



Washington University in St. Louis

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SCHOOL OF MEDICINE

Department of Radiation Oncology
Division of Medical Physics

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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

Subject: RIN 3150-AI26:

We are practicing radiation oncologists and medical physicists and have performed several hundred permanent brachytherapy procedures. We would like to comment on the proposed rules regarding the medical use of byproduct material for permanent implants published in the Federal Register Vol. 73, No. 152 issued on August 6, 2008. We are concerned that the proposed language in § 35.3045(a)(2) would result in inadvertently and inappropriately categorizing some medically acceptable implants as "medical events" and wish to make the following comments:

1. The proposed language for § 35.3045(a)(2) (i) on page 45643, column 3 reads: [It would be deemed a medical event if] The total source strength administered differing by 20 percent or more from the total source strength documented in the preimplantation written directive. Further on page 45637 column 3, (G) it is noted that the AU cannot modify the preimplantation WD during the administration of Brachytherapy.

Currently, many authorized users perform real-time, adaptive, interactive planning for which the written directive and the source strength to be implanted are based on the actual target volume dynamically determined during the procedure rather than based on the preimplant volume. Real-time planning takes into account any alterations in the prostate volume and shape that occur between the time of the preplan and the implant procedure and therefore represents the actual implant situation. Hence for those performing real-time, adaptive, implantation planning, the written directive refers to the final written directive after administration but before the patient leaves the post-treatment recovery area and not to an arbitrary preimplant WD. Additionally, a large number of practitioners determine the source strength, seed number, and total activity based on published nomograms or from preoperative volume studies (ultrasound, CT, or MR). These practices commonly order seeds in excess of that which is planned in order to accommodate the actual volume, shape, and dosimetry that are

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encountered during the actual procedure. As described earlier, many of these physicians also use real-time dosimetry and treatment planning to tailor the implant to the specific needs of the patient realized in the operating room. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find major discrepancies in the gland volume from the volumes determined during the preplan. Therefore, we would like to recommend that the written directive in this section refer to the total source strength implanted after administration but before the patient leaves the post-treatment recovery area rather than an arbitrary preimplantation WD.

2. The proposed language for § 35.3045(a)(2) (ii)) on page 45643, column 3 currently reads: [It would be deemed a medical event if] 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.

The definition of treatment site as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive" leads to some ambiguity as to whether it refers to the gross tumor volume (GTV), the clinical target volume (CTV) or the planning target volume (PTV). The expansion margin added to the GTV to create the PTV is a clinical decision dependent on tumor, normal tissue, patient specific factors, and AU preference. Hence, we would like to recommend that the definition of "treatment site" referred to in this section be clarified to include the gross tumor, the clinical target volume, and a variable planning margin as defined by the AU.

We further believe that there are situations where the treatment site may have to be modified in the operating room based on the patient exam and clinical judgment. For example, if gross disease, not appreciated by physical exam or preoperative imaging, was encountered during the implantation procedure, it would be necessary to extend the treatment site to encompass any adjacent tissues which included this disease. This could occur in prostate brachytherapy if the seminal vesicles were felt to be involved during an examination under anesthesia. Here again, we would like to recommend that there be some latitude in the proposed rules allowing the physician to define the treatment site in the operating room based on the patient exam.

3. The proposed language for § 35.3045 (a)(2)(iii) on page 45643, column 3 currently reads: [It would be deemed a medical event if] Brachytherapy source(s) implanted beyond 3 cm (1.2 in) from the outside boundary of the treatment site. Further in page 45638 column 2 (I) it is noted that even one sealed source implanted beyond the 3 cm boundary would constitute an ME.

It should be noted that in the normal course of some brachytherapy implants, a few seeds can end up beyond 3 cm (1.2 in) from the outside boundary of the

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treatment site due to a number of factors that are beyond the control of the AU, without having any adverse clinical effects. We are very much concerned that these situations will be deemed to be medical events, when in reality they happen in the normal course of some brachytherapy implant procedures. We are also concerned that some practitioners will simply abandon the permanent brachytherapy procedure rather than risk having medical events. This will be detrimental to patient care.

4. The proposed language for § 35.3045 (a)(2)(iv) on page 45644, column 1 currently reads: [It would be deemed a medical event if] A dose to the skin or an organ or tissue other than the treatment site exceeding by 0.5 Sv (50 rem) and by 50 percent or more the dose expected to that site if the administration had been carried out as specified in the preimplantation written directive.

If a single seed is implanted beyond 3 cm (1.2 in) from the outside treatment boundary of the treatment site, as outlined in § 35.3045 (a)(2)(iii) on page 45643, the proposed rule § 35.3045 (a)(2)(iv) would automatically apply and is not necessary in order to achieve the same level of regulation.

We are also concerned that the proposed rule does not specify any tissue volumes. Depending on the seed distribution in the implanted volume, frequently the planned dose distributions do not exactly conform to the treatment site and doses delivered to small volumes other than treatment site do exceed by 0.5 Sv (50 rem) and by 50 percent or more the dose expected, even though the administration was carried out as expected.

Thank you for affording us this opportunity to comment on the NRC's preliminary draft rule changes to 10 CFR 35.40 and 35.3045 related to medical events in brachytherapy.

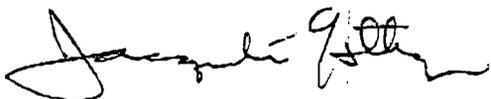
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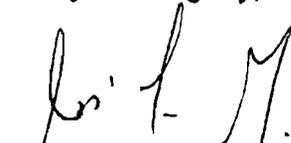
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