



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

April 21, 2004

SECRETARY

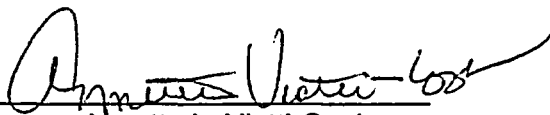
COMMISSION VOTING RECORD

DECISION ITEM: SECY-04-0045

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

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 21, 2004.

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 Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-04-0045

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|------------------|-------|----------|---------|-----------------|----------|---------|
| CHRM. DIAZ | X | | | | X | 4/6/04 |
| COMR. McGAFFIGAN | X | | | | X | 4/14/04 |
| COMR. MERRIFIELD | X | | | | X | 4/12/04 |

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on April 21, 2004.

NOTATION VOTE

RESPONSE SHEET

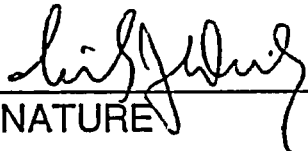
TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN DIAZ
SUBJECT: SECY-04-0045 - FINAL CRITERIA FOR THE
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A
REGULATORY ANALYSIS

Approved Disapproved _____ Abstain _____

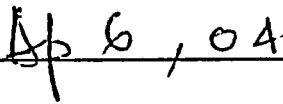
Not Participating _____

COMMENTS:

Recognizing that the guidance being provided with respect to Individual Requirements in Regulatory Analyses does not replace the staff's obligation to fully comply with the backfit provisions of 10 CFR §50.109, I believe the final guidance strikes a workable balance between the staff's need for flexibility and the need to ensure discipline in the preparation of Regulatory Analyses that accompany agency rulemakings. Subject to several edits (attached), I approve publication of the Final Criteria for the Treatment of Individual Requirements in Regulatory Analyses.



SIGNATURE



DATE

Entered on "STARS" Yes: No _____

criteria for the treatment of any individual requirement must be consistent with the standards of the backfitting rule. Under the backfit rule, any new requirement that is a backfit must be shown to be cost-justified and produce a "substantial increase" in overall safety. Lastly, their final two points in this section are in agreement with the NRC criteria. First, the commenter agrees with the NRC that in "cases where a new backfit requirement is being considered for inclusion in a voluntary alternative, to current regulations . . . NRC should consider imposing such a new requirement, if justified under the standards of Section 50.109, through the normal disciplined backfitting process, . . . rather than merely including it in a voluntary-alternative rule." Second, NRSRG "agree(s) with the NRC position that if an individual backfit requirement is *not* related to the objective of the regulatory initiative . . . , the 'requirement must be addressed and justified as a backfit separately.'"

Response: For the most part, the NRC agrees with these comments. With respect to the NRC's meaning of "cost-beneficial" in the situation discussed by the commenter, the NRC means that the regulatory initiative results in a larger net benefit than would accrue to an action without that requirement. (An individual requirement is related to the stated regulatory objective of the regulatory initiative and, overall, is cost justified and constitutes a substantial increase in safety.) *This sentence is incomplete and should be revised.*

Comment: NRSRG stated that there should be further guidance on backfitting issues related to the American Society of Mechanical Engineers (ASME) Code. Specifically, they state:

NRC's guidance should allow the NRC discretion to perform a cost-benefit analysis of individual new requirements contained in later editions of Section XI before they are incorporated wholesale into Section 50.55a. If the NRC finds that individual new requirements of later Code editions are not cost-beneficial for some or all plants, the

NRC should consider imposing the individual requirement as a backfit affecting all plants to which it applies, rather than merely including it in a voluntary-alternative rule affecting only those plants where the voluntary alternative is adopted.

A special case involves the NRC's periodic review and endorsement of ~~voluntary~~ consensus standards, such as new versions of the American Society of Mechanical Engineers (ASME) codes. These NRC endorsements can typically involve hundreds, if not thousands, of individual provisions. Thus, evaluating the benefits and costs of each individual provision in a regulatory analysis can be a monumental task. Further, the value gained by performing such an exercise appears limited. These ~~voluntary~~ consensus standards tend to be noncontroversial and have already undergone extensive external review and been endorsed by industry. Although regulatory actions endorsing these ~~voluntary~~ consensus standards must be addressed in a regulatory analysis, it is usually not necessary for the regulatory analysis to address the individual provisions of the ~~voluntary~~ consensus standards.

