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

August 10, 2010

OFFICE OF THE
SECRETARY

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS – SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – AMENDMENTS/MEDICAL EVENT DEFINITIONS (RIN 3150- AI26)

The Commission has disapproved the staff's recommendation to publish the reproposed amendments to Part 35 in the *Federal Register.*

The staff should work closely with the Advisory Committee on the Medical Uses of Isotopes and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by authorized users. The staff should hold a series of stakeholder workshops to discuss issues associated with the medical event definition. Areas for discussion should include, but not limited to, methods for defining medical events which continue to ensure the safe use of radioactive materials while providing flexibility to account for medically necessary adjustments and the terms and thresholds for reporting medical events to the NRC and patients.

Given the array of pending activities in the medical area, the staff should provide the Commission with an integrated plan denoting schedule and Agreement States participation, for completing this rulemaking along with other activities in the medical area such as developing guidance for incorporating ACMUI input into major medical policy issues and for licensing and inspection programs.

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR

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

OFFICE OF THE
SECRETARY

August 10, 2010

COMMISSION VOTING RECORD

DECISION ITEM: SECY-10-0062

TITLE: REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL – AMENDMENTS/MEDICAL EVENT DEFINITIONS (RIN 3150- AI26)

The Commission (with all Commissioners agreeing) disapproved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 10, 2010.

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 Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-10-0062

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO		X			X	7/27/10
COMR. SVINICKI		X			X	7/21/10
COMR. APOSTOLAKIS		X			X	7/15/10
COMR. MAGWOOD		X			X	7/20/10
COMR. OSTENDORFF		X			X	7/21/10

COMMENT RESOLUTION

In their vote sheets, all Commissioners disapproved 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 August 10, 2010.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Gregory B. Jaczko

SUBJECT: SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL—AMENDMENTS/ MEDICAL EVENT DEFINITIONS (RIN 3150-AI26)

Approved _____ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

SIGNATURE

7/22/10

DATE

Entered on "STARS" Yes _x_ No ___

Chairman Jaczko's Comments on SECY-10-0062
"Reproposed Rule: Medical Use of Byproduct Material –
Amendments/Medical Event Definitions"

I disapprove the staff's recommendation to publish, at this time, a reproposed rule in the *Federal Register* that would amend 10 CFR Part 35. I understand that previous Commissions have directed the staff to revise this rule to include an activity-based metric for medical events (MEs), rather than a dose-based metric, for permanent implant brachytherapy (actions which I supported at the time). This may have seemed like the right approach in 2006; however, I no longer believe that an activity based approach is appropriate. As the Commission heard at a recent meeting on this topic, there is continued disagreement in the medical community about the correct approach for a definition of medical events.

I believe that staff is correct to continue to protect public health and safety through its oversight of the use of radioactive materials in the medical community. MEs are an important tool for the staff and allow for both the detection of events that have the potential to harm the involved patients, and to detect possible problems before they rise to the level of harm. I believe that is the correct regulatory posture for this agency. As the Commission heard at the recent meeting, there is strong belief in the medical community that the proposed dose-based standard would lead to a dramatic increase in the number of medical events reported for prostate brachytherapy. Since the current standard, however, is dosed based, it is unclear to me why the agency is not seeing such large numbers of medical events now. This discrepancy may be a result of an incorrect reporting of medical events under the *current* definition. I believe the provisions in the proposal to require licensees to provide training on the requirements of 10 CFR 3045 will ensure that regardless of the definition, medical events are properly reported. As a result, I fully support this aspect of the staff proposal.

With regard to the actual definition of a medical event, I believe the staff should hold a series of stakeholder workshops to discuss and develop a refined dose-based standard for medical event reporting. The staff should specifically discuss with stakeholders the best method to account for the difficulties in determining a value for the target volume in these procedures, since (as was discussed in the meeting) the prostate may vary significantly in size in the months following the implantation of the radioactive seeds. For example, it may be that the ACMUI's proposal of using the concept of normalization to the initial prostate volume may be the right approach.

