

## POLICY ISSUE (Notation Vote)

December 27, 2002

SECY-02-0225

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations /RA/

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

PURPOSE:

The purpose of this paper is to obtain Commission approval to publish proposed criteria for the treatment of individual requirements in a regulatory analysis for public comment.

SUMMARY:

The Commission has raised concerns about “bundling” or aggregating individual components of a larger regulatory initiative in a single regulatory analysis. Such a practice may show that an overall regulatory initiative is justified, but likely will not illuminate whether there are separable components of the regulatory initiative that are not justified and hence should not be included in the rulemaking. In response to these concerns and direction from the Commission, the staff is proposing to revise its guidance on how to perform regulatory analyses. In general, the staff is proposing that the separate analysis of an individual component of a regulatory initiative is not needed if that individual component is necessary (e.g., it is needed to achieve the objectives of the rule). However, individual rule components that are related but not necessary must be cost-justified. This guidance addresses the treatment of individual requirements in a regulatory analysis, and is 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.

CONTACTS: Tammy Croote, NRR  
415-2621

Brian J. Richter, NRR  
415-1978

Clark Prichard, NMSS  
415-6203

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,<sup>1</sup> 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 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 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

. . . 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 must be demonstrated to be of little or no safety significance, any new requirement should be justifiable on some cost-benefit basis. The Commission challenges the staff to establish such a criterion in a manner that adds fairness and equity without adding significant complexity. The staff should develop a proposed resolution for this issue and provide it to the Commission for approval.

This issue once again surfaced in the fitness-for-duty rule. In SECY-01-0134, "Final Rule Amending the Fitness-for-duty Rule," dated July 23, 2001, the staff recommended withdrawing the OMB clearance request for a final rule and developing a new notice of proposed rulemaking. In an SRM dated October 3, 2001, the Commission approved that recommendation. Furthermore, the Commission provided the following specific instructions on the backfit analysis:

In the new fitness-for-duty rulemaking, the Commission will conduct an aggregate backfit analysis of the entire rulemaking. If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety

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<sup>1</sup>The "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058, Rev. 3, 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 Charter of the Committee to Review Generic Requirements.

benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4).

In SECY-01-0162, "Staff Plans for Proceeding With the Risk-informed Alternative to the Standards for Combustible Gas Control Systems in Light-Water-Cooled Power Reactors in 10 CFR 50.44 (WITS 20010003)," dated August 23, 2001, the 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 staff held a public meeting on March 21, 2002, to discuss its preliminary proposed criteria. (These criteria, as published on February 13, 2002, are presented in Attachment 2.) A number of comments and suggestions were received at the meeting. The comments and the staff's responses are described in Attachment 3.

The three most notable comments were as follows:

- (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, the staff has 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 staff 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 staff 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 and there would not be a reasonable expectation of added value because there is not a history of including inappropriate individual requirements. 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 staff disagrees with this comment as 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 staff 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 staff maintains that if an individual requirement is integral to the purpose of the rule, then that alone is a sufficient basis for its inclusion, and in fact, a decision on its inclusion or exclusion is not discretionary. However, the staff 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>2</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 staff has added specific language which states that while these regulatory actions must be addressed in a regulatory analysis, it is usually not necessary to analyze the individual code provisions

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<sup>2</sup>The NRC's longstanding policy has been to incorporate by reference 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 rulemaking to incorporate by reference the latest versions by reference into § 10 CFR 50.55a, subject to any modifications, limitations, or supplementations (i.e., exceptions) that are deemed necessary.

endorsed in these regulatory actions, except if these provisions or action endorsing them constitute backfits. Guidance on when such provisions are to be treated as backfits is provided in the Appendix to Attachment 1. This Appendix will also be published in the *Federal Register* notice for public comment. The staff believes it is appropriate to treat these regulatory actions somewhat differently since (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 such updating 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) the ASME codes undergo significant external review and discussion before being endorsed by the NRC. In these regulatory analyses, the major features of the code 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).

The recommended proposed criteria are provided in the *Federal Register* notice seeking public comment (Attachment 1) and may be summarized as follows:

- (1) If an individual requirement is necessary (e.g., it is needed in order for the regulatory initiative to resolve the problems and concerns and meet the stated objectives that are the focus of the regulatory initiative), the individual requirement should be included and need not be analyzed separately. Of course, the overall regulatory initiative is still subject to the cost-benefit test in accordance with the guidelines.
- (2) 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.<sup>3</sup>

In applying the guideline in (2) above, the NRC will need to separate out the discrete requirements in order to evaluate their effect on the cost-benefit results. Considerable care needs to be given to the level of disaggregation that one attaches to a discretionary requirement. 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. For further guidance, the analyst

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<sup>3</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.

