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THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

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OFFICE OF SECRETARY
RULEMAKINGS 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-A126, NRC-2008-0071) [See 73 FR 45635 (August 6, 2008)]

Dear Ms. Vietti-Cook:

I am the head of the prostate brachytherapy program at the M.D. Anderson Cancer Center in Houston. We treat approximately 100 patients with prostate cancer each year with permanent seed implants. Additionally, at our institution, we perform a large number of gynecologic, gastrointestinal, head and neck, breast, and thoracic brachytherapy procedures.

The recent U.S. Nuclear Regulatory Commission's (NRC's) proposed modifications to 10 CFR 35.40 and 35.3045 which establish separate medical event criteria and written directive requirements for permanent implant brachytherapy is concerning because it would inappropriately categorize some medically acceptable implants as "medical events".

1. Timing of Written Directive (WD) and Medical Events (ME)

The proposed rule language for 35.40(b)(6) and 35.3045(a)(2) would have a profound and inappropriate affect on common clinical practice. While we perform pre-planned implants with intraoperative optimization, many institutions perform real time brachytherapy implants with adaptive interactive planning. In real time planning, the written directive and the source strength to be implanted are based on the dynamically determined prostate volume rather than pre-implant volume. Therefore, the total source strength to be implanted is determined intraoperatively during the implant procedure. Even with our pre-planned approach, the written directive may be modified if the patient has been placed on cytoreduction hormone therapy and the intraoperative volume requires modification of the activity implanted in the treatment volume.

ASTRO's suggested revisions to the proposed legislation has my full support. I believe this modification will clarify that the activity implanted, as stated in the WD, will refer to the activity implanted after administration but before the patient leaves the post-treatment recovery area.

2. Definition of Treatment Site

"Treatment site" as described in 35.2 is defined as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive". This definition leads to some ambiguity regarding the exact volume of that "treatment site" referred to in 35.3045(a)(2)(ii).

Standard volumes have already been well defined in radiation oncology, including the gross tumor volume, which is the volume that contains gross disease. Additional margins have been defined such as the "clinical target volume" which takes into consideration microscopic subclinical spread of tumor. An additional margin commonly described is the "planning target volume" which takes into account many treatment planning uncertainties to optimize the dose to the target volume while minimizing dose to non-tumor critical structures.

It is my belief that the proposed changes to the regulations will have an adverse effect into clinical decision-making by specifying margin parameters and the amount of activity placed in the margin. The NRC will unwittingly interfer into common medical practice by dictating the amount of source strength the authorized user can place in the target volumes. The "treatment site" as defined under 35.2 raises ambiguities because it is unclear whether the "treatment site" refers to the gross tumor volume, clinical target volume, or planning target volume.

ASTRO's recommended changes to the definition of "treatment site" at 35.2 has my full support. The recommendation would reflect distinct clinical areas of treatment including the gross tumor, subclinical disease, and planning target volume. By incorporating ASTRO's suggested alternative. These suggested modifications to the proposed rule language are necessary because in the normal course of some medically acceptable brachytherapy implants, a few seeds may rest beyond 3 cm from the outside of the treatment site. While this does not commonly occur in our practice, a seed may migrate out of its prescribed location due to strand or seed migration. Migration may require seed removal from the bladder or urethra, and when placing seeds in the periprostatic region, migration of a seed may fall beyond 3 cm of intended placement.

If I can provide any additional information, please contact me at 713-563-8489. Thank you for the opportunity to comment on the NRC's proposed rule change to 10 CFR 35.40 and 35.3045 related to medical events in permanent implant brachytherapy. Please contact me at 713-563-8489/sjfrank@mdanderson.org if I can be of any assistance or you have any questions.

Thank you again for your time and consideration,

Steven J. Frank, M.D.
The University of Texas M. D. Anderson Cancer Center
Department of Radiation Oncology