

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 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-02-0225, which is accessible from ADAMS and at the NRC's Public Document Room as discussed above.) The three most significant issues raised were:

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

In response to this concern, the NRC has expanded the 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. 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. 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 fact 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.¹ 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 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

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