



MAYO CLINIC

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October 27, 2008

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Radiation Oncology

Annette L. Vietti-Cook  
Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
E-Mail: [rulemaking.comments@nrc.gov](mailto:rulemaking.comments@nrc.gov)DOCKETED  
IISNRC

October 29, 2008 (12:45pm)

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 practicing Radiation Oncologist at the Mayo Clinic in Rochester, Minnesota where I spend a good part of each day treating men with prostate cancer. Prostate brachytherapy, both permanent seed implant and temporary high-dose rate therapy, are a central focus of my clinical and research endeavors. In our practice, over a hundred men a year will receive a prostate brachytherapy procedure.

I am writing you in response to the proposed modifications by the U.S. Nuclear Regulatory Commission's (NRC) to 10 CFR 35.40 and 35.3045. Their intent to establish separate medical event criteria and written directive requirements for permanent brachytherapy would potentially result in labeling medically acceptable implants as "medical events" (ME's).

I would like to outline two areas in which I believe the proposed modifications fall short of the reality of brachytherapy practice and how they could potentially mis-categorize and unfairly punish well-intended and skilled physicians.

First, 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. Currently, we at Mayo are actively evaluating the role of such adaptive, real-time planning in our practice and anticipate incorporating it into our routine within the next 4 to 6 months.

Template = SECY-067

SECY-02

Our intent in incorporating real-time planning is that we believe intra-operative planning can be more accurate. 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, in our history of performing permanent brachytherapy using pre-planned techniques, we often modify our plan when intraoperatively we find major discrepancies in the gland or organ volume from the volumes determined during the preplan.

I whole-heartily support ASTRO's suggested revisions to the proposed regulations. I believe this modification will clarify that the source strength implanted as stated in the written directive refers to the source strength implanted after administration but before the patient leaves the post-treatment recovery area.

Secondly, 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). Within radiation oncology, there are various standard volumes already defined, including the gross tumor volume (GTV), 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," (CTV) 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" (PTV).

These expansion margins are not constant but change for different clinical situations, particularly if there is high degree of uncertainty and/or if there are no adjacent critical structures.

I strongly feel 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.

Once again, 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 feel that these suggested modifications to the proposed rule language are necessary because in the normal course of some 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. In my practice this has implications not just in prostate cancer implants but also in brachytherapy implants within the lung.

I appreciate the opportunity to comment on the NRC's proposed changes and hope that my comments, in conjunction with those provided from others within the medical community, will serve to help clarify and further develop the proposals prior to full implementation. Please feel free to contact me if I can answer any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'O. Macdonald', with a long horizontal flourish extending to the right.

O. Kenneth Macdonald  
Macdonald.orlan@mayo.edu



**Fax**

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