

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001



SECRETARY

February 15, 2006

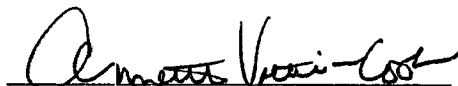
COMMISSION VOTING RECORD

DECISION ITEM: SECY-05-0234

TITLE: ADEQUACY OF MEDICAL EVENT DEFINITIONS IN 10 CFR  
35.3045, AND COMMUNICATING ASSOCIATED RISKS TO  
THE PUBLIC

The Commission (with Chairman Diaz and Commissioners McGaffigan and Jaczko approving and Commissioners Merrifield and Lyons approving in part and disapproving in part) acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 15, 2006.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

  
Annette L. Vietti-Cook  
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz  
Commissioner McGaffigan  
Commissioner Merrifield  
Commissioner Jaczko  
Commissioner Lyons  
OGC  
EDO  
PDR

VOTING SUMMARY - SECY-05-0234

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	1/12/06
COMR. McGAFFIGAN	X				X	1/25/06
COMR. MERRIFIELD	X	X			X	2/3/06
COMR. JACZKO	X				X	2/6/06
COMR. LYONS	X	X			X	2/4/06

COMMENT RESOLUTION

In their vote sheets, Chairman Diaz and Commissioners McGaffigan and Jaczko approved and Commissioners Merrifield and Lyons approved in part and disapproved in part the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on February 15, 2006.


NOTATION VOTE  
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: CHAIRMAN DIAZ  
SUBJECT: **SECY-05-0234 - ADEQUACY OF MEDICAL EVENT  
DEFINITIONS IN 10 CFR 35.3045, AND  
COMMUNICATING ASSOCIATED RISKS TO THE  
PUBLIC**

Approved  Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_  
Not Participating \_\_\_\_\_

COMMENTS:

I commend the staff and the ACMUI for providing sound and reasonable advice on these topics.

  
\_\_\_\_\_  
SIGNATURE

Jan 12, 06  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

NOTATION VOTE  
RESPONSE SHEET

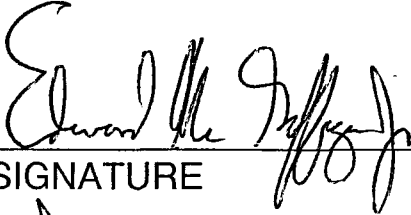
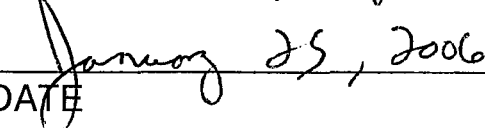
TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER MCGAFFIGAN  
SUBJECT: **SECY-05-0234 - ADEQUACY OF MEDICAL EVENT  
DEFINITIONS IN 10 CFR 35.3045, AND  
COMMUNICATING ASSOCIATED RISKS TO THE  
PUBLIC**

Approved  Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

See attached comments.

  
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SIGNATURE  
  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

### Commissioner McGaffigan's Comments on SECY-05-0234

I approve the staff's recommendations in SECY-05-0234, which address: (1) the  $\pm 20$  percent delivered dose variation in 10 CFR 35.3045(a), as an appropriate threshold for ME reporting for all medical use modalities except permanent implant brachytherapy; (2) development of a rulemaking plan, as proposed by the staff; and (3) actions to improve public understanding of the risks associated with medical events (MEs).

Regarding the topic of improving public understanding of the risks associated with MEs, I initially found it troubling that the staff had not endorsed and supported the first four of the five recommendations (staff also accepted one suggestion) provided by the Advisory Committee on Medical Uses of Isotopes (ACMUI). The ACMUI has obviously taken great care to develop its recommendations, which are rooted in the considerable combined experience and knowledge of the individual members. I feel it is appropriate to caution the staff that, in general, when it considers this or any other Commission advisory committee's recommendations, it should never feel that its hands are bound inextricably to past Commission decisions. Upon appropriate reflection and consideration of changing circumstances or new information, the staff should always make its recommendations to the Commission on the basis of the best current policy and the best current regulatory practice -- and not solely on past precedents established by the Commission. The Commission can change its decisions.

In this case, I have examined in more detail each of the rejected ACMUI recommendations and find myself in agreement with the staff for the reasons outlined below:

In its first recommendation for improving public communication, the ACMUI suggests that the patient reporting requirement in 10 CFR 35.3045(e) be amended to require informing the patient and/or friends and relatives of MEs only if the licensee determines that the ME may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decisions. This is an issue with which the Commission grappled in the Part 35 rulemaking. We may not have reached a perfect solution. But, the ACMUI's third criterion for deciding whether to notify patients, which is whether it is "materially relevant to the patient's future medical treatment decisions," would seemingly capture all MEs, insofar as patients are, or should be, generally concerned with the quality of care provided. So, I'm not sure the ACMUI recommendation is any better than the existing provision.

