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July 2, 2003

The Honorable Annette L. Vietti-Cook
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTN: Rulemakings and Adjudications Staff

Re: Regulatory Analysis Guidelines: Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis (68 Fed. Reg. 19162)

Dear Ms. Vietti-Cook:

The Nuclear Regulatory Services Group ("NRS"), a consortium of power reactor licensees represented by the law firm of Ballard Spahr Andrews & Ingersoll, LLP, submits the following comments on the NRC's proposed modifications to its Regulatory Analysis Guidelines, NUREG/BR-0058, Rev. 3. These modifications include the proposed criteria for the treatment of individual requirements in a regulatory analysis. The criteria will provide guidance for the Staff on how to prepare a regulatory analysis for a rulemaking or other initiative that includes multiple new regulatory requirements.

In our view, the Staff's proposed criteria represent a positive step in providing detailed guidance in this area for the first time. Our comments are intended to help refine the criteria to ensure that all proposed new regulatory requirements receive a proper analysis of their costs and benefits.

Comments

1. Separate Analysis Of Individual Requirements Should Be Required To The Extent Practicable

Licensees have been concerned in the past that an "aggregate" regulatory analysis, in which a cost-benefit analysis is performed on a bundling of all new provisions contained in a proposed rule, could allow relaxations of existing regulations to "mask" unjustified new

requirements. As the NRC recognizes, "the net benefit from the relaxation of one requirement could potentially support a second requirement that is not cost-justified." 68 Fed. Reg. at 19162. According to the NRC's proposed criteria, the need for "disaggregation" of requirements for purposes of the regulatory analysis should be based on "reasonableness and practicality . . ." 68 Fed. Reg. at 19163. The NRC, however, stops short of making disaggregation the standard practice:

While the NRC agrees that it often makes sense to divide a rule into discrete elements in performing regulatory analyses . . . the NRC does not believe that there should be a general requirement for a separate analysis of each individual requirement of a rule.

Under the NRC's proposed criteria, the decision whether to perform a separate analysis will turn on whether inclusion of the particular individual requirement is "a *necessary component* of the regulatory initiative." 68 Fed. Reg. at 19164 (emphasis added). If it is, then a bundled regulatory analysis will be permitted. On the other hand, when a proposed aspect of a rulemaking is not a "necessary component" to accomplish the stated objectives, a separate analysis will generally have to be performed to demonstrate that the individual requirement is cost-beneficial.

In our view, the proposed criteria should go further to make separate analysis of individual requirements the norm. Without a clear expectation that separate analysis should ordinarily be required for discrete new requirements, we are concerned that the criteria will be read to imply that bundling requirements in a single regulatory analysis is generally acceptable. Accordingly, we recommend that the criteria set forth a general expectation that discrete individual requirements of a proposed rule or other regulatory initiative should be disaggregated for purposes of the regulatory and backfitting analyses whenever it is practicable to do so. In other words, disaggregation of requirements should be the preferred approach, with the burden on the NRC to justify why separate analysis of individual requirements is not appropriate in a given case.

2. The Criteria Must Be Consistent With The Standards Of The Backfitting Rule

According to the NRC's proposed criteria, when a separate analysis of individual requirements is deemed appropriate, the following guideline would apply:

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.

If the individual requirement would not have a positive cost-benefit contribution, it would not warrant further consideration in the rulemaking.

The proposed criteria indicate that the individual requirement must be both "related" to the stated objective of the regulatory initiative and be "cost-beneficial." Clarification should be provided of what is meant by "cost-beneficial" in this context. Under the NRC's backfitting rule, 10 C.F.R. 50.109(a)(3), any new rule or other requirement that constitutes a backfit can only be adopted if the analysis demonstrates that it will be cost-justified *and* produce a "substantial increase" in overall safety. At a minimum, then, the NRC's criteria in the Regulatory Analysis Guidelines should make clear that any individual new requirement must be shown to produce an increase in safety, and the rulemaking or other regulatory initiative (to the extent it constitutes a backfit) must be shown to produce in the aggregate the "substantial increase" in overall safety required under Section 50.109(a)(3).

As the proposed criteria recognize, there may be cases where a new backfit requirement is being considered for inclusion in a voluntary alternative to current regulations. In this case, we agree that the NRC should consider imposing such a new requirement, if justified under the standards of Section 50.109, through the normal disciplined backfitting process, i.e., "as a backfit . . . rather than merely including it in a voluntary-alternative rule" 68 Fed. Reg. at 19164. On a similar point, we agree with the NRC position that if an individual backfit requirement is *not* related to the objective of the regulatory initiative (but has been included, for example, to eliminate duplicative rulemakings), the "requirement must be addressed and justified as a backfit separately." 68 Fed. Reg. at 19164, n. 5.

3. Guidance on Backfitting Issues Related To The ASME Code

An appendix to the proposed criteria provides guidance on the special case of NRC endorsement of new editions of the ASME Code. The appendix, entitled "Guidance on Backfitting Related to ASME Codes," sets forth the NRC's view that the backfitting rule does not apply to incorporation by reference into 10 C.F.R. 50.55a of later editions of Section XI of the ASME Code. The NRC's position is based on the fact that the ASME Code is a consensus standard and that 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."

The guidance does recognize, however, that there are circumstances where the NRC considers it appropriate to treat as a backfit the endorsement of a later ASME Code edition. These circumstances include: (1) where the later provisions represent a "substantially different direction" or expanded scope of Code requirements to additional components (e.g., the rulemaking on containment inspection requirements under subsections IWE and IWL); and (2) where the NRC requires implementation of the updated Code provisions on an expedited schedule (e.g., the expedited implementation of Appendix VIII of Section XI on qualifications for UT examinations).

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We appreciate the NRC's effort to provide guidance in this area. In addition to the circumstances noted where NRC endorsement of the ASME Code can constitute a backfit, the NRC should also recognize that there are times when it would be appropriate to perform a regulatory analysis weighing the costs and benefits of significant new requirements embodied in later editions of Section XI before incorporating those by reference into 10 C.F.R. 50.55a. Rather than merely being an "update" to Section XI, later editions can include new or augmented inspection regimes, or other new requirements, that have a substantial impact on some operating plants. Accordingly, the 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.

* * * *

We appreciate the opportunity to comment on the NRC's proposed revisions to the Regulatory Analysis Guidelines. Should you have any questions concerning these comments, please contact us.

Very truly yours,

A handwritten signature in black ink, reading "Daniel F. Stenger". The signature is written in a cursive, flowing style.

Daniel F. Stenger
Counsel to the Nuclear Regulatory Services
Group