



# MEMORIALCARE®

34

## LONG BEACH MEMORIAL MEDICAL CENTER THE THOMAS AND DOROTHY LEAVEY RADIATION ONCOLOGY CENTER

Tel (562) 933-0300 Fax (562) 933-0301

October 28, 2008

PR 35  
(73FR45635)

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

DOCKETED  
USNRC

October 30, 2008 (4:00pm)

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 Nisar Syed, M.D., Medical Director of Radiation Oncology, Long Beach Memorial Medical Center. I have been in practice for more than 25 years and considered as one of the pioneers in brachytherapy procedures. We perform approximately 100-125 permanent implant brachytherapy procedures on prostate cancer patients each year.

I am writing this email to you because of the NRC's proposed modifications to CFR 35.40 and 35.3045 to establish separate "medical events" criteria, and inappropriately categorizing medically accepted procedures.

Although we do evaluate the size and extent of the tumor and the approximate radioactivity of iodine-131 and number of seeds as a pre-plan, we depend totally on the real time planning at the time of the procedure. Presently, we have found that real-time planning is the only accurate method of determining the number of sources, strength of the radioactive sources and the total activity required. There are definite changes that occur from the time the patient is seen in the pre-planning to the time of the procedure due to changes in the size and shape of the prostate as a result of hormone manipulation, etc. At present, we do not even do anything at all, as we totally depend upon the real time plan at the time of the brachytherapy procedure.

Myself and my associates are very concerned with the proposed regulations, specifying margin parameters and source strength, etc, which interferes with our medical judgment and may compromise treatment outcomes. We 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.

THE STANDARD OF EXCELLENCE IN HEALTH CARE

Template = SECY-067

SECY-02

Page 2  
Annette L. Vietti-Cook  
October 28, 2008

I hope you will take into consideration our serious concern regarding the above modifications being suggested by the NRC.

Best regards,

Sincerely,



AM Nisar Syed, M.D.  
Medical Director  
Radiation Oncology Center  
Long Beach Memorial Medical Center