



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

March 21, 2003

OFFICE OF THE  
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM:      SECY-02-0225

TITLE:                      PROPOSED CRITERIA FOR THE TREATMENT  
                                    OF INDIVIDUAL REQUIREMENTS IN A  
                                    REGULATORY ANALYSIS

The Commission (with Chairman Meserve and Commissioners Dicus, McGaffigan, and Merrifield agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of March 21, 2003. Commissioner Diaz approved in part and disapproved in part.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook", written over a horizontal line.

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-02-0225

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	2/3/03
COMR. DICUS	X				X	2/21/03
COMR. DIAZ	X	X			X	3/3/03
COMR. McGAFFIGAN	X				X	3/11/03
COMR. MERRIFIELD	X				X	2/13/03

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Dicus, McGaffigan, and Merrifield approved the subject paper. Commissioner Diaz approved in part and disapproved in part. Commissioner Diaz disapproved the staff's recommendation that the Commission approve the staff's issuance of the final criteria "if there are no significant changes due to public comments." In light of the broad application and general significance of the proposed criteria, Commissioner Diaz would have preferred that the staff should resubmit the criteria, and provide examples of significant comments, to the Commission for its review. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on March 21, 2003.

NOTATION VOTE

RESPONSE SHEET

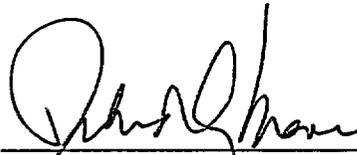
TO: Annette Vietti-Cook, Secretary  
FROM: CHAIRMAN MESERVE  
SUBJECT: **SECY-02-0225 - PROPOSED CRITERIA FOR THE  
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A  
REGULATORY ANALYSIS**

Approved  Disapproved  Abstain

Not Participating

COMMENTS:

Subject to the attached edits to the proposed Federal Register notice.



\_\_\_\_\_  
SIGNATURE

February 3, 2013

\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No

format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415-5905 (e-mail: [CAG@nrc.gov](mailto:CAG@nrc.gov)).

Certain documents related to <sup>the</sup> this proposed criteria, including comments received and the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 3, July 2000, may be examined, and/or copied for a fee, at the NRC's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. The documents listed below are also accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic Reading Room on the internet at the NRC Web site, <http://www.nrc.gov/reading-rm/adams.html> under the following ADAMS accession numbers:

Regulatory Guide 1.174: ML003740133

Regulatory Analysis Guidelines, NUREG/BR-0058, Rev. 3: ML003738939

Regulations Handbook, NUREG/BR-0053, Rev. 5: ML011010183

Commission paper, SECY-00-0198: ML003747699

SRM regarding SECY-00-0198: ML010190405

Commission paper, SECY-01-0134: ML011970363

SRM regarding SECY-01-0134: ML012760353

Commission paper, SECY-01-0162: ML012120024

SRM regarding SECY-01-0162: ML013650390

Commission paper, SECY-02-XXXX: ML022840460

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference Staff at 1-800-397-4209, 301-415-4737 or by email to [pdr@nrc.gov](mailto:pdr@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Tammy Croote, Office of Nuclear Reactor Regulation, Washington, DC 20555-0001, telephone (301) 415-2621, e-mail [txc1@nrc.gov](mailto:txc1@nrc.gov).

SUPPLEMENTARY INFORMATION:

Background

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is justified. However, bundling different requirements in a single analysis could potentially mask the inclusion of an inappropriate individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis, the net benefit from one requirement could potentially support another requirement that is not cost-justified.

The issue of bundling different requirements in a single rulemaking has been raised by the Commission and the NRC staff in a number of contexts. In 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)," dated September 14, 2000, the NRC staff discussed development of a voluntary risk-informed alternative rule. The NRC staff recommended not to allow selective implementation of parts of the voluntary alternative and not to apply the Backfit Rule. In a staff requirements memorandum (SRM) dated January 19, 2001, the Commission agreed that selective implementation of individual elements of a risk-informed alternative should not be permitted. The Commission also agreed that, since implementation of the risk-informed alternative version of 10 CFR 50.44 is voluntary, a backfit analysis of that version is not required. Furthermore, the Commission stated that

<sup>90r[A]</sup>  
a disciplined, meaningful, and scrutable process needs to be in place to justify any new requirements that are added as a result of the development of risk-informed alternative versions of regulations. Just as any burden reduction

10 CFR 50.44," dated August 23, 2001, the NRC staff proposed to identify any revisions that would be needed to existing guidance to put into place a disciplined, meaningful, and scrutable process for assessing any new requirements that could be added by a risk-informed alternative rule. Consistent with past practice and public expectations, the staff indicated that it planned to seek stakeholder input before reporting its recommendations to the Commission. In an SRM dated December 31, 2001, the Commission directed the staff to

. . . provide the Commission with recommendations for revising existing guidance in order to implement a disciplined, meaningful, and scrutable methodology for evaluating the value-impact of any new requirements that could be added by a risk-informed alternative rule.

