



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

January 19, 2001

OFFICE OF THE
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0198

TITLE: STATUS REPORT ON STUDY OF RISK-INFORMED
CHANGES TO THE TECHNICAL REQUIREMENTS OF 10
CFR PART 50 (OPTION 3) AND RECOMMENDATIONS ON
RISK-INFORMED CHANGES TO 10 CFR 50.44
(COMBUSTIBLE GAS CONTROL)

The Commission (with Chairman Meserve and Commissioners Dicus, McGaffigan, and Merrifield agreeing and Commissioner Diaz agreeing in part and disagreeing in part) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of January 19, 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 Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-00-0198

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	11/6/00
COMR. DICUS	X				X	11/8/00
COMR. DIAZ	X	X			X	12/4/00
COMR. McGAFFIGAN	X				X	12/21/00
COMR. MERRIFIELD	X				X	11/20/00

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Dicus, McGaffigan, and Merrifield approved the staff's recommendation and provided some additional comments. Commissioner Diaz approved in part and disapproved in part the staff's recommendation and provided some additional comments. Commissioner Diaz proposed tasking the staff to establish criterion to ensure rules are scrutinized in a meaningful and disciplined manner to pass backfit criteria applicable to risk-informed rulemaking. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on January 19, 2001.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

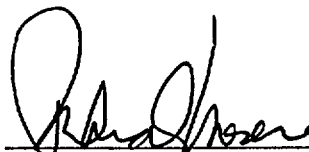
SUBJECT: SECY-00-0198 - STATUS REPORT ON STUDY OF RISK-
INFORMED CHANGES TO THE TECHNICAL
REQUIREMENTS OF 10 CFR PART 50 (OPTION 3) AND
RECOMMENDATIONS ON RISK-INFORMED CHANGES TO
10 CFR 50.44 (COMBUSTIBLE GAS CONTROL)

Approved X/w comments Disapproved _____ Abstain _____

Not Participating _____ Request Discussion _____

COMMENTS:

See attached sheet.



SIGNATURE

March 6, 2000

DATE

Entered on "STARS" Yes X No _____

COMMENTS OF CHAIRMAN MESERVE ON SECY-00-0198

I approve the staff's recommendations in SECY-00-0198. Specifically, I agree:

1. Selective implementation by licensees of individual elements of a risk-informed alternative version of 10 CFR 50.44 should not be permitted.
2. The staff should evaluate, using the backfit process, potential changes to the current requirements of 10 CFR 50.44 that could result in a substantial safety enhancements to determine if they are cost-beneficial as well. However, since implementation of the risk-informed alternative version of the rule is voluntary on the part of licensees, I agree with the staff's position that a backfit analysis of that version is not required.
3. The staff should proceed with rulemaking on the risk-informed alternative version of 10 CFR 50.44, including completion of outstanding technical work (e.g., development of the combustible gas source terms) and necessary regulatory analyses.

Detailed comments on each of these issues follow.

Selective Implementation. The staff's approach to risk-informing a rule includes a thorough evaluation of all aspects of a rule so as to provide a harmonized and coherent approach that both eliminates needless regulatory burden and improves safety through more thorough application of risk insights. Allowing licensees to implement portions of the rule selectively would serve to defeat the philosophy that has guided the effort. It would raise the danger that licensees could select only those changes that reduce burden, while ignoring those that improve safety. If such an approach were seen to be acceptable, public confidence in the process would no doubt be reduced. Moreover, such selective implementation, in the worst case, could cause a situation in which every licensee could have, in effect, a "customized" and unique set of regulatory requirements, which could severely impact the staff's ability to assess risk and to determine if a licensee was truly in regulatory compliance.

Backfit. The backfit issue, as presented by the staff, may at first glance appear similar to the issue of selective implementation. That is, it may appear to some that the staff is selectively implementing parts of the risk-informed version of the rule by seeking to make portions mandatory for all licensees. However, I view this issue in a different light. During its evaluation of a regulation, staff may find elements of an existing rule that should be considered for modification or supplementation in order to provide a substantial increase in the overall protection of public health and safety. The fact that awareness of the issue happens to arise in the context of the effort to risk-inform the regulations should not stand as a barrier to the implementation of necessary change. However, the disciplined analysis required by 10 CFR 50.109 should be applied so as to determine whether such a backfit can be justified.

Rulemaking. Based on the documentation included with SECY-00-0198 and certain related information, such as the ACRS letter of September 13, 2000, on this issue, I conclude that the staff has developed sufficient information to proceed with the development of a risk-informed alternative version of 10 CFR 50.44. The framework that the staff has developed to implement the task seems appropriate. I would, however, like to offer some comments on this effort.

I note that the staff intends, as part of the risk-informed version of 10 CFR 50.44, to develop a set of plant-design-specific "source terms" for combustible gas. I would caution the staff against making the requirements in the rule overly prescriptive in this regard so as not to lead to the premature "ossification" of the methods for calculating source terms. The requirements should be sufficiently flexible to permit improvements in the methodology if and when better models become available.

