

November 13, 1998

COMMISSION VOTING RECORD

DECISION ITEM: SECY-98-263

TITLE: PROPOSED RULE: REVISION OF 10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL

The Commission (with Commissioners Dicus, McGaffigan, and Merrifield agreeing) approved Option 2B of the subject paper as recorded in the Staff Requirements Memorandum (SRM) of November 13, 1998. Chairman Jackson would have preferred Option 2A and Commissioner Diaz would have preferred Option 1.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commissioners, and the SRM of November 13, 1998.

John C. Hoyle
Secretary of the Commission

Attachments: 1. Voting Summary
2. Commissioner Vote Sheets
3. Final SRM

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR
DCS

VOTING SUMMARY - SECY-98-263

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACKSON		X			X	11/12/98
COMR. DICUS	X				X	11/10/98
COMR. DIAZ		X			X	11/12/98
COMR. McGAFFIGAN	X				X	11/10/98
COMR. MERRIFIELD	X				X	11/10/98

COMMENT RESOLUTION

In their vote sheets, Commissioners Dicus, McGaffigan, and Merrifield agreeing approved Option 2B of the subject paper, agreeing to extend the comment period and the due date for submitting a rule to the Commission by 30 days. Chairman Jackson disapproved the paper and preferred Option

2A to extend the comment period by 30 days, but not the due date for submittal to the Commission. Commissioner Diaz disapproved the paper and preferred Option 1 which did not allow any extensions. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on November 13, 1998.

Chairman Jackson's Comments on SECY 98-263

From a policy perspective, I have no objection to the extension of the comment period since this schedule was developed by the staff to meet the overall Commission directed completion date of the rule. However, the staff has indicated that a 30 day extension would negatively impact its scheduled meetings with the full ACMUI and the appropriate subcommittees; therefore, to the extent that it would be necessary to eliminate these meetings to allow an additional 30 day comment period, I disapprove the request to extend the 30 day comment period. I am disappointed that such a request to extend the comment period and the overall deadline is provided at such a late date. Given the enhanced participatory method under which this proposed rule has been developed, the fact that the Commission has addressed this issue as part of its Directions Setting Initiatives, and the significant period of time previously available to comment on this rulemaking, I believe that ample time and opportunity have already been provided to those who wished to comment. Therefore, I disapprove the staff recommendation to extend the completion date for the final rule. If the Commission does decide to approve the request for a 30 day extension of the comment period, the staff should eliminate or reschedule subsequent activities such as the meetings with the ACMUI to meet the May 29, 1998 rule completion date.

I approve the request for a "point of contact" in each Commission Office to assist the staff in resolving issues as it continues to develop the final rule; however, the staff should be aware that these individuals will still need to consult with each of the respective Commissioners prior to providing "Commission direction" on any issue. As such, this informal process should not be used by the staff as a means of receiving instantaneous feedback from the Commission, nor should it be used to circumvent the established Commission procedures for developing and promulgating policy.

Commissioner Dicus' comments on SECY-98-263:

I reluctantly approve option 2B, namely providing 30 day extensions of the comment period for the proposed revision to Part 35 and the final rule date.

The 30 day extension of the comment period is not unreasonable because it will permit stakeholders to fully develop their comments on the proposed rule especially in light of the most recent public workshop discussions. My approval of the recommendation to extend the final rule date is based on the importance of enabling staff to hold meaningful discussions with ACMUI before submitting the proposed final rule to the Commission.

Given the enhanced participatory process that was utilized for this proposed rule and the long time that this matter has been under review, I find the request from stakeholders for a risk assessment at this late stage to be a disappointing development. That said, I am willing to consider such a request but I am not willing to delay further the rulemaking process on that account at this time. When staff submits the proposed final rule to the Commission, staff should include discussion of the risk assessment as an option and provide the pros and cons for this option.

Commissioner McGaffigan Comments for SECY PAPER 98-263

I approve Option 2B, mainly because I do not want the staff to be forced to give up meetings with the ACMUI subcommittees. Nonetheless, I urge the staff to find ways to meet the existing final due date. Each Commissioner's naming a point of contact with the staff for the rulemaking will help, and I am designating Janet Schlueter as my point of contact. However, I would think that more could be done to get the rulemaking done on schedule. For example, as much as possible the staff should avoid sequential referrals and seek concurrent involvement of reviewers and parties. The Commission has more than once gotten an important final rule out on a schedule like the one facing us now, and without slighting parties. We should be able to do the same now.

Commissioner Merrifield comments on SECY-98-263

I accept the staff recommendation of Option 2B.