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.” The staff examined these proposed criteria in order to make a determination about whether the criteria would affect some of the regulations and their analyses that are currently being developed. In particular, the staff examined the criteria with respect to the following three rules: (1) 10 CFR 26 (Fitness-for-duty), (2) 10 CFR 50.69 (Special Treatment Requirements), (3) 10 CFR 50.44 (Combustible Gas Control in Containment). With regard to the Part 26 rule, the staff believes this guidance is consistent with the direction given by the Commission to include an individual rule requirement only if it “...is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4).” The Part 26 rule and its analysis, both currently underway, are being developed consistent with this direction. Regarding the 50.69 rulemaking, the staff believes the rule and its analysis have been developed consistent with these proposed criteria because the rule has been constructed with the minimum requirements necessary to achieve its objective. With respect to the 50.44 rulemaking, the staff also examined the rule and analysis and concluded that the proposed criteria are consistent with the analytical approach employed.

In addition, the staff examined the analysis of a recently issued final rule endorsing various ASME codes, and found that the regulatory and backfit analyses performed were generally consistent with the guidance regarding ASME codes that the staff is proposing.

The staff believes these criteria would provide for 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. They would also provide guidance on including individual requirements in other types of rules, including those subject to backfit analysis. While the staff does not believe that these proposed criteria would fundamentally change the way regulatory analyses are performed—since regulatory analyses are usually developed by estimating the costs and benefits of individual rule components—the staff does believe these changes provide further clarity in how to treat individual components of a regulatory initiative. The staff also believes that these proposed criteria are consistent with the direction and recent decisions from the Commission regarding those rules in which this issue originally surfaced.

The staff recommends publishing these proposed criteria for public comment. If the Commission approves this recommendation, the staff will publish the proposed criteria, consider the public comments, and issue the final criteria provided that there are no significant changes due to public comments. However, if there are significant changes to the criteria, the staff will submit the final recommended criteria for the approval of the Commission. These proposed criteria address only the treatment of individual requirements in a regulatory analysis, and if the Commission approves these final recommended criteria, the staff will add these criteria to the guidance currently provided in NUREG/BR-0058, Revision 3, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission.”<sup>4</sup> These proposed revisions to

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<sup>4</sup>Additional guidelines may be found in other sources such as: §§ 10 CFR 50.109, 70.76, 72.62, and 76.76 which control generic or plant-specific backfitting at nuclear power plants, special nuclear materials facilities, independent spent fuel storage facilities, and gaseous diffusion plants, respectively; the Charter of the CRGR, which controls some generic actions; and Management Directive 8.4, which controls plant-specific backfitting at nuclear power plants.

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.

COORDINATION:

The Office of General Counsel has reviewed this paper and has no legal objections.

The Committee to Review Generic Requirements has reviewed this paper and concurs with the proposed criteria.

The Advisory Committee on Reactor Safeguards has decided to defer its review until a revision to NUREG/BR-0058 has been drafted.

RECOMMENDATIONS:

1. That the Commission approve the recommended criteria for publication in the *Federal Register* for public comment (Attachment 1).
2. That the Commission approve the staff to issue the final criteria if there are no significant changes due to the public comments.

***/RA by William F. Kane Acting For/***

William D. Travers  
Executive Director  
for Operations

Attachments:

1. *Federal Register* Notice
2. Preliminary proposed criteria discussed at public meeting
3. Comments received at public meeting

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WITS Number: 200100143

\*See previous concurrence

ADAMS Accession Number: ML023440333

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**ATTACHMENT 1**

**Federal Register Notice with Recommended Criteria**

NUCLEAR REGULATORY COMMISSION

10 CFR Chapter I

Regulatory Analysis Guidelines:

Proposed Criteria for the Treatment of Individual  
Requirements in a Regulatory Analysis

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for Comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) is making available for public comment proposed criteria for the treatment of individual requirements in a regulatory analysis. The concern is that aggregating or “bundling” different requirements in a single analysis could potentially mask the inclusion of an inappropriate individual requirement. Therefore, the NRC proposes to modify its Regulatory Analysis Guidelines, NUREG/BR-0058, Rev. 3 by adding guidance to address this concern.

