

**Rulemaking Comments**

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**From:** Lynne Fairobent [lynne@aapm.org]  
**Sent:** Friday, November 07, 2008 1:47 PM  
**To:** Rulemaking Comments  
**Subject:** AAPM comments on RIN 3150-AI26  
**Attachments:** AAPM\_permanent\_implants\_comments\_11-07-08.pdf

Attached please find comments form the American Association of Physicists in Medicine regarding Medical Use of Byproduct Material—Amendments/Medical Event Definitions.

Lynne Fairobent

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November 7, 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) and 73 FR 58063 (October 6, 2008)]**

Dear Ms. Vietti-Cook:

The American Association of Physicists in Medicine (AAPM)<sup>1</sup> appreciates the opportunity to provide comments on Comments on Proposed Rule for Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150-AI26, NRC-2008-0071) [See 73 FR45635 (August 6, 2008) and 73 FR 58063 (October 6, 2008)]. AAPM commends the U.S. Nuclear Regulatory Commission (NRC) for clarifying many of the issues raised in our comments to the proposed language issued February 7, 2008 and revised February 21, 2008.

Although, AAPM agrees with many of the NRC's proposed rule modifications to 10 CFR 35.40 and 35.3045 to establish separate medical event criteria and written directive requirements for permanent implant brachytherapy, AAPM believes additional clarification needs to be made and offers the following comments.

1. RIN 3150-AI26 states: "is proposing to amend its regulations that govern medical use of byproduct material related to reporting and notifications of medical events (MEs) to clarify requirements for permanent implant brachytherapy. The proposed amendments would change criteria for defining an ME for permanent implant brachytherapy from dose-based to activity-based; add a requirement to report, as an ME any administration requiring a written directive (WD) if a WD was not prepared; clarify requirements for

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<sup>1</sup> The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

WDs for permanent implant brachytherapy; and make certain administrative and clarification changes.” However, the proposed changes go beyond permanent implant brachytherapy procedures. The language used places no limitation on the applicability of the new requirements and therefore impact all brachytherapy procedures.

2. As we stated in our February 28, 2008 letter, we feel that the language in §35.3045(a) places an unnecessary burden on both licensees and NRC. Draft language classifies the failure to complete a written directive as a medical event. We support the concept of written directives and understand their importance. However, the mere fact of not completing a written directive does not elevate to the severity of a medical event. Classification as a medical event necessitates reporting to the patient and referring physician that would cause undue concern and stress to both. Further, NRC should recognize that a summary of medical events must be periodically reported to Congress. Inclusion of such minor, non-safety related violations would add unneeded bulk to this summary, potentially rendering it useless, as significant medical errors could easily be lost in the mix. In conclusion we believe that existing regulations, under which failure to prepare a written directive is a violation, but not a medical event, provide adequate protection. If the primary goal is to be able to track the incidence of this occurrence, we recommend that NRC consider re-establishing a category of reportable event.
3. For permanent implant brachytherapy, it is indeed vital that the Authorized User record the information required in §35.40(b)(6)(i) and (ii). AAPM concurs with the changes made from the February 2008 draft that allows for the documenting the total source strength implanted prior to the patient leaving the post-treatment recovery area.

However, AAPM feels that, while the intent of the proposed regulation is laudable, it could have serious negative impact on what is becoming current practice in permanent prostate implant brachytherapy. Many facilities are moving to what is known as “real time planning” for these procedures. In this method, only the intended dose to the planned treatment volume, as expressed typically as D90, is known prior to the beginning of the procedure. A volume study of the prostate is performed in the operating room and the procedure starts. As needles and seeds are implanted, an iterative process ensues to achieve the desired dosimetry, adjusting the location and number of seeds as required to optimize results. In this scenario, it is impossible to comply with the proposed requirement to state a pre-implantation total source strength that will be confidently accurate to within 20%. In a large-volume facility performing 500 implants in a year, even a 1% miss rate would lead up to 5 medical events per year when no adverse event actually occurred.

We propose allowing for using either total source strength as in the current Proposed Rule, or a dose-based written directive. We would recommend in the dose case that the written directive be defined as the intended D90 to the volume defined by the Authorized User, with evaluation of the D90 to the defined volume at the time of the end of the procedure as displayed by the treatment planning computer used during the procedure. In the end, the final regulation must be compatible with advanced real time planning of permanent implants.

4. The proposed language for § 35.3045(a)(2) (i) on page 45643, column 3 currently reads:  
*A licensee shall report as a medical event any administration requiring a written directive if a written directive was not prepared or any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material for permanent implant brachytherapy (excluding sources that were implanted in the correct site but migrated outside the treatment site) results in – (i)The total source strength administered differing by 20 percent or more from the total source strength documented in the preimplantation written directive.*

AAPM believes that the word *preimplantation* should be deleted. Deletion of this word would not significantly change the meaning of the regulation but would allow for the recognition that clinical realities may dictate an appropriate deviation by 20% or more from the pre-implantation written directive. Permanent implant prostate brachytherapy is increasingly becoming a real-time procedure, with the authorized user physician making modifications to the treatment under imaging guidance during the procedure and, in some cases, creating post-plans with dosimetric analysis before deciding whether seed implantation is complete. The clinical goal of the procedure is not to implant the total source strength stated in the “preimplantation” part of the written directive; instead, the clinical goal is to obtain an optimal dose distribution covering the target tissue, while keeping the dose distributions to nearby radiosensitive organs low enough to minimize the risk of significant complications. Indeed, under some implementations, the total source strength may not be known at all prior to beginning the implant, only the intended organ dose (D90 to the AU-defined volume). The physician must be permitted the flexibility to modify the implanted source strength during the procedure to achieve the clinical goal.

Instead of defining a medical event with respect to the total source strength stated in the “pre-implantation” written directive, which is merely an estimate, an ME should be defined in terms of the total source strength stated in the “postimplantation” part of the written directive, that which corresponds to the requirement of § 35.40 (b)(6)(ii).

5. AAPM concurs with the comments by the American Society for Therapeutic Radiology and Oncology and the American Brachytherapy Society that the definition for *Treatment Site* in 10 CFR § 35.2 should be changed to state: “the anatomical description of the tissue intended to receive a radiation dose, including gross tumor, the clinical target volume, plus a variable planning target volume, as described by the AU in a written directive.” AAPM recognizes that if this recommended change is adopted, definitions for “gross tumor”, “the clinical target volume” and “variable planning target volume” would also have to be added to 10 CFR § 35.2.
6. AAPM also concurs that § 35.3045 (a)(2)(ii) be revised as follows:
  - (ii) The total source strength administered outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning target volume as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive.

AAPM Comments RIN 3150-AI26, NRC-2008-0071  
November 7, 2008

AAPM is prepared to discuss these comments with NRC staff. If you have questions, please contact Lynne Fairbent, AAPM's Manager of Legislative and Regulatory Affairs at [lynne@aapm.org](mailto:lynne@aapm.org) or 301-209-3364.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas E. Pfeiffer". The signature is written in a cursive style with a large initial 'D'.

Douglas E. Pfeiffer, MS, DABR  
Chair  
AAPM's Government and Regulatory Affairs Committee

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