In its second public communication recommendation, the ACMUI raises the issue of licensee liability. Specifically, ACMUI recommends that the licensee's identity be kept out of the public record. In its October 2005 meeting, the discussion of this item led to a follow-on recommendation on this issue, which is that the staff should withhold ME reporting data from the public until the ME can be confirmed. The staff endorses and supports this latter recommendation, which I feel addresses the core issue in this ACMUI recommendation -- that licensees not be burdened with the public and patient perception problems that arise from the fraction of initially-reported events (10-25%) that are not later confirmed as MEs.

In its third recommendation, ACMUI encouraged NRC to develop a more graded and risk-informed process for responding to ME reports that ties the intensity and immediacy of its inspection response to individual patient risk and public health implications of the event. In response, the staff expressed several clear and concise reasons why it feels that its reactive inspections are already graded and risk-informed. From my reading of the transcript of the October 2005 ACMUI meeting, the ACMUI did not seem in particular disagreement with the

staff's position. In fact, one member noted, without opposition, that the staff's position "fulfills the spirit" of the ACMUI recommendation. I am, therefore, inclined to agree with the staff on this matter that this recommendation is already NRC policy.

The ACMUI's fourth public communication recommendation, to extend the 24-hour notification requirement to 7 days for those MEs that have not harmed the patient, have little potential to harm the patient, or are not materially relevant to the patient's future medical treatment decisions, would also appear to be partially addressed by a 5-day delay in public disclosure of MEs to allow time for them to be confirmed. I support the staff's view that the 24-hour requirement permits NRC to conduct a timely, thorough, systematic, and formal assessment in a manner which is consistent with other reporting requirements for licensed material. Also, as stated above, the staff support and endorse the ACMUI's October 2005 recommendation on public communication, which I feel addresses the core issue in this ACMUI recommendation -- that licensees not be burdened with the public and patient perception problems that arise from the fraction of initially-reported events (10-25%) that are not later confirmed as MEs.

Finally, in addition to the four specific means by which staff intends to communicate the guiding principles for ME definitions (article in NMSS Licensee Newsletter, Regulatory Information Summary, letters/discussions, and Event Summary footnotes), staff should develop a Fact Sheet or Backgrounder for publication on NRC's website. This will ensure that a concise summary of NRC's key messages on this topic is readily-available and retrievable.

EMJ  
1/25/06

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER MERRIFIELD  
SUBJECT: **SECY-05-0234 - ADEQUACY OF MEDICAL EVENT  
DEFINITIONS IN 10 CFR 35.3045, AND  
COMMUNICATING ASSOCIATED RISKS TO THE  
PUBLIC**

Approved *in part* Disapproved *in part* Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

*See attached comments.*

  
\_\_\_\_\_  
SIGNATURE

*2/3/06*  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_


Comments from Commissioner Merrifield on SECY-05-0234:

I approve, as modified in the following paragraphs, the staff recommendations concerning medical event definitions and communication of associated risks to the public.

I want to recognize and compliment both the staff and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in developing the recommendations currently before the Commission. Revising our medical regulations (10 CFR Part 35) and procedures have been a significant activity throughout my tenure as a Commissioner. A major revision to 10 CFR Part 35 was issued several years ago. This was followed by an intense rulemaking activity focused on training and experience requirements. As a result of continuing concerns raised by the medical community, the Commission directed the staff, with the assistance of ACMUI, to focus on the definition of medical events and better communication of medical events. This paper was provided in response to that direction and represents a quality product on the part of both the staff and ACMUI. SECY-05-0234 does a good job articulating and documenting the basis for the plus or minus 20% criteria for determining if a medical event has occurred. As modified in the following two paragraphs, I approve the staff recommendations in SECY-05-0234 as well as the staff resolution of the comments by ACMUI. Many of these efforts can be implemented without rulemaking and staff should proceed to implement them as appropriate.

First, I disapprove the staff proposal to develop a rulemaking plan. Staff should proceed directly with the development of a proposed rule. The original purpose of requiring staff to develop a rulemaking plan was to obtain Commission buy in before committing potentially significant staff resources to developing a proposed rule. In SECY-05-0234, the Commission has enough information to determine that this rulemaking effort is necessary. Therefore, staff should proceed to the proposed rulemaking stage. I anticipate that the staff plan for developing the proposed rule would follow a path very similar to the activities associated with the effort for the training and experience rulemaking, with public input on the drafting of the proposed rule. By this vote, I am not establishing a priority for this effort. Staff should develop whatever data is necessary to properly prioritize the activity and provide an information paper to the Commission outlining the schedule, activities, and priority for completing the effort. If the Commission wants to modify the schedule, planned activities, or staff determined priority, staff will be appropriately directed at that time.