The staff should also work with stakeholders to address the apparent misunderstanding of medical events and the impact that the reporting of these events has on the patients. Unless this issue is addressed, there will always be a reluctance to have medical events reported regardless of the definition. Specifically, the staff should consider approaches for the agency and licensees to take to better educate patients and medical professionals about the role medical events play in NRC requirements.

7/27/10

Gregory B. Jaczko Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL—AMENDMENTS/ MEDICAL EVENT DEFINITIONS (RIN 3150-AI26)

Approved _____ Disapproved __XX__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __XX__ None ___

SIGNATURE

07/21/10

DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Svinicki's Comments on SECY-10-0062
Reproposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions (RIN 3150 – AI26)

I join Commissioners Apostolakis, Magwood, and Ostendorff in disapproving the staff's recommendation to publish in the *Federal Register* the reproposed amendments to Part 35 (Enclosure 1 to SECY-10-0062), at this time. In its public meeting on July 8, 2010 regarding the reproposed amendments, the Commission heard substantive concerns from the medical community about the potential impact of these changes on the practice of medicine. Of particular note, in my mind, were concerns that the proposed changes might interfere with the clinical judgments of medical practitioners to such an extent that the delivery of a beneficial treatment modality – "real-time" brachytherapy prostate implantation – would be impeded, or abandoned entirely, in favor of inferior or more invasive treatment modalities.

Therefore, the staff should, as proposed by my fellow Commissioners, work with the Advisory Committee on the Medical Uses of Isotopes, as well as the broader medical and stakeholder communities, to develop an approach keeping the well-being of patients foremost. Finally, to assist the Commission in its decision making on these complex medical matters, I agree with my colleagues that any future SECY paper proposing to amend 10 CFR Part 35 should include a discussion of substantive differences of opinion with or within the medical community regarding the amendments, and should include also the staff's proposed resolution of (or rebuttal to, if necessary) these issues.

Kristine L. Svinicki 07/21/10

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL—AMENDMENTS/ MEDICAL EVENT DEFINITIONS (RIN 3150-AI26)

Approved _____ **Disapproved** X **Abstain** _____

Not Participating _____

COMMENTS: **Below** X **Attached** ___ **None** ___

Staff should work with ACMUI and the medical community to develop a workable definition that addresses the NRC regulatory needs and that is reflective of the practice of permanent implant brachytherapy. Staff should provide the workable definition and associated licensing guidance documents to the Commission.

SIGNATURE

7/15/10

DATE

Entered on "STARS" Yes X No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

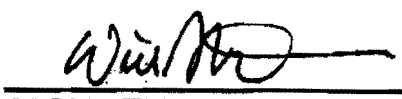
FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL—AMENDMENTS/ MEDICAL EVENT DEFINITIONS (RIN 3150-AI26)

Approved _____ Disapproved _X_ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___



SIGNATURE

20 July 2010

DATE

Entered on "STARS" Yes _X_ No ___

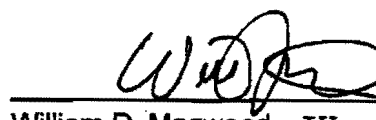
Commissioner Magwood's Vote on SECY-10-0062

I disapprove the staff's proposal to publish a reproposed rule in the Federal Register that would amend 10 CFR Part 35. I appreciate the staff's work in developing this proposed rule and its interest in assuring the agency's ability to respond to the medical events such as those documented at VA hospitals during 2008. However, the interest to assure a regulatory response to events must be balanced with the medical judgment of qualified physicians. Given the very ardent concerns raised by the medical community, including the ACMUI, it is not evident that this balance has been achieved.

Many aspects of the rule raise complex issues that I believe need to be discussed in detail with the medical community—including the agency's approach to the use of pre-application written directives that limit the actions that can be taken by physicians in the course of a procedure. The logic of the current approach is based on the agency's need to assess whether a medical event has occurred. However, it is my view that our first interest must be to facilitate a safe and effective treatment for patients. The staff should return to this matter with that priority in mind.