DATES: Submit comments on the proposed criteria by (75 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission,  
Washington, DC 20555-0001. ATTN : Rulemakings and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 p.m. on Federal workdays (Telephone 301-415-1678).

You may also provide comments via the NRC's interactive rulemaking website at <http://ruleforum.llnl.gov>. This site provides the capability to upload comments as files (any

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 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

. . . 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

must be demonstrated to be of little or no safety significance, any new requirement should be justifiable on some cost-benefit basis. The Commission challenges the staff to establish such a criterion in a manner that adds fairness and equity without adding significant complexity. The staff should develop a proposed resolution for this issue and provide it to the Commission for approval.

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In the new fitness-for-duty rulemaking, the Commission will conduct an aggregate backfit analysis of the entire rulemaking. If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4).

In SECY-01-0162, "Staff Plans for Proceeding With the Risk-informed Alternative to the Standards for Combustible Gas Control Systems in Light-Water-Cooled Power Reactors in

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-XXXX, 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 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 and there would not be a reasonable expectation of added value because there is not a history of including inappropriate individual requirements. 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 as 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 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

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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

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<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 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

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<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.

comment stage.<sup>6</sup> 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 NRC should consider imposing the individual requirement as a backfit (where it would affect all plants to which it applies) rather than merely including it in a voluntary-alternative rule (where it would affect 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 non-controversial and have already undergone extensive external review and been endorsed by industry. Therefore, while 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 such updating is part of the regulatory process; (2)

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<sup>6</sup>See NUREG/BR-0053, Revision 5, March 2001, “U.S. Nuclear Regulatory Commission Regulations Handbook,” Section 7.9, for discussion of how to treat comments.

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. However, some aspects of these regulatory actions are backfits which must be addressed and justified individually. For example, NRC endorsement (incorporation by reference) of the ASME Boiler and Pressure Vessel Code (BPV) provisions on inservice inspection and inservice testing, and the ASME Operations and Maintenance (OM) Code, are not ordinarily considered backfits, because it has been the NRC's longstanding policy to incorporate later versions of the ASME codes into its regulations. However, under some circumstances NRC's endorsement of a later ASME BPV or OM Code is treated as a backfit. The application of the Backfit Rule to ASME code endorsements is discussed in the Appendix below. Aside from these backfits, these regulatory analyses should include consideration of the major features (e.g., process changes, recordkeeping requirements) of the regulatory action which should then be aggregated to produce qualitative or quantitative estimates of the overall burdens and benefits in order to determine if the remainder of the action is justified.

Dated at Rockville, Maryland, this            day of            , 2002.

FOR THE NUCLEAR REGULATORY COMMISSION

Annette L. Vietti-Cook,  
Secretary of the Commission

## **APPENDIX**

### **Guidance on backfitting related to ASME codes**

Section 50.55a requires nuclear power plant licensees to construct ASME *Boiler and Pressure Vessel Code* (BPV Code) Class 1, 2, and 3 components in accordance with the rules provided in Section III, Division 1, of the ASME BPV Code; inspect Class 1, 2, 3, Class MC, and Class CC components in accordance with the rules provided in Section XI, Division 1, of the ASME BPV Code; and test Class 1, 2, and 3 pumps and valves in accordance with the rules provided in the ASME *Code for Operation and Maintenance of Nuclear Power Plants* (OM Code). From time to time the NRC amends 10 CFR 50.55a to incorporate by reference later editions and addenda of: Section III, Division 1, of the ASME BPV Code; Section XI, Division 1, of the ASME BPV Code; and the ASME OM Code.

#### **Section A. Incorporation by reference of later editions and addenda of Section III, Division 1 of ASME BPV Code**

Incorporation by reference of later editions and addenda of Section III, Division 1, of the ASME BPV Code is prospective in nature. The later editions and addenda do not affect a plant that has received a construction permit or an operating license or a design that has been approved, because the edition and addenda to be used in constructing a plant are, by rule, determined on the basis of the date of the construction permit, and are not changed thereafter, except voluntarily by the licensee. Thus, incorporation by reference of a later edition and addenda of Section III, Division 1, does not constitute a “backfitting” as defined in § 50.109(a)(1).