The NRC believes this is appropriate for several reasons:

(1) It has been longstanding NRC policy to incorporate later versions of the ASME Code into its regulations; and thus, licensees know when receiving their operating licenses that updating the ASME Code is part of the regulatory process;

(2) Endorsement of the ASME Code is consistent with the National Technology Transfer and Advancement Act, inasmuch as the NRC has determined that there are sound regulatory reasons for establishing regulatory requirements for design, maintenance, inservice inspection and inservice testing by rulemaking; and

(3) These ~~voluntary~~ consensus standards undergo significant external review and discussion before being endorsed by the NRC.

Some aspects of these regulatory actions endorsing ~~voluntary~~ consensus standards are backfits which must be addressed and justified individually. For example, NRC endorsement

Section C. Other circumstances where the NRC does not apply the backfit rule to the endorsement of a later code

Other circumstances where the NRC does not apply the backfit rule to the endorsement of a later code are as follows--

(1) When the NRC takes exception to a later ASME BPV or OM code provision, ~~but~~ *and* merely retains the current existing requirement, prohibits the use of the later code provision, or limits the use of the later code provision, the Backfit Rule does not apply because the NRC is not imposing new requirements. However, the NRC provides the technical and/or policy bases for taking exceptions to the code in the Statement of Considerations for the rule.

(2) When an NRC exception relaxes an existing ASME BPV or OM code provision but does not prohibit a licensee from using the existing code provision.

Section D. Endorsement of later ASME BPV or OM codes that are considered backfits

There are some circumstances when the NRC considers it appropriate to treat as a backfit the endorsement of a later ASME BPV or OM code--

(1) *When the NRC endorses a later provision of the ASME BPV or OM code that takes a substantially different direction from the currently existing requirements, the action is treated as a backfit.* An example was the NRC's initial endorsement of Subsections IWE and IWL of Section XI, which imposed containment inspection requirements on operating reactors for the first time. The final rule dated August 8, 1996 (61 FR 41303), incorporated by reference in § 50.55a the 1992 Edition with the 1992 Addenda of IWE and IWL of Section XI to require that containments be routinely inspected to detect defects that could compromise a containment's structural integrity. This action expanded the scope of § 50.55a to include components that were not considered by the existing regulations to be within the scope of ISI. Because those

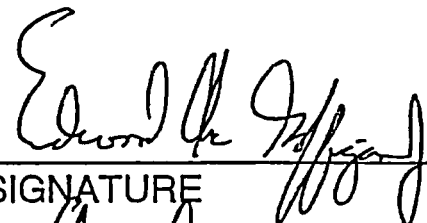
NOTATION VOTE

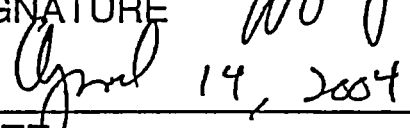
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: SECY-04-0045 - FINAL CRITERIA FOR THE
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A
REGULATORY ANALYSIS

w/comments and edits
Approved Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:
See attached comments and edits.



SIGNATURE


DATE

Entered on "STARS" Yes No _____

Commissioner McGaffigan's Comments on SECY-04-0045

I approve the publication of the final criteria for treatment of individual requirements in a regulatory analysis in the *Federal Register* and to incorporate and publish those criteria in Revision 4 of NUREG/BR-0058.

The Commission challenged the staff to develop a disciplined, scrutable methodology, to publish that methodology for public comment, and to revise or refine the methodology as part of addressing stakeholder comments. SECY-04-0045 provides to the Commission the final product of this process. I join with Chairman Diaz in believing that this final guidance strikes a "workable balance" between the needs both for flexibility and discipline when conducting regulatory analyses for rulemakings. I also support the Chairman's clarifying edits and append a few additional editorial corrections.

I note Commissioner Merrifield's desire to re-insert in the criteria a sentence regarding individual cost analyses. This sentence previously received support by a majority of the Commission. Commissioner Merrifield is correct that the sentence was included in the proposed criteria published in the *Federal Register*, and I recognize that there was no public comment received to support deletion of this sentence. However, I did not support the inclusion of this sentence originally and I continue to believe that the suggestion of a need for separate cost analyses for each sub-requirement of a rule will overburden our rulemaking process for complex rules.

A handwritten signature in black ink, appearing to be 'E. J. ...', located at the bottom right of the page.

