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

OFFICE OF THE
SECRETARY

October 3, 2001

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0134

TITLE: FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of October 3, 2001.

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 Meserve
Commissioner Dicus
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-01-0134

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	8/9/01
COMR. DICUS	X					8/26/01
COMR. McGAFFIGAN	X				X	9/18/01
COMR. MERRIFIELD	X				X	7/31/01

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 October 3, 2001.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MESERVE

SUBJECT: **SECY-01-0134 - FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE**

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

SIGNATURE

August 9, 2001

DATE

Entered on "STARS" Yes ✓ No ____

CHAIRMAN MESERVE'S COMMENTS ON SECY-01-0134

I support the staff's request to proceed with Option 3 as presented in SECY 01-0134. It is unfortunate that previous interactions between the staff and external stakeholders did not result in the discussion and resolution of the various issues in contention as the rule was being developed. Obviously much time and effort has been spent on this matter for a number of years and it is disappointing that the final rule requires further consideration. Nonetheless, given the scope and significance of the rule and the controversy that surrounds it, I believe that a full examination of the entirety of the rule is now necessary. I thus encourage the staff to proceed along the path defined by Option 3 and to keep the Commission informed, through periodic updates, of the status of the rulemaking effort.

I also concur in the staff's plans to prepare an interim enforcement policy authorizing the exercise of enforcement discretion with respect to practices regarding "suitable inquiry" and "pre-access testing," as described in SECY-01-0134.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-01-0134 - FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE**

Approved __x__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

Greta Joy Dicus
SIGNATURE

August 26, 2001
DATE

Entered on "STARS" Yes __x__ No ____

24 JUL 01 3:19

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-01-0134 - FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE**

Approved w/comments X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

Edward McGaffigan Jr.
SIGNATURE

September 18, 2001
DATE

Entered on "STARS" Yes X No ____

Commissioner McGaffigan's Comments on SECY-01-0134

I approve Option 3 to withdraw the OMB clearance request and to publish a new notice of proposed rulemaking.

I also concur in the staff's plans to prepare an interim enforcement policy authorizing the exercise of enforcement discretion with respect to practices regarding "suitable inquiry" and "pre-access testing," as described in SECY-01-0134.

The Commission has been trying for approximately a decade to update its Fitness for Duty (FFD) rule. Indeed, when NRC first issued the rule in 1989, the Commission recognized that it would likely need to be updated and instructed the staff to inform it of any changes needed after 18 months of experience with implementing the rule. Unfortunately little thought was apparently given then to what an obstacle the backfit rule (10 CFR § 50.109) would become to updating the FFD rule (or any other comprehensive rule).

In SECY-92-308 the staff proposed amendments to the FFD rule. That set off a debate within the Commission on whether the backfit rule needed to be amended to cover situations such as the Appendix J and FFD rulemakings where seemingly worthwhile changes to the regulations cannot be shown to result in a "substantial increase in the overall protection of the public health and safety or the common defense and security," as required by § 50.109. That was ultimately resolved in an SRM issued June 30, 1993, the last day of Commissioner Curtiss' tenure, in which the Commission voted 4 - 1 (Curtiss in the minority) that the "substantial increase" criterion, as promulgated in 1985, was "flexible enough to allow for qualitative arguments that a given proposed rule would substantially increase safety" and "flexible enough to allow for arguments that consistency with national and international standards, or the incorporation of widespread industry practices, contributes either directly or indirectly to a substantial increase in safety." In making this argument, the Commission majority pointed to the 1985 Commission majority's discussion of the "substantial increase" criterion: "the standard is not intended to be interpreted in a manner that would result in disapprovals of worthwhile safety or security improvements having costs that are justified in view of the increased protection that would be provided."