**Section B. Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV and OM Codes**

Incorporation by reference of later editions and addenda of Section XI, Division 1, of the ASME BPV Code and the ASME OM Code affect the ISI and IST programs of operating reactors. However, the Backfit Rule generally does not apply to incorporation by reference of later editions and addenda of the ASME BPV (Section XI) and OM codes for the following reasons--

(1) The NRC's longstanding policy has been to incorporate later versions of the ASME codes into its regulations; thus licensees know when receiving their operating licenses that such updating is part of the regulatory process. This is reflected in § 50.55a which requires licensees to revise their ISI and IST programs every 120 months to the latest edition and addenda of Section XI of the ASME BPV Code and the ASME OM Code incorporated by reference into § 50.55a that is in effect 12 months prior to the start of a new 120-month ISI and IST interval. Thus, when the NRC endorses a later version of a code, it is implementing this longstanding policy.

(2) ASME BPV and OM codes are national consensus standards developed by participants with broad and varied interests, in which all interested parties (including the NRC and utilities) participate. This consideration is consistent with both the intent and spirit of the Backfit Rule (*i.e.*, the NRC provides for the protection of the public health and safety, and does not unilaterally imposed undue burden on applicants or licensees).

(3) Endorsement of these ASME codes 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.

**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 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 where 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. Since those requirements involved a substantially different direction, they were treated as backfits, and justified in accordance with the standards of 10 CFR 50.109.



(2) When the NRC requires implementation of later ASME BPV or OM code provision on an expedited basis, the action is treated as a backfit. This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expedited language. An example was the final rule dated September 22, 1999 (64 FR 51370), which incorporated by reference the 1989 Addenda through the 1996 Addenda of Section III and Section XI of the ASME BPV Code, and the 1995 Edition with the 1996 Addenda of the ASME OM Code. The final rule expedited the implementation of the 1995 Edition with the 1996 Addenda of Appendix VIII of Section XI of the ASME BPV Code for qualification of personnel and procedures for performing UT examinations. The expedited implementation of Appendix VIII was considered a backfit because licensees were required to implement the new requirements in Appendix VIII prior to the next 120-month ISI program inspection interval update. Another example was the final rule dated August 6, 1992 (57 FR 34666), which incorporated by reference in § 50.55a the 1986 Addenda through the 1989 Edition of Section III and Section XI of the ASME BPV Code. The final rule added a requirement to expedite the implementation of the revised reactor vessel shell weld examinations in the 1989 Edition of Section XI. Imposing these examinations was considered a backfit because licensees were required to implement the examinations prior to the next 120-month ISI program inspection interval update.

(3) When the NRC takes an exception to a ASME BPV or OM code provision and imposes a requirement that is substantially different from the current existing requirement as well as substantially different than the later code.

An example of this is that portion of the final rule dated September 19, 2002, in which the NRC adopted dissimilar metal piping weld ultrasonic (UT) examination coverage requirements.

**ATTACHMENT 2**

**Preliminary Proposed Criteria Discussed at Public Meeting**

## Preliminary Proposed Criteria Discussed at Public Meeting

Normally, in considering a proposed rulemaking action, the NRC performs an aggregate regulatory analysis for the entire rule to determine whether or not it is justified. However, there is a concern that aggregation or bundling of 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 relaxation of one requirement could potentially support an unrelated requirement that is not cost-justified. In the case of a rule that is subject to a backfit analysis, the net benefit from one requirement could potentially support an unrelated requirement that is not cost-justified.<sup>1</sup> To address this concern, in presenting a rulemaking alternative that constitutes an aggregation or bundling of requirements, the analyst should include an individual requirement only if it is integral to the purpose of the rule or justified on a cost-benefit basis.

In this context, an individual requirement is considered integral to the purpose of the rule if it is:

- (1) Necessary to achieve the stated objectives of the rule;
- (2) Needed, in combination with other elements of the rule, to establish a coherent regulatory approach, such as the key principles discussed in Regulatory Guide 1.174;<sup>2</sup>
- (3) Not separable from other elements of the rule; or

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<sup>1</sup>This discussion does not apply to backfits that qualify under one of the exceptions in 10 CFR 50.109(a)(4) (i.e., backfits that are necessary for compliance or adequate protection). 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.

<sup>2</sup>Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," July 1998, includes five key principles, four of which would be appropriate to consider in connection with a risk-informed voluntary alternative rule:

- (1) The proposed change is consistent with the defense-in-depth philosophy;
- (2) The proposed change maintains sufficient safety margins;
- (3) If there is an increase in core damage frequency or risk, it should be small and consistent with the intent of the NRC's safety goal policy statement, published in the Federal Register on August 4, 1986 (51 FR 30028); and
- (4) The impact of the proposed change should be monitored using performance measurement strategies.