My second comment concerns the staff plans to publically communicate generic issues related to the definition of medical events. As part of this plan, staff should also prepare a fact sheet for the Office of Public Affairs and its regional offices.



2/3/05



NOTATION VOTE  
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: **COMMISSIONER JACZKO**


SUBJECT: **SECY-05-0234 - ADEQUACY OF MEDICAL EVENT DEFINITIONS IN 10 CFR 35.3045, AND COMMUNICATING ASSOCIATED RISKS TO THE PUBLIC**

Approved   X   Disapproved        Abstain       

Not Participating       

COMMENTS:

See attached comments.

  
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SIGNATURE

2/6/06  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes   X   No

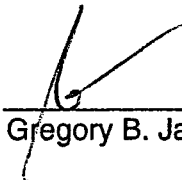
**Commissioner Jaczko's Comments on SECY-05-0234  
Adequacy of Medical Event Definitions in 10 CFR 35.3045, and  
Communicating Associated Risks to the Public**

I approve the staff's recommendations in SECY-05-0234 to retain the reporting and notification provision in 10 CFR 35.3045 if the prescribed dose differs by more or less than 20 percent, and the staff actions to improve public understanding of the risks associated with medical events (MEs).

In approving the staff's recommendations to improve the public communication of MEs and retain the prescribed dose variation in 10 CFR 35.3045, I am aware of the unique challenges we face in balancing the safety of the public against intruding unnecessarily into the practice of medicine. I believe the staff, in considering the recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), has provided the Commission with a set of recommendations that continues to allow us to fulfill our statutory mandate to protect the public while recognizing the important role of the authorized user in administering byproduct materials to patients. Therefore, I approve of the staff's recommendations in this area because I believe it strikes the right balance between the needs of the Commission, the public, and those in the regulated community.

Additionally, I agree with the staff to not support the ACMUI recommendation to keep ME reports out of the public record. As the staff has identified correctly in this paper, the ACMUI's recommendation in regard to ME reporting is counter to the Commission's policy of public openness and transparency in the conduct of agency business. Because this is the one area regulated by the Commission that physically touches the lives of the public everyday I would not support less reporting.

The staff should prioritize this rulemaking effort as appropriate and include it in the next version of the Rulemaking Activity Plan to the Commission.

  
\_\_\_\_\_  
Gregory B. Jaczko

2/6/06  
\_\_\_\_\_  
Date


NOTATION VOTE  
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER LYONS  
SUBJECT: **SECY-05-0234 - ADEQUACY OF MEDICAL EVENT  
DEFINITIONS IN 10 CFR 35.3045, AND  
COMMUNICATING ASSOCIATED RISKS TO THE  
PUBLIC**

Approved in part  Disapproved in part  Abstain \_\_\_\_\_  
Not Participating \_\_\_\_\_

COMMENTS:

See attached comments.

  
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SIGNATURE  
  
2/7/06  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_


Commissioner Lyons Comments on SECY-05-0234

I appreciate the efforts of the ACMUI and its Medical Event Subcommittee in developing recommendations that carefully address the definitions of Medical Events (MEs), written directives (WD) requirements, and improvements to the public understanding of risks associated with MEs. Although the NRC staff does not support certain specific ACMUI suggestions related to improving public understanding of risk, I am pleased that the ACMUI and the NRC staff both agreed that the  $\pm 20\%$  variance threshold is reasonable and should be retained to ME definitions and WD requirements provide a satisfactory approach for addressing issues raised by the 2003 medical use events that prompted the NRC to reconsider the adequacy of our WD and ME rules.

I approve the staff's recommendations to:

1. Retain the  $\pm 20\%$  delivered dose variation from prescription, in 10 CFR 35.3045(a), as an appropriate threshold for all medical use modalities except permanent implant brachytherapy;
2. Take actions to improve public understanding of the risks associated with Medical Events. The staff's recommendations supports the ACMUI's guiding principles as likely to improve public understanding or risks. I also agree with Commissioner McGaffigan and Merrifield on development of fact sheet to relay key messages.

I agree with Commissioner Merrifield that there is no need to develop a rulemaking plan to modify both the WD requirements in 10 CFR 35.40(b)(6) and the ME reporting requirements in 10 CFR 35.3045 to permanent implant brachytherapy medical use, to convert from dose-based to activity-based. I recommend that staff take the necessary steps to properly prioritize the activity and proceed to the proposed rulemaking stage.

  
\_\_\_\_\_  
Peter B. Lyons

2/7/06  
\_\_\_\_\_  
Date