society for Therapeutic Radiology and Oncology  
8280 Willow Oaks Corporate Drive, Suite 500  
703 839-7300 main  
703 839-7366 direct  
703 839-7367 fax  
[www.astro.org](http://www.astro.org)  
[www.rtanswers.org](http://www.rtanswers.org)

---

**From:** Richard Martin  
**Sent:** Monday, February 25, 2008 2:17 PM  
**To:** 'Rulemaking.Comments@nrc.gov'  
**Cc:** Emily Wilson  
**Subject:** FW: NRC Comment Letter -- Attached

Dear Sir or Madam,

Please find attached comments on behalf of the American Society for Therapeutic Radiology and Oncology (ASTRO) regarding RIN 3150-AI26—Nuclear Regulatory Commission's Medical Use of Byproduct Material—Amendments/Medical Event Definitions.

Sincerely,

Richard J. Martin, Esq.  
Legislative and Regulatory Analyst  
Government Relations  
American Society for Therapeutic Radiology and Oncology  
8280 Willow Oaks Corporate Drive, Suite 500  
703 839-7300 main  
703 839-7366 direct  
703 839-7367 fax  
[www.astro.org](http://www.astro.org)  
[www.rtanswers.org](http://www.rtanswers.org)

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by TWMS01.nrc.gov  
([148.184.200.145]) with mapi; Wed, 27 Feb 2008 16:06:10 -0500  
Content-Type: application/ms-tnef; name="winmail.dat"  
Content-Transfer-Encoding: binary  
From: Emile Julian <Emile.Julian@nrc.gov>  
To: Secy <SECY@nrc.gov>  
Date: Wed, 27 Feb 2008 16:06:09 -0500  
Subject: FW: NRC Comment Letter -- Attached  
Thread-Topic: NRC Comment Letter -- Attached  
Thread-Index: Ach3yp0pGaKVXukdRvKb8mDUZ1MICAARbsQAAEQOmAAMnV4IAA2SHgQ  
Message-ID:  
<CEEA97CC21430049B821E684512F6E5E4DA262E2D9@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:  
<CEEA97CC21430049B821E684512F6E5E4DA262E2D9@HQCLSTR01.nrc.gov>  
MIME-Version: 1.0