(4) Needed to ensure that the rule does not significantly increase risk. As an example of this category, if a rule provides a relaxation in one requirement for the purpose of reducing unnecessary burden, a compensating increase in another requirement might be needed to support a finding that risk is not significantly increased.

If an individual requirement is not integral to the purpose of the rule, it must be cost-justified. This means that the individual requirement must add more to the rulemaking action in terms of benefit than it does in terms of cost. It does not mean that the individual requirement, by itself, must provide a substantial increase in the overall protection of the public health and safety or the common defense and security.

As a practical matter, a rulemaking action is generally divided into discrete elements for the purpose of estimating costs and benefits in a regulatory analysis. Thus, it should be apparent to the analyst whether or not there are individual elements that must be excluded because they are neither integral to the purpose of the rule nor cost-justified. The analyst may rely on his or her judgment to make this determination. It is not necessary to provide additional documentation or analysis to explain how the determination was made.

When a draft regulatory analysis is published for comment along with a proposed rule, the NRC may receive a comment to the effect that an individual requirement is neither integral to the purpose of the rule nor cost justified. If the comment provides a reasonable indication that this is the case, the NRC's response in the final rule should either agree with the comment or explain how, notwithstanding the comment, the individual requirement is determined to be integral to the purpose of the rule or cost-justified. To provide a reasonable indication, the comment must:

- (1) Identify the specific regulatory provision that is of concern;
- (2) Explain why the provision is not integral to the purpose of the rule, with supporting information as necessary; and

(3) Demonstrate, with supporting information, that the regulatory provision is not cost-justified.

Comments that do not provide a reasonable indication need not be addressed in detail.<sup>3</sup>

A special case involves the NRC's periodic review and endorsement of new versions of the ASME Codes. Some aspects of those rulemakings are not addressed in regulatory analyses. However, for those matters that are addressed in regulatory analyses, the same principles as discussed above should be applied. Further details are provided below.

The NRC's longstanding policy has been to incorporate new versions of the ASME Codes into its regulations. Furthermore, the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113) directs Federal agencies to adopt technological standards developed by voluntary consensus standard organizations. The law allows an agency to take exception to specific portions of the standard if those provisions are deemed to be inconsistent with applicable law or otherwise impractical.

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 rulemaking to incorporate the latest versions by reference into 10 CFR 50.55a, subject to any modifications, limitations, or supplementations (i.e., exceptions) that are deemed necessary.<sup>4</sup> It is generally not necessary to address new provisions of the updated ASME Codes in the regulatory analyses for these rulemakings. However:

(1) When the NRC endorses a new provision of the ASME Code that takes a substantially different direction from the currently existing requirement, the action should be

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<sup>3</sup>NUREG/BR-0053, Revision 5, March 2001, "United States Nuclear Regulatory Commission Regulations Handbook," Section 7.9, provides further discussion of comments that should be treated in detail.

<sup>4</sup> NRC regulations require licensees to periodically update their inservice inspection and inservice testing programs to the latest ASME Code incorporated by reference in 10 CFR 50.55a(b).

addressed in the regulatory analysis. An example was the NRC's endorsement of new Subsections IWE and IWL, which imposed containment inspection requirements on operating reactors for the first time. Since those requirements involved a substantially different direction, they were considered in the regulatory analysis, treated as backfits, and justified in accordance with the standards of 10 CFR 50.109.

(2) If the NRC takes exception to a new Code provision and imposes a requirement that is a substantial change from the currently existing requirement, the action should be addressed in the regulatory analysis.

(3) When the NRC requires implementation of a new Code provision on an expedited basis, the action should be addressed in the regulatory analysis. This applies when implementation is required sooner than it would be required if the NRC simply endorsed the Code without any expediting language.

When the NRC takes exception to a new Code provision, but merely maintains the currently existing requirement, it is not necessary to address the action in the regulatory analysis (or to justify maintenance of the status quo on a cost-benefit basis). However, the NRC explains any exceptions to the ASME Code in the Statement of Considerations for the rule.

**ATTACHMENT 3**

**Comments Received at Public Meeting**

## Comments Received at Public Meeting

**Comment A.** There should be different guidance for different types of rules.

**Response.** The NRC disagrees with this comment as 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.

**Comment B.** For rules that provide risk-informed voluntary alternatives to current regulations, an individual requirement should have to be cost-justified and integral to the purpose of the rule rather than cost-justified or integral to the purpose of the rule.