Finally, now that the staff has obtained some experience in the "Option 3" process, I believe that it would be prudent for the staff to review the resource estimates associated with the overall Option 3 effort and determine if those estimates are consistent with the resources expended on the work reported in SECY-00-0198. If the staff finds that more resources will be required, it should provide the Commission with an updated estimate.

NOTATION VOTE

RESPONSE SHEET

2000 SEP 18 AM 9:27

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-00-0198 - STATUS REPORT ON STUDY OF RISK-INFORMED CHANGES TO THE TECHNICAL REQUIREMENTS OF 10 CFR PART 50 (OPTION 3) AND RECOMMENDATIONS ON RISK-INFORMED CHANGES TO 10 CFR 50.44 (COMBUSTIBLE GAS CONTROL)**

Approved x Disapproved Abstain

Not Participating

COMMENTS:

See attached.

Preta Joy Dicus
SIGNATURE

November 8, 2000
DATE

Entered on "STARS" Yes x No

Comments of Commissioner Dicus on SECY-00-0198

The staff should proceed with development of the risk-informed alternative to 10 CFR Part 50.44.

Regarding the staff's recommendation for prohibiting selective implementation, I will hold my final determination until I have a proposed rule in front of me to more clearly study the potential impact of such a measure.

Regarding the policy decision on backfit considerations, I would agree that a voluntary initiative does not need a backfit analysis. I would also note that this initiative would undergo a regulatory analysis as part of the rulemaking process and will receive review of its benefits through that process. I do agree that the staff should forward any risk-informed changes that have a potential to enhance safety to the generic issue program for further review. In addition, if any requirements are found that do not contribute to safety they should be removed.

I commend the staff on its efforts to bring this issue to the stage at which it is today. I am very interested in seeing the staff's first proposal for risk-informing a requirement of Part 50 as expeditiously as possible. In that vein, I would request that the staff provide within 30 days of this SRM a recommendation for actions that could shorten the time for development of the proposed rule.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-00-0198 - STATUS REPORT ON STUDY OF RISK-INFORMED CHANGES TO THE TECHNICAL REQUIREMENTS OF 10 CFR PART 50 (OPTION 3) AND RECOMMENDATIONS ON RISK-INFORMED CHANGES TO 10 CFR 50.44 (COMBUSTIBLE GAS CONTROL)**

Approved ☒ *[initials]* Disapproved ☒ *[initials]* Abstain _____

Not Participating _____

COMMENTS:

SEE ATTACHED COMMENTS

--REC'D BY HJD--

3 SEP 00 4:27

[Signature]
SIGNATURE

December 4, 2000
DATE

Entered on "STARS" Yes ☒ No _____

COMMISSIONER DIAZ' COMMENTS ON SECY-00-0198

I believe that, as we inch forward in the construct of risk-informed regulation, we will eventually reach a fork in the road with, I hope, clearly marked destinations: the road to mostly deterministic regulation and the road to mostly risk-informed regulation. This point of decision-making should be cleared of obstacles and have well-defined processes. Two recurrent and important policy issues are in front of us and need resolution before we reach that fork: selectivity and the application of backfit analysis to "voluntary" rules. NRC "voluntary" rules or "voluntary" parts of a rule are not subjected to the backfit analysis. Yet, "voluntary" applies only to the adoption; compliance is mandatory once adopted. Thus, it would be possible, using this criterion, to assemble a compendium of risk-informed regulations, embodying relevant requirements of Part 50, that have little or no backfit analysis because adoption of each component would be "voluntary." Would changes to the compendium of rules be exempted from backfit because they are "voluntary"? As indicated above, we should also add "selectivity" to the issues requiring early resolution.

Since I am convinced that the decision before us is more far-reaching than the specifics of SECY-00-0198, I am compelled to express my views on the overall, long-term regulatory issues. The reality is that the agency is on an uncharted course where the complexity due to duality of regulations could grow exponentially, thus making predictability and fairness of implementation very difficult to achieve. I strongly believe that predictability needs to anchor risk-informed rulemaking. There has to be fairness and equity for every risk-informed rule as for the sum total, always founded on assurance of adequate protection. And we need to maintain progress in the development, the acceptance and the implementation of risk-informed regulation. We should also be mindful that risk-informed regulation, because of its very nature, should not be hampered by minor and unnecessary prescriptive additions.

I do not advocate throwing the backfitting (section 50.109) book indiscriminately at risk-informed regulation, but neither can I support throwing the book away. I believe the development of risk-informed rules needs to be bound by three objectives, at least: 1) rules have to be consistent with the criteria of adequate protection; 2) rules have to be consistent with each other and other applicable rules; and 3) rules need to be scrutinized, in a meaningful and disciplined manner, to pass backfit criteria applicable to risk-informed rulemaking. I am sure my fellow Commissioners would agree with criterion 1 and 2 above. The challenge for us is how to establish the third criterion in a manner that adds fairness and equity without adding significant complexity, therefore, I respectfully propose we task the staff with the resolution of this issue.