Response: The NRC does not agree with the commenter that disaggregation of all requirements is by default either practicable or desirable. The underlying purpose of a regulatory analysis is to provide decision makers with a tool for choosing between options or alternatives. When a regulatory initiative has a number of discreet, yet *necessary* requirements, the decision maker's choice is not whether to include or exclude *necessary* individual requirements but, rather, whether or not to enact the initiative as a whole. Determining the costs of each necessary requirement provides no additional value to the regulatory analysis because those costs are not discretionary with respect to the proposed action under review. Thus, ^{the separate} analyses of necessary individual requirements present information which is irrelevant to the decision making.

Further, as stated in the proposed criteria, published for public comment in the *Federal Register* on April 18, 2003 (68 FR 19162): "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 substantially different alternatives with potentially meaningful results." This implies that the analyst must be able to demonstrate that any aggregation in the analysis would not result in different conclusions of the analysis. Therefore, the NRC still does not believe that disaggregation in all cases should be the preferred approach and stands by the position stated in the proposed criteria. As stated in the guidance, "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." Also, NRC believes that its guidance is consistent with OMB Circular A-4, cited above.

Comment: NRSR states that if, according to the criteria, an individual requirement must be both "related" to the stated objective of the regulatory initiative and be "cost-beneficial," then the NRC should clarify what it means by "cost-beneficial." The commenter also states that the

criteria for the treatment of any individual requirement must be consistent with the standards of the backfitting rule. Under the backfit rule, any new requirement that is a backfit must be shown to be cost-justified and produce a "substantial increase" in overall safety. Lastly, their final two points in this section are in agreement with the NRC criteria. First, the commenter agrees with the NRC that in "cases where a new backfit requirement is being considered for inclusion in a voluntary alternative, to current regulations . . . NRC should consider imposing such a new requirement, if justified under the standards of Section 50.109, through the normal disciplined backfitting process, . . . rather than merely including it in a voluntary-alternative rule." Second, NRSB "agree(s) with the NRC position that if an individual backfit requirement is *not* related to the objective of the regulatory initiative . . . , the requirement must be addressed and justified as a backfit separately."

Response: For the most part, the NRC agrees with these comments. With respect to the NRC's meaning of "cost-beneficial" in the situation discussed by the commenter, the NRC means that the regulatory initiative results in a larger net benefit than would accrue to an action without that requirement. An individual requirement is related to the stated regulatory objective of the regulatory initiative and, overall, is cost justified and constitutes a substantial increase in safety.

Comment: NRSB stated that there should be further guidance on backfitting issues related to the American Society of Mechanical Engineers (ASME) Code. Specifically, they state:

NRC's guidance should allow the NRC discretion to perform a cost-benefit analysis of individual new requirements contained in later editions of Section XI before they are incorporated wholesale into Section 50.55a. If the NRC finds that individual new requirements of later Code editions are not cost-beneficial for some or all plants, the

NRC should screen out those new individual requirements in accordance with the standards of the backfitting rule.

Response: The Commission's policy regarding Inservice Inspection (ISI) requirements is to assure the integrity of the reactor coolant system (RCS) boundary and containment as they relate to defense-in-depth considerations, that do not lend themselves to cost/benefit analyses. Further, in this specific instance, cost/benefit analyses are not well suited to determine if new requirements that address aging ^{of} components are appropriate because of the many uncertainties associated with the effects of aging.

When the Commission formulated its policy, the then Chairman stated that: "Both the ASME and the AGRS have strongly urged that the Commission maintain the current updating requirement" and that -

ASME asserts that the failure of the NRC to incorporate later editions of the Code in the requirements, absent justification under a backfit analysis, would serve to undermine ASME because of the disincentive of volunteers to engage themselves in an ASME process that will not necessarily affect operating plants? Moreover, because some states routinely establish requirements based on current ASME codes, the acceptance of the staff's approach would create the anomaly that non-nuclear facilities might be required to conform to more modern codes than nuclear facilities.

The Chairman also indicated he was aware "that industry participates in the development of the ASME codes and that costs are considered in the amendment process. Thus, although the revisions may not be analyzed with the rigor required by our backfit analysis, the costs and benefits are implicitly weighed."