#### Discussion

In order to obtain stakeholder input before reporting its recommendations to the Commission, the NRC staff published its preliminary proposed criteria on February 13, 2002, (67 FR 6663) and held a public meeting on March 21, 2002. A number of comments and suggestions were received at the meeting. (The complete Response to Comments document can be found as Attachment 3 to SECY-02-<sup>0225</sup>~~XXX~~, which is accessible from ADAMS and at the NRC's Public Document Room as discussed above.) The three most significant issues raised were:

- (1) There is concern about the provision that allows the analyst to rely on his or her judgment in determining which individual requirements should be analyzed separately.

In response to this concern, the NRC has expanded the ~~added more~~ guidance regarding the appropriate level of disaggregation in an analysis. Specifically, this guidance states that a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality, and that a more detailed disaggregation would only be

appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. While the NRC agrees that it often makes sense to divide a rule into discrete elements in performing regulatory analyses—and this is how the NRC generally performs these analyses—the NRC does not believe that there should be a general requirement for a separate analysis of each individual requirement of a rule. This could lead to unnecessary complexities <sup>Q</sup> and ~~there would not be a reasonable expectation of added value~~ <sup>AT</sup> because ~~there is not a history of including inappropriate individual requirements~~ <sup>T</sup>. While the decision on the appropriate level of disaggregation is subjective, this decision—as with any regulatory decision—must undergo the agency's extensive internal review process. This typically includes a review by agency staff and management, the Committee to Review Generic Requirements, appropriate advisory committees, the Executive Director for Operations, and the Commission. In addition, the public may comment on the appropriate level of disaggregation in any public comment opportunity provided in accordance with standard NRC procedures for the development of generic requirements.

- (2) There should be different guidance for different types of rules, rather than general guidance for any type of rule.

The NRC disagrees with this comment <sup>Q</sup> as <sup>T</sup> the current Regulatory Analysis Guidelines consistently present broad policy positions that are designed to be applicable to all regulatory initiatives that are subject to regulatory analysis requirements. Further, the NRC believes that having different guidance for different types of rules may unnecessarily complicate the regulatory analysis process. In addition, it is possible that some rules may fall into more than one category (such as a rule that is both risk-informed and a backfit), in which case it would be unclear which criteria to use when analyzing a rule.

- (3) For a risk-informed voluntary alternative to current regulations, an individual requirement should be integral to the purpose of the rule *and* cost-justified rather than integral to the purpose of the rule *or* cost-justified.

The NRC maintains that if an individual requirement is integral to the purpose of the rule, then that <sup>fact</sup> alone is a sufficient basis for its inclusion, and in fact, a decision on its inclusion or exclusion is not discretionary. However, the NRC finds that if a requirement is not deemed integral, it should be included if it is cost-justified. This alone is a sufficient basis because cost-benefit methodology directs one to select the alternative with the largest net benefit. This is clearly stated in OMB guidance and guidance contained elsewhere in NRC's Regulatory Analysis Guidelines. Clearly, if an individual requirement is cost-justified, its inclusion will result in a larger net benefit than an alternative that excludes the individual requirement. (Note, the proposed criteria no longer contain the phrase "integral to the purpose of the rule," but rather use the word "necessary" and provide examples of when a requirement may be deemed necessary.)

Internal NRC comments also raised the question of how to perform analyses of NRC's periodic review and endorsement of new versions of the American Society of Mechanical Engineers (ASME) codes.<sup>1</sup> Such endorsements typically involve numerous individual code provisions that are currently evaluated in the aggregate. The concern here is that these proposed criteria for the treatment of individual requirements in a regulatory analysis may be interpreted as requiring the justification of each code change individually. In response to these comments, the NRC has added specific language which states that while these regulatory

---

<sup>1</sup>The NRC's longstanding policy has been to incorporate new versions of the ASME codes into its regulations. ASME codes are updated on an annual basis to reflect improvements in technology and operating experience. The NRC reviews the updated ASME codes and conducts rulemakings to incorporate the latest versions by reference into 10 CFR 50.55a, subject to any modifications, limitations, or supplementations (i.e., exceptions) that are considered necessary.

actions must be addressed in a regulatory analysis, it is usually not necessary to analyze the individual code provisions endorsed in these regulatory actions, except if these provisions or the action endorsing them constitute backfits. In these regulatory analyses, the major features of the codes should be considered, then aggregated to produce estimates of the overall burdens and benefits in order to determine if the regulatory action is justified. If there are some aspects of these regulatory actions that are backfits, these must be addressed and justified individually (and separately from the analysis of the remainder of the action) as discussed in the Appendix to the proposed criteria.