**Response.** The NRC maintains that if an individual requirement is integral to the purpose of the rule, then that 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.)

**Comment C.** How does a risk-informed alternative rule proceed if some element of the rule is found to be a candidate for backfitting?



**Response.** The revised criteria state that in some cases an increased requirement may be justifiable under the criteria of 10 CFR 50.109(a)(3) (i.e., it may be cost-justified and provide a substantial increase in the overall protection of the public health and safety or the common defense and security). If so, the requirement should be considered for imposition as a backfit (where it would affect all plants to which it applies) rather than merely being included in a voluntary alternative rule (where it would affect only those plants where the voluntary alternative is adopted). The revised criteria do not, however, specify whether or how a risk-informed alternative rule will proceed if one of its elements is being considered for backfitting. It is expected that such decisions will be made on a case by case basis.

**Comment D.** Objectives must be clearly stated by the NRC staff and approved by the Commission.

**Response.** The NRC agrees that the objectives of a rule should be clearly stated. The revised criteria indicate that the objectives of the rule are those stated in the preamble (also known as the Statement of Considerations) of the rule. The objectives, along with other parts of the *Federal Register* notice, are approved by the Commission if the rule is of the type that requires Commission approval, as is usually the case for the rules of interest in this discussion.

**Comment E.** How will the new guidelines be implemented?

**Response.** The NRC staff's current plans are to recommend proposed criteria to the Commission. If the Commission approves the recommendation, the staff then plans to publish these criteria for public comment. After considering these comments, the NRC staff will develop and issue 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 final recommended criteria for the approval of the Commission. The NRC plans to incorporate the criteria into a revision to NUREG/BR-0058. There may be other changes to NUREG/BR-0058, beyond incorporation of these criteria, that will also be addressed in the revision.

**Comment F.** Backfit Rule language seems to focus on individual requirements, but the Executive Order mandating regulatory analyses is focused on an aggregate approach.

**Response.** The NRC believes that an approach of analyzing individual components of a rule is consistent with the regulatory philosophy of Executive Order 12866 that agencies should select regulatory approaches that maximize net benefits. The NRC does not believe that Executive Order 12866 requires either an individual or aggregate approach.

**Comment G.** There is a concern that the new guidelines will erode the standard of 10 CFR 50.109(a)(3), which for certain backfits requires “a substantial increase in the overall protection of the public health and safety or the common defense and security.

**Response.** The NRC does not believe that the criteria would erode the “substantial increase” standard. The proposed criteria do not require that each individual rule requirement which must be separately analyzed under the proposed guidelines meet the “substantial increase” standard.

**Comment H.** Instead of allowing the analyst to rely on his or her judgment to determine the individual requirements that may be included in a draft regulatory analysis or backfit analysis at the proposed rule stage, each discrete new requirement should be analyzed individually.

**Response.** 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 and there would not be a reasonable expectation of added value because there is not a history of including inappropriate individual requirements. However, the public may comment on the appropriate level of disaggregation in any public comment opportunity provided in accordance with standard NRC procedures.

**Comment I.** There should be more specific guidance with regard to the analyst relying on his or her judgment at the proposed rule stage.

**Response.** In response to this comment, the NRC has 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.

**Comment J.** The analyst's judgment should be explained.

**Response.** Requiring an explanation of why it is permissible to include each individual element or sub-element of the rule would be essentially similar to requiring individual analyses.

**Comment K.** With regard to the four conditions that constitute "integral to the purpose of the rule," how are they related? Are all four needed? Especially "not separable."

**Response.** The revised criteria do not make use of the term "integral to the purpose of the rule" and the four conditions are not used.

**Comment L.** How is "defense-in-depth" related to the four conditions that constitute "integral to the purpose of the rule"?

**Response.** The four conditions are no longer referenced in the proposed criteria.

**Comment M.** After the end of a public comment period, how can public input be made in the process when changes occur?

**Response.** Late comments will be considered when time permits. Sometimes a public meeting such as an ACRS briefing or a Commission briefing provides an opportunity to find out what is happening and/or make comments. If an OMB clearance is needed, there is an additional opportunity to comment.

**Comment N.** We are concerned when we provide data, it will be used in proper context.

**Response.** The NRC agrees that data provided should be used in proper context.