



Advancing Molecular Imaging and Therapy

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Submitted Electronically: rulemaking.comments@nrc.gov

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
US Nuclear Regulatory Commission
Washington, DC 20555-0001
Attn: Rulemakings and Adjudications Staff

Re: RIN 3150-AI26, Medical Use of Byproduct Material—Amendments/Medical Event Definitions, Revision 1

Dear NRC Rulemakings and Adjudications Staff:

The Society of Nuclear Medicine (SNM)—an international professional organization representing more than 16,000 members dedicated to promoting the science, technology, and practical application of molecular imaging and therapy—appreciates the opportunity to comment on the Nuclear Regulatory Commission's (NRC) 10 CFR Part 35 preliminary draft rule addressing reportable medical events in permanent brachytherapy.

The SNM is primarily concerned with two issues. The first is the length of the comment period for this draft rule. Revision 1 to this rule was distributed on February 22, 2008, just days before the end of the comment period (February 26, 2008), with significant changes to the text of the original draft language, distributed on February 8, 2008. These changes are significant enough that they warrant additional time for public review and comment. **The SNM therefore recommends that the comment period be extended.**

The second issue that is of concern to the SNM, is the definition of a medical event. Upon initial review of the preliminary draft language, the SNM believed that the criteria for defining a medical event was specific to permanent implant brachytherapy, and would not have an adverse effect on the practice of nuclear medicine. However, upon review of Revision 1, we now believe that this new definition may, in fact, have a significant impact on the practice of nuclear medicine.

As written in §30.3045(a), the language defines a medical event as the failure to prepare a written directive, when one was required, for any type of therapy, not just permanent implant brachytherapy. The SNM supports the concept of written directives and understands their importance. However, not completing a written directive is not an incident worthy of being defined as a medical event. Especially since summaries of medical events are periodically reported to Congress, and inclusion of such minor violations could do two things: needlessly expand the number of incidents reported to Congress (with the expected hearings and other congressional action to follow – none of which would assist in accomplishing the intent of the rule); and, potentially render it useless, as more significant medical errors could easily be lost in the mix. It is also important to note that the changes to the definition are inconsistent with the original recommendations made by the ACMUI to leave the criteria for modalities other than permanent implant brachytherapy unchanged. **The SNM recommends that §30.3045 be rewritten to clarify the definition of a medical event as it applies solely to permanent implant brachytherapy, leaving the criteria for other modalities unchanged.**

Template = SECY-067

SECY-02



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The SNM appreciates the opportunity to comment on this issue, and is ready to discuss these comments with the NRC. Please contact Hugh Cannon, Director of Health Policy and Regulatory Affairs at hcannon@snm.org, or 703.708.9000, ext. 1322.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. J. B. McEwan'.

Alexander J.B. McEwan, MD
President
SNM

Secy

From: Tomlinson Cindy [CTomlinson@snm.org]
Sent: Monday, March 03, 2008 12:56 PM
To: Secy
Subject: FW: RIN 3150-AI26
Attachments: SNM Comment Letter to NRC - RIN3150-AI26 - 3.3.08.pdf

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Thread-Topic: RIN 3150-AI26

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