After this Solomonic decision, the staff went back to the drawing board on FFD (and decided to amend Appendix J by creating an Option B, which I believe is now universally followed, rather than the original staff plan of SECY-91-348, to exempt the Appendix J rule from the backfit rule). In SECY-95-262, the staff, having parsed the proposed FFD rule clause-by-clause, subclause-by-subclause, stated that they "cannot conclude each of the proposed new requirements ... would provide a substantial increase in safety ... Nevertheless, the staff believes that the proposed requirements would enhance the ability of licensees to deter and detect substance abuse and remove unfit workers from activities covered by the rule." The staff therefore proposed to ask for public comment on the "substantial increase" criterion on a subclause-by-subclause level and on whether worthwhile exceptions should be made to the backfit rule. In early 1996 the Commission approved publication of the proposed rule with minor changes. The public comment period ended on August 7, 1996. Over the next three years the staff worked on a massive final rule package (without further stakeholder interaction) that ended up recommending 36 worthwhile exceptions to the backfit rule. The Commission instead decided that in the aggregate the worthwhile changes met the "substantial increase" criterion and the final rule, as approved by the Commission on December 4, 2000, made no worthwhile exceptions. It was always in my view a mission impossible for the staff to find that

each subclause of a comprehensive rule revision would separately meet the substantial increase criterion or otherwise meet one of the backfit rule's exceptions. A rule of reason needed to be applied to the changes so that they could be considered in the aggregate and the 1985 and 1993 Commission guidance that "substantial" could be interpreted flexibly to mean "worthwhile" could be applied in the aggregate.

I recite this history because I believe that it is essential that the staff not have to repeat its subclause level analysis of backfit rule considerations in any new FFD proposed rule. If they enter that morass again we will not have a final FFD rule for many more years. Problems with the current rule that the staff has been trying to fix for a decade will remain problems.

I propose that the Commission embrace an aggregate backfit analysis from the outset of this new attempt at FFD rulemaking and also interpret "worthwhile" as a synonym of "substantial" in the "substantial increase" criterion of the backfit rule, as the 1985 and 1993 Commission majorities did and instruct the staff that:

> In the future, the Commission will conduct an aggregate backfit analysis of an entire rulemaking, unless there is a reasonable indication (presumably from public comment) that: (i) a proposed change is not reasonably related to the unified regulatory purpose of the rulemaking, <u>and</u> (ii) the proposed change imposes costs disproportionate to the safety benefit attributable to that change. In such cases, the Commission will perform an analysis of that proposed change <u>in addition</u> to the aggregate analysis of the entire rulemaking. That analysis will need to show that the individual change is worthwhile, that is, has costs that are justified in view of the benefits that would be provided.

If we do this, I believe that the staff can conclude a renewed FFD rulemaking reasonably promptly. If we do not, I am afraid additional redwood forests will be wiped out to provide the reams of paper that will be consumed in the minutiae of backfit analysis of any FFD rule.

In arguing that we should essentially adopt "worthwhile" as a synonym of "substantial" as the 1985 and 1993 Commission majorities did, I should make it clear that my sympathies are with the minorities in both of those votes (Commissioners Bernthal and Asselstine in 1985 and Commissioner Curtiss in 1993). We would be better off today if rulemaking had been exempt from the backfit rule, but not from regulatory analysis, as Commissioner Bernthal argued. We would be better off today if the Commission had adopted Option 2 in SECY-93-086 ("amend the backfit rule by deleting, revising or supplementing the safety enhancement criterion for addressing rulemakings which are worthwhile but do not meet this criterion") rather than issuing the Solomonic decision that the backfit rule should be flexibly interpreted and that "substantial" and "worthwhile" are essentially synonyms. These words are obviously not synonyms in most dictionaries. But if the Commission and the staff can get their rulemaking work done by hearkening back to the Commission's confused 1985 Statement of Considerations, I'm for the path of least resistance.

EMc2

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-01-0134 - FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:
See attached comments.

