

**Rulemaking Comments**

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**From:** Sheetz, Michael A [msheetz@pitt.edu]  
**Sent:** Monday, November 03, 2008 9:43 AM  
**To:** Rulemaking Comments  
**Subject:** [Docket No: NRC-2008-0071];[FR Doc: E8-23534];[Page 58063]; Medical Use of Byproduct Material: Amendments/Medical Event Definitions; Extension of Comment Period; RIN 3150-AI26

**Comments on proposed rule in 10 CFR Part 35, “Medical Use of Byproduct Material” to change medical event definitions, RIN 3150–AI26:**

I recommend that the requirement in Part 35.3045(a) to report as a Medical Event “any administration requiring a written directive if a written directive was not prepared” to be deleted from the new rule language and/or, at a minimum, revised to address the following concerns:

This requirement is vague in that it does not clearly define if it is intended to include a written directive that fails to include certain required elements as constituting a written directive that was not adequately prepared; thereby necessitating the requirement to report incomplete written directives as Medical Events. If it is the intention of the NRC that written directives that are missing certain required elements should be reported as Medical Events, then the regulation should address the specific, critical elements of the written directive that must be missing in order to require such reporting. This requirement is also inconsistent with the provision in 35.40(a)(1) to allow for an oral directive under certain circumstances.

The Medical Event reporting criteria were previously based on deviations from a prescribed plan for the delivery of patient or human subject radiation dose or dosage; thus focusing on real patient or human subject radiation safety issues and potential NRC licensee operational problems/issues. While the importance of a prepared written directive is acknowledged, it must be recognized that the prescribed plan for the delivery of patient or human subject radiation dose (dosage) may be addressed via other mechanisms such as verbal communication of the prescribed dose (dosage) or the establishment of standard prescribed dose (dosage) via written facility policies and procedures. Thus, it is felt that the preparation of written directive, while important, constitutes primarily an administrative requirement that does not warrant reporting as a Medical Event in its absence or the absence of certain required elements.

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DOCKETED  
USNRC

November 3, 2008 (10:42am)

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ADJUDICATIONS STAFF

Template = SECY-067

SECY-C2

Received: from mail1.nrc.gov (148.184.176.41) by OWMS01.nrc.gov  
(148.184.100.43) with Microsoft SMTP Server id 8.1.291.1; Mon, 3 Nov 2008  
09:43:29 -0500

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([136.142.251.58]) by mail1.nrc.gov with ESMTP; 03 Nov 2008 09:43:29 -0500

Received: from PITT-EXCH-06.univ.pitt.edu ([136.142.251.48]) by

pitt-ht-01.univ.pitt.edu ([136.142.251.58]) with mapi; Mon, 3 Nov 2008

09:43:26 -0500

From: "Sheetz, Michael A" <msheetz@pitt.edu>

To: "'Rulemaking.Comments@nrc.gov'" <Rulemaking.Comments@nrc.gov>

Date: Mon, 3 Nov 2008 09:43:25 -0500

Subject: [Docket No: NRC-2008-0071];[FR Doc: E8-23534];[Page 58063]; Medical  
Use of Byproduct Material: Amendments/Medical Event Definitions; Extension  
of Comment Period; RIN 3150-AI26

Thread-Topic: [Docket No: NRC-2008-0071];[FR Doc: E8-23534];[Page 58063];

Medical Use of Byproduct Material: Amendments/Medical Event Definitions;

Extension of Comment Period; RIN 3150-AI26

Thread-Index: Ack9woc+2w0VAbnURHe2bwbqJRO0cA==

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