The NRC has now developed proposed criteria regarding the treatment of individual requirements in a regulatory analysis and wishes to obtain input from interested members of the public. The NRC intends to review and analyze the comments, develop final criteria, and issue the final criteria provided there are no significant changes due to public comments. However, if there are significant changes to the criteria, the staff will submit the recommended revised final criteria for the approval of the Commission. These proposed criteria address only the treatment of individual requirements in a regulatory analysis, and if approved, the criteria will be added to the Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 3). These proposed revisions to the Guidelines are not intended to change the application of the Backfit Rule, 10 CFR 50.109. Analysts and decision makers must still apply the requirements of this rule in making analytical and regulatory decisions. In addressing the treatment of individual requirements in a regulatory analysis, these criteria are intended to provide guidance to staff and management in making decisions about which individual requirements may be bundled into a single regulatory analysis.

#### Proposed Criteria

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is justified. However, aggregating or

“bundling” different requirements in a single analysis could potentially mask the inclusion of an inappropriate individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis,<sup>2</sup> the net benefit from one requirement could potentially support another requirement that is not cost-justified.<sup>3</sup>

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine whether or not it is appropriate to include them. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives<sup>4</sup> that are the focus of the regulatory initiative.

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should follow the following guideline:

If the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to

---

<sup>2</sup>“The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” (NUREG/BR-0058) have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the Backfit Rule and the provisions of the CRGR Charter.

<sup>3</sup> This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not they are justified (though costs may be considered in determining how to achieve a certain level of protection).

<sup>4</sup>The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and benefits of the regulatory initiative with and without the individual requirement included, and a direct comparison of those results.<sup>5</sup>

In applying this guideline, the NRC will need to separate out the discrete requirements in order to evaluate their effect on the cost-benefit results. In theory, each regulatory initiative could include several discretionary individual requirements and each of those discretionary requirements could be comprised of many discrete steps, in which each could be viewed as a distinct individual requirement. This raises the potential for a large number of iterative cost-benefit comparisons, with attendant analytical complexities. Thus, considerable care needs to be given to the level of disaggregation <sup>that is required</sup> ~~that one attaches to a discretionary requirement~~. In general, a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality. For example, more detailed disaggregation is only appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results. Alternatively, individual elements that contribute little to the overall costs and benefits and are noncontroversial may not warrant much, if any, consideration. In general, it will not be necessary to provide additional documentation or analysis to explain how this determination is made, although such a finding can certainly be challenged at the public

---

<sup>5</sup>There may be circumstances in which the analyst considers including an individual requirement that is unrelated to the overall regulatory initiative. For example, an analyst may consider combining certain unrelated requirements as a way to eliminate duplicative rulemaking costs to the NRC and thereby increase regulatory efficiency. Under these circumstances, it would be appropriate to combine these discrete individual requirements if the overall effect is to make the regulatory initiative more cost-beneficial. In those instances in which the individual requirement is a backfit, the requirement must be addressed and justified as a backfit separately. These backfits are not to be included in the overall regulatory analysis of the remainder of the regulatory initiative.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER DICUS  
SUBJECT: **SECY-02-0225 - PROPOSED CRITERIA FOR THE  
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A  
REGULATORY ANALYSIS**

Approved xx Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

See attached

Aneta Joy Dicus  
SIGNATURE  
February 21, 2007  
DATE

Entered on "STARS" Yes x No \_\_\_\_\_

Commissioner Dicus' Comments on  
SECY-02-0225  
PROPOSED CRITERIA FOR THE TREATMENT OF INDIVIDUAL  
REQUIREMENTS IN A REGULATORY ANALYSIS

I approve the staff's request to publish the proposed criteria for the treatment of individual requirements in a regulatory analysis in the Federal Register subject to Chairman Meserve's edits.