Another Commissioner commented:

10 CFR 50.109 has served the NRC, our licensees, and our stakeholders well, and thus, my decision to not subject ASME Code updates to its backfit provisions was made only after I carefully considered how the staff's recommended option should exacerbate the complexity, inconsistency, and program divergence associated with our current update process. My decision also came after considering the diverse makeup of the ASME members that produce Code changes and the consensus process they use. I believe that considerations of increased safety versus cost are implicit in the ASME consensus process.

In sum, NRSB's suggested approach is inconsistent with the Commission's previous guidance to the staff.

III. Final 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 cost-justified. However, aggregating or "bundling" different requirements in a single analysis could potentially mask the inclusion of an unnecessary 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 unnecessary requirement that is not cost-justified. Similarly, in the case of other types of rules, including those subject to backfit analysis,¹ the net benefit from one requirement could potentially support another requirement that is not cost-justified.²

¹"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.

² 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

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine if it is appropriate to include each individual requirement. 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 objectives³ 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~~^{adhere to} 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 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.

documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

³The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

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 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.

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 discrete step 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 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 comment stage.⁵ For further guidance, the analyst is referred to principles regarding the appropriate level of detail to be included in a regulatory analysis, as discussed in Chapter 4 of the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission."

In some cases, an individual requirement that is being considered for inclusion in a voluntary alternative to current regulations may be justifiable under the backfit criteria. In these cases the individual requirement is both cost-justified and provides a substantial increase in the overall protection of the public health and safety or the common defense and security. If so, the requirement is justifiable under the backfit criteria.

⁵See NUREG/BR-0053, Revision 5, March 2001, "U.S. Nuclear Regulatory Commission Regulations Handbook," Section 7.9, for discussion of how to treat comments.

included in the regulatory analysis. (An example would be a regulatory action whose sole impact would be to require licensees to carry additional insurance.) Information on identifying transfer payments is included in the Handbook. In addition, depreciation is an accounting concept that should not be included as an impact.

In analyzing impacts, the staff also has to be sensitive to the true impact (cost) to licensees. For example, the practice of allocating no replacement energy costs by claiming that the requirement can be accomplished during a regularly scheduled outage is not always practical or reasonable. In reality, the cumulative effect of all new requirements can add incremental downtime, and therefore, analysts should attribute appropriate replacement energy cost penalties to their respective regulatory actions, if appropriate. Further, for new requirements that have extremely high implementation costs or that will greatly increase operating costs, the analyst needs to consider the possibility that the imposition of these impacts may result in some facilities no longer being economical to operate and, thus, having to terminate operations. The Handbook should be consulted for additional information related to potential premature facility closures.

4.3.4 Evaluation of Values and Impacts

The evaluation of quantified estimates of the values and impacts associated with a proposed regulatory action involving NRC licensees generally involves expressing values and impacts on a common basis, for example, constant dollars from a reference year. Because the values and impacts need to be estimated for the entire period that members of society will be affected by the proposed regulatory action, a present-worth basis is normally used to allow meaningful

summations and comparisons. Although this approach provides a rational basis for evaluating values and impacts, it has a number of complexities and controversies. In order to place all values and impacts on a common basis, a conversion factor is needed that reflects the monetary worth of a unit of radiation exposure. The currently recommended value for this dollar conversion factor is \$2000 per person-rem.²¹ This dollar value only captures the health effects attributable to radiological exposure. In select regulatory applications, such as certain severe power reactor accident scenarios, a radiological release could also result in offsite property consequences whose monetary consequences would need to be addressed separately and treated as an additive factor in the overall value-impact assessment.

The basis for the NRC's new conversion factor policy is provided in "Reassessment of NRC's Dollar Per Person-Rem Conversion Factor Policy," NUREG-1530. Guidance on how the dollar per person-rem conversion factor is to be applied as well as guidance on valuing offsite property consequences is included in the Handbook.

To provide meaningful summations, consistent with OMB guidance, all values and impacts, including public health and safety, are to be expressed on a present-worth basis. The principle for regulatory analysis is that future health effects should be valued the same as current effects and present-worth techniques achieve this. For

²¹The \$2000 per person-rem conversion factor will be subject to periodic review by the NRC based on changes to the underlying assumptions. The dollar per person-rem conversion factor will only be adjusted if changes in the underlying parameters cause the base conversion factor (when rounded to the nearest thousand dollars) to shift up or down by a thousand dollars or more. Any future change in the dollar per person-rem conversion factor will be noted in subsequent revisions to the Handbook.

example, based on a given conversion factor, health and safety consequences are consistently valued at a fixed dollar value per person-cSv (person-rem). Thus, the monetary worth of a person-cSv (person-rem) averted is assigned a fixed value (in constant dollars) regardless of when the consequences occur in time. The present-worth calculation is simply determining how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future to avert a person-cSv (person-rem). By using present-worth, the health and safety effects, that is, person-cSv (person-rem), regardless of when averted in time, are valued equally.