SIGNATURE

7/31/01
DATE

Entered on "STARS" Yes ✓ No _____

Commissioner Merrifield's Comments on SECY-01-0134

I approve the staff's recommended Option 3. I strongly agree with the staff that Option 3 provides the greatest benefits in terms of public confidence, as well as clarity, efficiency, and effectiveness of the rule. As the staff points out, Option 3 also provides opportunities for combining and better integrating ongoing agency efforts in this important area. I also approve the staff's plans to propose an interim enforcement policy to authorize the exercise of enforcement discretion pending rulemaking for licensees that follow certain practices that are discussed in SECY-01-0134.

The Commission has been very clear in its support of prudent fitness-for-duty (FFD) measures aimed at ensuring that the nuclear power plant workplace is drug and alcohol free. It was in that spirit that, despite lingering concerns, I approved the final FFD rule outlined in SECY-00-0159. However, based on the information provided in SECY-01-0134 and information provided to me by the staff in briefings that I have had since the Commission affirmed the final rule on December 4, 2000, I am convinced that there are serious shortcomings with the final rule and the cost-benefit analysis. Thus, I support withdrawing the OMB clearance request.

As I stated in my April 9, 2001, memorandum to my Commission colleagues, during the rulemaking process associated with the final FFD rule, I, along with other Commissioners, vigorously scrutinized the rulemaking package and raised concerns about specific technical issues, the backfit analysis, and the cost-benefit analysis. In response to much of this scrutiny, the staff repeatedly reassured Commissioners that they had reassessed their analyses and conclusions, and remained confident in the rulemaking package. After the Commission approved the final rule, numerous stakeholders raised significant concerns about the rule, the bases behind the rule, and the rule's cost-benefit analysis. Some of these concerns were new to the staff, reflecting that there should have been more opportunities for dialogue between the staff and stakeholders during the very long rulemaking process. However, many of the remaining concerns mirrored the concerns raised by Commissioners during the rulemaking process. This stakeholder scrutiny caused the staff to once again reassess aspects of the rulemaking package. This reassessment was apparently more thorough and comprehensive than previous ones because it led the staff to recommend withdrawing the OMB clearance request and pursuing the course set out in Option 3. Stating the obvious, had there been better communication between the staff and stakeholders during the rulemaking process, and had the staff been more thorough in their original reassessments, I believe the Commission would have made a more informed decision on the final rule.

In SECY-01-0134, the staff summarizes NEI's objections to the final rule and the concerns raised by various stakeholders during the March 20-22, 2001 workshop. However, based on my discussions with the staff, I am not convinced that even today we fully understand the scope of stakeholder concerns associated with the final rule. With that in mind, and given that it has been 5 years since the public had an opportunity to comment on the proposed rule, I strongly believe that it would be prudent to solicit stakeholder feedback on all of the rule's provisions (Option 3). Option 3 is the only option that will provide for a full airing of stakeholder views on the entire rulemaking package; it is the only option that will enable commenters to suggest improvements to the rule in areas other than those that the staff is most focused on; and, I believe it is the only option that will enable me to make a fully-informed decision on this rulemaking effort. From my perspective, Options 1 and 2 are simply untenable.

I am disappointed in the staff's performance that led to the Commission's decision on the final rule last December. I am also disappointed that the March workshop served to point out that there is inconsistency in the manner in which our regional offices oversee licensee FFD programs and inconsistent implementation of existing FFD regulations by our licensees. Having said this, I am confident that the NRR team now assigned to this rulemaking effort is committed to and capable of resolving the difficult issues that are before them. I am encouraged by the fact that this team has clearly laid out stakeholder concerns for the Commission's consideration and has recommended a sound and prudent option for addressing these concerns. Should a majority of the Commission support Option 3 as I hope, I strongly encourage the staff to actively engage stakeholders on not only the rulemaking package, but also on the important details (guidance) surrounding the actual implementation of that rulemaking. I also encourage the staff to keep the Commission fully and currently informed as it proceeds with ongoing initiatives in the area of fitness-for-duty.

I am confident that the staff has learned some important lessons from this rulemaking experience. I trust that they will capitalize on these lessons during future rulemaking efforts.

7/31/01