I wish to commend the staff for their open and transparent efforts to develop these criteria. I also wish to thank the stakeholders who participated in our public meeting to discuss the proposed criteria. In reviewing SECY-02-0225, I note that the public comments received on the proposed criteria were of high quality and were thought provoking. I believe the staff has done a commendable job in addressing these comments and I support the staff's positions regarding these comments. However, I believe that to continue this open and transparent process, the staff should provide the final criteria to the Commission for review not only if there are significant changes to the criteria (as proposed by the staff) but also if there are significant adverse comments regarding the criteria.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER DIAZ  
SUBJECT: **SECY-02-0225 - PROPOSED CRITERIA FOR THE  
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A  
REGULATORY ANALYSIS**

Approved XX *[Signature]* in part Disapproved XX *[Signature]* in part Abstain \_\_\_\_\_  
Not Participating \_\_\_\_\_

COMMENTS:

See attached comment, and attached edit.

*[Signature]*  
\_\_\_\_\_  
SIGNATURE

*March 3, 03*  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes X No \_\_\_\_\_

COMMISSIONER DIAZ'S COMMENTS ON SECY-02-0225: PROPOSED CRITERIA  
FOR THE TREATMENT OF INDIVIDUAL REQUIREMENTS IN A REGULATORY ANALYSIS

I approve the staff's request to publish, for comment, proposed criteria for the treatment of individual requirements in a regulatory analysis. This is an important effort, which I advocated in my vote on SECY-00-0198 and have supported subsequently, for ensuring that rulemaking initiatives are scrutinized in a meaningful and disciplined manner. Such criteria can enhance the efficiency and transparency of regulatory initiatives, including risk-informed initiatives, and avoid the masking of individual requirements that are not cost-justified.

The criteria should also serve to strengthen the stability and predictability of our regulatory activities. In this regard, I note that the proposed revisions "are not intended to change the application of the Backfit Rule, 10 CFR 50.109." Draft Federal Register Notice at 8. Thus, for example, if some aspects of the NRC's endorsement of a voluntary standard are backfits, "these must be addressed and justified individually." *Id.*

I disapprove the staff's recommendation that the Commission approve the staff's issuance of the final criteria "if there are no significant changes due to public comments." In light of the broad application and general significance of the proposed criteria, I believe that the staff should resubmit the criteria, and provide examples of significant comments, to the Commission for its review.

actions must be addressed in a regulatory analysis, it is usually not necessary to analyze the individual code provisions endorsed in these regulatory actions, except if these provisions or the action endorsing them constitute backfits. In these regulatory analyses, the major features of the codes should be considered, then aggregated to produce estimates of the overall burdens and benefits in order to determine if the regulatory action is justified. If there are some aspects of these regulatory actions that are backfits, these must be addressed and justified individually (and separately from the analysis of the remainder of the action) as discussed in the Appendix to the proposed criteria.

The NRC has now developed proposed criteria regarding the treatment of individual requirements in a regulatory analysis and wishes to obtain input from interested members of the public. The NRC intends to review and analyze the comments, develop final criteria, and issue the final criteria provided there are no significant changes due to public comments. However, if there are significant changes to the criteria, the staff will submit the recommended revised final criteria for the approval of the Commission. These proposed criteria address only the treatment of individual requirements in a regulatory analysis, and if approved, the criteria will be added to the Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 3). These proposed revisions to the Guidelines are not intended to change the application of the Backfit Rule, 10 CFR 50.109. Analysts and decision makers must still apply the requirements of this rule in making analytical and regulatory decisions. In addressing the treatment of individual requirements in a regulatory analysis, these criteria are intended to provide guidance to staff and management in making decisions about which individual requirements may be bundled into a single regulatory analysis.

#### Proposed Criteria

In evaluating a proposed regulatory initiative, the NRC usually performs a regulatory analysis for the entire rule to determine whether or not it is justified. However, aggregating or

NOTATION VOTE

RESPONSE SHEET

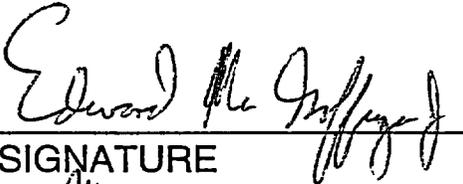
TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER MCGAFFIGAN  
SUBJECT: **SECY-02-0225 - PROPOSED CRITERIA FOR THE  
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A  
REGULATORY ANALYSIS**

Approved  <sup>w/comments</sup> Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

See attached comments.



SIGNATURE

March 11, 2003

DATE

Entered on "STARS" Yes  No \_\_\_\_\_

**Commissioner McGaffigan's Comments on SECY-02-0225**

I approve the publication in the *Federal Register* for public comment of the staff's recommended criteria for the treatment of individual requirements in a regulatory analysis, subject to the edits by Chairman Meserve.

