

November 6, 2008 (4:30pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

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**Cancer Services**

**Infirmiry Health System**

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November 5, 2008

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:

My name is John R. Russell, and I am a practicing Radiation Oncologist in the Mobile, Alabama community. I have been in the practice of Radiation Oncology since 1976. Beginning with training in that area in Radiation Oncology, I have personally performed multiple interstitial implants of radioactivity, to include such sites as the soft palate, base of tongue, floor of mouth, neck tissue containing cancerous lymph nodes, endobronchial treatment of lung malignancies, high-dose rate brachytherapy endovascular applications for treatment of restenosis following cardiac angioplasty, prostate seed implant, soft tissue sarcoma implant, breast cancer treatment using implanted temporary irradiation sources, and endoluminal treatment of esophageal cancer recurrences. Additionally, in the 1980s, I have employed hyperthermia and external beam irradiation for treatment of superficial malignancies. I also participated during that era in high-dose rate Iodine 125 implants of brain tumors in conjunction with our Neurosurgery staff. The implants most commonly performed in our facility at this time are those related to the prostate and to the lung. We have a large prostate permanent seed implant program, with over 650 implants performed to date. Usually, we are implanting these tumors with a volume of approximately three to four patients per month or more.

I am writing to you in regard to the proposed language included in the U.S. Nuclear Regulatory Commission's proposed modifications to 10 CFR 35.40 and 35.3045. As you are aware, these modifications deal with establishing separate medical event criteria and written directive requirements for permanent implant brachytherapy.

Template = SECY-067

SECY-02

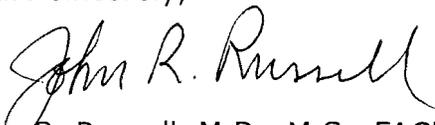
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I am concerned that the wording now suggests medically acceptable interstitial treatments as "medical events." I would urge you to carefully consider the definition of the medical event in relationship to implant therapy. The treatment site also is in need of careful wording. Our implant technique does account for variable anatomy and variable tumor anatomy from patient to patient. Margins are specified in normal tissues to verify and deliver radiation doses where microscopic disease may be harbored but not visible by any currently available imaging technology.

If further information is needed, I would be happy to address those issues.

Thank you for the opportunity to communicate my concerns in regard to the proposed changes. My e-mail address is [jrroam@aol.com](mailto:jrroam@aol.com).

Yours sincerely,



John R. Russell, M.D., M.S., FACR, FACRO  
Medical Director, Radiation Oncology  
Mobile Infirmary Medical Center  
Mobile, Alabama

JRR.db

*Return Receipt Requested*