

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 if 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>

<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 the 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

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. 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.

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.<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

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.

<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.

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 is required. 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.<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

<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.