I therefore recommend that the staff work closely with the ACMUI and the broader medical community to develop an approach that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, and enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by users. This work should include a reconsideration of the term "medical event" and how it is used by the agency.

When a new proposal to amend 10 CFR part 35 is presented to the Commission, I recommend that staff include a comment/resolution section which will detail how recommendations provided by ACMUI and other stakeholders are addressed.



20 July 2010

William D. Magwood, IV Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-10-0062 – REPROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL—AMENDMENTS/ MEDICAL EVENT DEFINITIONS (RIN 3150-AI26)

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

7/21/10
DATE

Entered on "STARS" Yes X No ___

Commissioner Ostendorff's Comments on SECY 10-0062, "Reproposed Rule: Medical Use of Byproduct Material- Amendment/Medical Event Definitions"

I disapprove the staff's proposal to publish for comment the reproposed amendments to 10 CFR 35. While I agree with the changes proposed by the staff in the areas of increased training, post- procedure evaluation of doses within a timely manner, and the need for a dose-based event definition, the reproposed rule would not provide adequate flexibility to permit necessary emergent medical judgments during permanent implant brachytherapy procedures. The rule may also unnecessarily elevate the importance of cases in which a written directive is required but not completed by requiring that such cases be reported to the NRC.

I commend the staff for reanalyzing the appropriate course of action based on the 2008 medical events at the Veterans Administration. In this case the staff re-evaluated the implications of the activity-based medical event criteria following these events. Through this evaluation, the staff recognized that the rule had unintended consequences which would make the rule inconsistent with the NRC's original regulatory intent of ensuring radiological safety. This type of questioning attitude and continuous learning is an example of the strong safety culture at the NRC.

However, I believe that the policies outlined in the Commission's 2000 Policy Statement on the Medical Use of Byproduct Material should guide the Commission's actions here. That Policy Statement states that the "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." The Policy Statement further states that the "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." In my view, the proposed changes to Part 35 are inconsistent with these policy directives. The NRC staff and the Commission have heard overwhelmingly from our stakeholders that the reproposed rule would not provide sufficient flexibility for authorized users to make adjustments to the number or placement of seeds during "real time" brachytherapy. Due to the nature of permanent brachytherapy implant procedures, emergent conditions may cause an authorized user to determine it is medically necessary to make adjustments to the treatment which may result in changes to the dose given. Furthermore, the medical community has indicated that the 20% variance in the intended dose permitted by the current rule does not provide sufficient flexibility to account for such needed adjustments. Based on the various options proposed by stakeholders which permit flexibility to allow for medical judgments while also holding licensees accountable for ensuring radiological safety, I do not think it is necessary in the case of permanent brachytherapy implants for the NRC to intrude on medical decisions made to adjust the number or placement of seeds.

The revision to the rule would also require that, in some instances, cases where a written directive is required but is not completed be reported as medical events. This would elevate such issues to a level that may not be warranted or consistent with other reporting requirements in 10 CFR Part 35. Historically, medical events have been defined as events which involve radiological exposure to a patient that differs from what was planned. I recognize that written directives form the basis for determining if a medical event occurred, and therefore the requirement to complete a written directive is important. On the other hand, the staff's proposed change may result in difficulties in distinguishing such events, which are more administrative in nature, from radiologically significant events. This could result in confusion in interpreting event-trending results and in communicating such occurrences to patients. The staff should explore options for ensuring that the NRC is made aware of such occurrences, without requiring that they be reported to the NRC.

Therefore, I disapprove of the staff's proposal to publish the reproposed rule for public comment. Staff should engage stakeholders to pursue options that will provide flexibility to account for needed adjustments during permanent brachytherapy procedures while still protecting public and worker radiological safety. The staff should also pursue options to ensure that the NRC is made aware of cases in which a written directive is not completed as required, without declaring such occurrences as medical events. The staff should resubmit the reproposed rule to the Commission with its evaluation of various solutions to these issues.