I join with Commissioner Merrifield in applauding the staff's work in producing criteria that appear to implement the Commission's guidance to develop a disciplined, scrutable methodology. However, consistent with my vote on SECY-00-0159, I do not support the additional edit proposed by Commissioner Merrifield.

I agree with Commissioner Diaz that the staff should submit the proposed final criteria to the Commission, including the disposition of the public comments received.

A handwritten signature in black ink, appearing to be "E. Diaz", located to the right of the third paragraph.

NOTATION VOTE

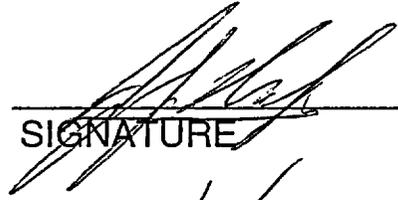
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER MERRIFIELD  
SUBJECT: **SECY-02-0225 - PROPOSED CRITERIA FOR THE  
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A  
REGULATORY ANALYSIS**

Approved  Disapproved  Abstain   
Not Participating

COMMENTS:

*See attached comments.*

  
\_\_\_\_\_  
SIGNATURE  
*2/13/03*  
\_\_\_\_\_  
DATE

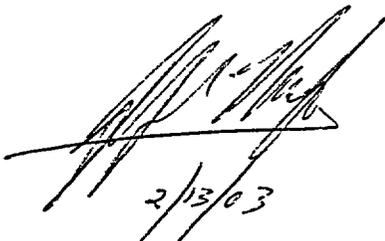
Entered on "STARS" Yes  No

Commissioner Merrifield's Comments on SECY-02-0225

I approve that staff's request to publish in the Federal Register the proposed criteria for the treatment of individual requirements in a regulatory analysis, allowing 75 days for public comment, subject to Chairman Meserve's edits and one additional modification. In addition, I approve the staff's request to issue the final criteria if there are no significant changes due to the public comments.

I am pleased to see that the staff has finally developed a set of criteria which appears to satisfy the Commission's desire to have a disciplined, meaningful and understandable methodology for evaluating the value-impact of any new requirements. I believe that the staff's recommendation, as outlined in the proposed criteria for a regulatory analysis with one modification, better aligns with the Commission's instructions on backfit analyses as outlined in the SRM dated October 3, 2001.

I continue to be concerned with the staff's approach for evaluating the cost-benefit of new "necessary" requirements that are aggregated. As I have previously stated in my vote on SECY-00-0159, "It is important that the merits of each component, irrespective of whether it is ultimately aggregated for purposes of the backfit analysis, are carefully explained and its cost is separately itemized." Otherwise when the overall cost associated with the aggregated requirements is challenged, the Agency has no basis to defend itself, as was the case during the course of the Part 26 rule changes. Therefore, the staff should incorporate the attached edit to the proposed criteria so it is clear that the cost of each component of the proposed rule is separately itemized in the regulatory analysis and equates to the aggregated cost estimates.



Handwritten signature and date: 2/13/03

"bundling" different requirements in a single analysis could potentially mask the inclusion of an inappropriate individual requirement. In the case of a rule that provides a voluntary alternative to current requirements, the net benefit from the relaxation of one requirement could potentially support a second requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis,<sup>2</sup> the net benefit from one requirement could potentially support another requirement that is not cost-justified.<sup>3</sup>

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine whether or not it is appropriate to include them. Clearly, in certain instances, the inclusion of an individual requirement is necessary. This would be the case, for example, when the individual requirement is needed for the regulatory initiative to resolve the problems and concerns and meet the stated objectives<sup>4</sup> that are the focus of the regulatory initiative.

However, there will also be instances in which the individual requirement is not a necessary component of the regulatory initiative, and thus the NRC will have some discretion regarding its inclusion. In these circumstances, the NRC should follow the following guideline:

If the individual requirement is related (i.e., supportive but not necessary) to the stated objective of the regulatory initiative, it should be included only if its overall effect is to

---

<sup>2</sup>"The Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," (NUREG/BR-0058) have been developed so that a regulatory analysis that conforms to these Guidelines will meet the requirements of the Backfit Rule and the provisions of the CRGR Charter.

<sup>3</sup> This discussion does not apply to backfits that the Commission determines qualify under one of the exceptions in 10 CFR 50.109(a)(4). Those types of backfits require a documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not they are justified (though costs may be considered in determining how to achieve a certain level of protection).

<sup>4</sup>The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

*Even though the inclusion of individual requirements is necessary in this case, the analyst must obtain separate cost estimates for each requirement in deriving the total cost estimate presented for the aggregated requirements.*