Continue-

COMMISSIONER DIAZ' COMMENTS ON SECY-00-0198 (Continued)

In the meantime, regarding SECY-00-0198,

- I approve the staff recommendation to proceed with rulemaking for the risk-informed alternative to 10 CFR 50.44;
- I agree that selective implementation of parts of a specific risk-informed rule not be allowed;
- I agree with Chairman Meserve that "[t]he staff should evaluate, using the backfit process, potential changes to the current requirements of 10 CFR 50.44 that could result in a substantial safety enhancements to determine if they are cost-beneficial as well."

A handwritten signature in black ink, appearing to be 'WDJ', is located below the third bullet point of the list.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

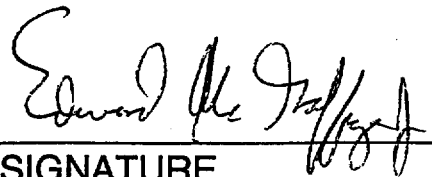
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Approved X ^{w/comment} Disapproved _____ Abstain _____

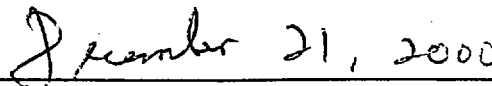
Not Participating _____

COMMENTS:

See attached comment.



SIGNATURE



DATE

Entered on "STARS" Yes X No _____

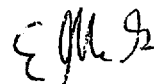
Commissioner McGaffigan's Comments on SECY-00-0198

I commend the staff for their efforts in advancing the state of risk-informed regulation. The staff should proceed with the rulemaking and regulatory analysis for the risk-informed alternative to 10 CFR 50.44.

With regards to the staff recommendation to prohibit selective implementation, I share their concerns, even though I am mindful that the Commission did not prohibit selective implementation of the voluntary Alternate Source Term (SECY-98-158). In that case, the Commission allowed licensees the opportunity to utilize "selective application of the revised source term unless such requests involve non-conservative or technically unjustified applications." Nonetheless, I join with the Chairman and Commissioners Merrifield and Diaz in approving the staff recommendation to prohibit selective implementation.

On backfit considerations, I agree with the staff that a voluntary alternative does not require a formal backfit analysis. It is permissible, as stated in the SECY, for risk-informed alternative rules to "include a combination of elimination, modification, and addition of requirements" without a backfit analysis. Indeed, this is central to the "two-edged sword" of risk-informed regulation.

With that said, however, I agree with Commissioner Diaz that some disciplined and scrutable process needs to be in place that justifies any new requirements. Just as any burden reduction must be demonstrated to be of little or no safety significance, any new requirement should be justifiable on some cost-benefit basis. If risk-informed alternative regulations are used as opportunities to create new requirements that could not be justified on some cost-benefit basis, then those same regulations will almost surely be considered sufficiently burdensome that they would never get used by licensees as-written. Such regulations would likely be targets for the very selective implementation requests that the staff wishes to preclude. Failing that, the regulations might later require still another round of risk-informed rulemaking revisions to be of any value to stakeholders.



NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-00-0198 - STATUS REPORT ON STUDY OF RISK-INFORMED CHANGES TO THE TECHNICAL REQUIREMENTS OF 10 CFR PART 50 (OPTION 3) AND RECOMMENDATIONS ON RISK-INFORMED CHANGES TO 10 CFR 50.44 (COMBUSTIBLE GAS CONTROL)**

Approved ☒ Disapproved ☐ Abstain ☐

Not Participating ☐

COMMENTS:

See attached comments.


SIGNATURE

11/20/00
DATE

Entered on "STARS" Yes ☒ No ☐

Comments of Commissioner Merrifield on SECY-00-0198

I approve of the staff's recommendations in SECY-00-0198. The staff should proceed with the rulemaking and regulatory analysis for the risk-informed alternative to 10 CFR 50.44 as expeditiously as possible.

In particular, I feel strongly that selective implementation within a specific rule is not consistent with the intent of risk-informed regulation. I agree with Chairman Meserve's comments on this matter. Specifically, selective implementation within a specific rule, "would raise the danger that licensees could select only those changes that reduce burden, while ignoring those that improve safety. If such an approach were seen to be acceptable, public confidence in the process would no doubt be reduced." Again, these are my views regarding selective implementation within a specific rule. My views on selective implementation in the broader context of risk-informing Part 50 (i.e., among different rules), are discussed in my vote on SECY-98-300.

With regard to backfitting, I concur with the staff position that, since implementation of a risk-informed alternative to a rule is a voluntary action on the part of a licensee, a backfit analysis is not required. However, the discipline required by the provisions of 10 CFR 50.109 should be utilized in the evaluation of any risk-informed changes that show potential for substantial safety enhancement.

Per my previous comments on SECY-99-264, I would like to continue to stress the importance of communication and involvement of stakeholders in the process to risk-inform our regulations. I again encourage the staff to continue to work with our stakeholders to gain their insights into how to most effectively prioritize and communicate our efforts.



11/20/00