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

SECRETARY

April 21, 2011

COMMISSION VOTING RECORD

DECISION ITEM: SECY-11-0035

TITLE: INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 21, 2011.

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-11-0035

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO	X					4/7/11
COMR. SVINICKI	X				X	4/14/11
COMR. APOSTOLAKIS	X				X	4/11/11
COMR. MAGWOOD	X				X	4/15/11
COMR. OSTENDORFF	X				X	4/6/11

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and some provided additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 21, 2011.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Gregory B. Jaczko

SUBJECT: SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached ___ None _X__

SIGNATURE

4/7/11

DATE

Entered on "STARS" Yes _x_ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___

SIGNATURE

04/14/11

DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Svinicki's Comments on SECY-11-0035
Integrated Plan, Title 10 of the Code of Federal Regulations Part 35, Medical Use of Byproduct Material, Activities and Options for Streamlining the Medical Rulemaking Petition and Rulemaking Process

In this paper, the staff has done a commendable job of laying before the Commission the complexity and interrelated nature of its work in this area. With respect to the review of medical petitions, I approve the staff's recommended Option 2 to decrease the petition resolution time to 9 months. With respect to the process for medical-related rulemakings, I approve the staff recommendation of making no change.

There are two conditions that add to the complexity of comment gathering and resolution for these medical-related rules. First, the number of Agreement States has grown significantly over the past decade. Since our Agreement State partners play an essential role in shaping these rules, we must allow time to solicit and consider their input. Second, the advice of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) is a key technical input that allows informed decision-making on medical-related rules prior to final NRC action. As a federal advisory committee, the ACMUI must be provided the requisite time to work through its consensus process in formulating final committee positions. Coordinating the development of regulatory bases and rule language with both of these groups adds time to the staff's schedules but is essential for appropriately informed final rules.

Kristine L. Svinicki 04/14/11

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

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

Not Participating _____

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

On the issue of streamlining the review of petitions for rulemaking on medical uses of byproduct material ("medical petitions"), I approve the staff's recommendation to decrease the petition resolution time to 9 months for medical petitions (Option 2). However, this approval is subject to the condition that the staff continue to place first priority on those petitions, whether medical or otherwise, that require immediate attention as a result of their health and safety implications.

On the issue of streamlining rulemakings on medical uses of byproduct material, I approve the staff's recommendation of adherence to the existing rulemaking process and full implementation of existing flexibilities regarding stakeholder interactions (Option 1).

SIGNATURE

4/11/11

DATE

Entered on "STARS" Yes X No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

15 April 2011

DATE

Entered on "STARS" Yes X No ___

Commissioner Magwood's Comment on SECY -11-0035 SECY-11-0035- 10 CFR Part 35, Medical Use of Byproduct Material, Activities and Options for Streamlining the Medical rulemaking Petition and Rulemaking Processes

I approve staff's recommendations for streamlining the medical petition time to 9 months by giving medical petitions a higher priority and maintaining the status quo on the rulemaking development process. Although I am approving staff's recommendation, I do so with a strong reservation that expanding the rulemaking to add very complex issues in one rulemaking will be anything but efficient. Having heard from a number of stakeholders regarding the immediate need for resolution on the training and experience attestation requirements and the definition of Medical Events, I am concerned that addressing several very complex issues in one rulemaking will not result in an efficiency gain. Therefore, I am recommending that after conducting stakeholder workshops, staff should inform the Commission of its estimate of the overall schedule to complete this rulemaking and inform the Commission of any potential impacts this schedule could have on the medical industry at large. I also support Commissioner Ostendorff's comment that Staff should, where possible, develop innovative approaches to further streamline the rulemaking process.

4/15/11

William D. Magwood, IV **Date**

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-11-0035 – INTEGRATED PLAN, TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 35, MEDICAL USE OF BYPRODUCT MATERIAL, ACTIVITIES AND OPTIONS FOR STREAMLINING THE MEDICAL RULEMAKING PETITION AND RULEMAKING PROCESSES

Approved Y Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached Y None ___

SIGNATURE

4/6/11

DATE

Entered on "STARS" Yes X No ___

Commissioner Ostendorff's comments on SECY-11-0035, " Integrated Plan, Title 10 of the Code of Federal Regulations Part 35, Medical Use of Byproduct Material, Activities and Options for Streamlining the Medical Rulemaking Petition and Rulemaking Processes"

I approve of the staff's plans for streamlining the medical petition review process and maintaining the status quo timeline for the medical rulemaking process. The staff should, where possible, develop innovative approaches to further streamline the rulemaking process through the use of less formalized, more efficient means of obtaining ACMUI input on major policy issues, risk informing the medical regulations, and completing rulemaking activities in parallel.

I appreciate the staff's efforts in providing the Commission with the status and integration of the various Commission-directed efforts in the medical area. The number and scope of activities in the integrated plan emphasizes the importance and intensity of the staff's efforts in the medical area. The diverse and strong views on the appropriate regulatory approaches in the medical field necessitate a methodical rulemaking process that provides ample opportunity for stakeholder involvement. I wholeheartedly support fulsome stakeholder involvement in the rulemaking process and agree that ample time is needed to ensure the agency's rules are well founded.

However, I believe there are additional areas within the medical rulemaking process where additional efficiencies can be gained through implementation of innovative approaches to stakeholder involvement and risk informing our regulations. For example, the staff should work with ACMUI to develop approaches, such as less formal interaction outside of regularly scheduled ACMUI meetings, to shorten the staff's process for obtaining ACMUI input on less controversial or more fully vetted policy issues. I also agree with the staff's assessment that risk informing Part 35 would have long term efficiency benefits, but would require the short term investment of significant resources. The staff should, during the comprehensive rulemaking, consider whether there are areas of the regulations which could be further risk informed without a significant expenditure of resources or delay in the rulemaking, taking into consideration issues such as the safety significance and transboundary nature of the regulated activity. The staff should evaluate the possibility of further streamlining the comprehensive rulemaking by completing actions in parallel within existing resources.