Based on OMB guidance, present-worth calculations should be presented using both 3-percent and 7-percent real discount rates (Ref. 14). The 3-percent rate approximates the real rate of return on long-term U.S. Government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the recommended discount rate specified in the latest version of OMB Circular A-94. This circular was most recently updated in October 1992 (Ref. 13) and specifies the use of a 7-percent real discount rate. OMB's 7-percent rate approximates the marginal pre-tax real rate of return on an average investment in the private sector in recent years and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. Because the distribution of regulatory impacts on capital and consumption are not always well known, two sets of base case estimates should be developed and presented, one at 3 percent and one at 7 percent. The use of alternative discount rates as a further sensitivity

analysis, is appropriate as long as sufficient justification is provided for use of that rate. An alternative analysis, using a 3-percent real discount rate, should also be prepared for sensitivity analysis purposes. The base case, using for example OMB's currently recommended 7-percent rate, reflects recent economic conditions, yet NRC actions typically involve a 30- to 60-year time horizon. Given that uncertainties expand as one attempts to project further into the future, it is considered prudent to examine the result of assuming a lower rate as part of a sensitivity analysis. There are also theoretical arguments in the economics literature that support the use of lower rates (Ref. 14). A 3-percent rate is proposed for the alternative case because it approximates the long-term risk-free real rate of return on investment based on historical data. If the alternative rate does not alter the bottom-line result, simply indicating this conclusion is sufficient. If there is a different conclusion or if the net value determination is significantly altered, this result should be discussed and placed in perspective for the decision maker. For certain regulatory actions, such as those involving decommissioning and waste disposal issues, the regulatory analysis may have to consider consequences that can occur over hundreds or even thousands of years. OMB recognizes that special considerations arise when comparing benefits and costs across generations. Under these circumstances, OMB continues to see value in applying discount rates of 3 and 7 percent. However, ethical and technical arguments can also support the use of lower discount rates. Thus, if a rule will have important intergenerational consequences, one should consider supplementing the analysis with an explicit discussion of the intergenerational concerns, such as how future generations

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-04-0045 - FINAL CRITERIA FOR THE
TREATMENT OF INDIVIDUAL REQUIREMENTS IN A
REGULATORY ANALYSIS**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments edit.



SIGNATURE

4/12/04

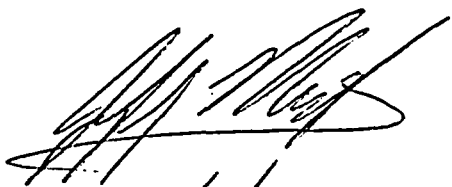
DATE

Entered on "STARS" Yes No

Commissioner Merrifield's Comments on SECY-04-0045

I approve that staff's recommendation to publish the final criteria for treatment of individual requirements in a regulatory analysis in the Federal Register and to incorporate and publish these criteria in Revision 4 of NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," subject to the following.

This paper is deficient in that it did not totally address the Commission's direction in the Staff Requirements Memorandum (SRM) for SECY-02-0225. Specifically, the Commission directed the staff to incorporate language associated with obtaining separate cost estimates for each requirement when deriving the total cost estimate for aggregated requirements. There was much deliberation on this issue and the Commission approved language provided by the staff. However, this language was not included in the current paper. The staff should incorporate the attached language from the previous SRM into the final criteria and Revision 4 to NUREG/BR-0058, 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.



4/12/04

"Even though inclusion of individual requirements is necessary in this case, the analyst should obtain separate cost estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements"

Insert

Therefore, when analyzing and making decisions about regulatory initiatives that are composed of individual requirements, the NRC must determine if it is appropriate to include each individual requirement. 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 objectives³ 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 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.⁴

documented evaluation rather than a backfit analysis, and cost is not a consideration in deciding whether or not the exceptions are justified (though costs may be considered in determining how to achieve a certain level of protection).

³The stated objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule.

⁴There 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 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.