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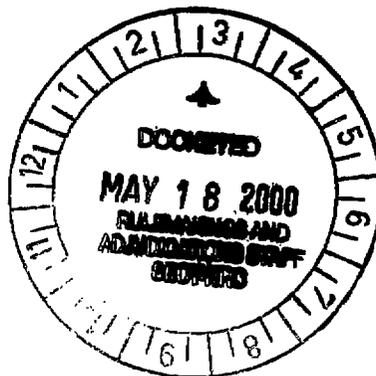
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**(65FR11488)**

May 17, 2000



Annette L. Vietti-Cook  
Secretary of the Commission  
Attn: Rulemakings and Adjudications Staff  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

**SUBJECT: Comments on the NRC Advance Notice of Proposed Rulemaking to Risk-Inform the Special Treatment Requirements (65 Fed. Reg. 11,488)**

Dear Ms. Vietti-Cook:

This letter provides the comments of the Nuclear Utility Backfitting and Reform Group ("NUBARG") on the U.S. Nuclear Regulatory Commission ("NRC") Advance Notice of Proposed Rulemaking ("ANPR"), "Risk-Informing Special Treatment Requirements." 65 Fed. Reg. 11,488 (March 3, 2000).<sup>1</sup> NUBARG appreciates having the opportunity to provide comments on the backfitting and reform aspects of the ANPR.

The ANPR provides an alternative risk-informed approach for special treatment requirements of 10 C.F.R. Part 50 (e.g., quality assurance, environmental qualifications, technical specifications, and reporting) that would focus on those structures, systems, and components ("SSCs") that have been identified as important to protect public health and safety by using a risk-informed approach. The ANPR identifies three strategies of the rulemaking plan: (1) increase the use of risk-informed methods; (2) maintain overall safety while

<sup>1</sup> NUBARG is a consortium of utilities, operating a substantial number of U.S. nuclear power reactors. NUBARG was formed in the early 1980s and actively participated in the development of the NRC's backfitting rule in 1985. NUBARG has subsequently monitored the NRC's implementation of the backfitting rule.

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reducing unnecessary burden on licensees and the NRC; and (3) conduct the process in a manner that encourages public participation and results in public confidence in the product and process.

Concurrently with plans to risk-inform special treatment requirements, the NRC is involved in a process designed to risk-inform other requirements in Part 50. We recognize that the ANPR does not include a specific discussion on backfitting; however, one of the specific questions, for which comments and supporting reasons were requested, asks commenters to provide an estimate of the expected costs and benefits of implementing risk-informed special treatment requirements, indicating that the Commission is concerned with the potential backfitting implications of the proposed approach. Because the rulemaking plan for special treatment requirements is likely to establish a precedent for future risk-informed rulemaking plans, we believe it is important that the regulatory process provisions be applied appropriately and consistently with other NRC requirements, especially the backfitting rule in 10 C.F.R. 50.109. Therefore, we provide the following comments regarding application of the backfitting rule to the rulemaking outlined in the ANPR.

Backfitting is defined by the Commission to be the modification of or addition to SSCs, facility design, procedures, or organizations that may result from new or amended provisions in the Commission's rules. 10 C.F.R. § 50.109(a)(1). In the Statement of Considerations for the backfitting rule, the Commission discussed its decision to apply the backfitting rule to rulemaking, stating the following:

*Since there is no practical difference between a backfit that is imposed pursuant to a rule or a staff position interpreting a rule, the Commission will alter the final rule to require a documented analysis of required backfits regardless of the source. A plant-specific backfit analysis will not be required in rulemaking and the factors specified in the rule will be reviewed only on a generic basis for rulemaking purposes. Because there must be safety reasons for the agency to impose any changes to a regulatory requirement or a staff position applicable to the licensee, because the safe[ty] consequences are unknown until analyzed, and because the Commission should fully understand the effects of a proposed backfit before its imposition, it is of little consequence how a backfit is imposed. Safety and sound management require that analysis precede imposition of a new or modified regulatory requirement or staff position. It follows that those backfits imposed by rulemaking should undergo the same scrutiny as*

*proposed by other means.* 50 Fed. Reg. 38101 (1985). (Emphasis added.)

The NRC proposes to amend the regulations to provide an alternative approach for special treatment requirements. When a licensee elects to implement the alternative approach, the associated regulatory requirements are then imposed on that licensee and become part of the licensing basis for the plant. Because the new requirements will be imposed on the group of licensees that elect to implement the alternative, the extent to which implementation of the alternative imposes additional requirements on those licensees is subject to the backfitting requirements. The backfitting rule prohibits imposition of new requirements or changes in Staff positions without justification that these requirements are necessary to protect the public health and safety, ensure compliance, or provide a substantial increase in overall protection of public health and safety. *See* 10 C.F.R. § 50.109. The Commission adopted these processes to ensure against the imposition of unnecessary or overly burdensome regulatory requirements. Failure to apply these processes to "voluntary" alternative approaches could result in overly burdensome regulatory provisions that are not necessary for adequate protection of the public health and safety, which is inconsistent with both the backfitting rule and the NRC's strategy for the rulemaking plan. In addition, the unnecessary imposition of requirements will be a disincentive for licensees to adopt the alternatives.

Similarly, when the Commission provides an alternative approach in a regulation, if a licensee implements the alternative approach, any additional requirements beyond the provisions for the alternative approach that are imposed on the licensee are subject to the backfitting rule. Though the ANPR does not suggest that the NRC would impose requirements beyond those that will be included in the final rule, we believe that application of the backfitting rule would be required on a plant-specific basis if this situation does occur.

We believe that, not only is the backfitting rule applicable, but that there are a number of benefits in applying the backfitting rule to these "voluntary" alternative approaches. Experience has shown that the disciplined process required by the backfitting rule has enhanced the quality of NRC rulemaking. That experience also shows that the flexibility inherent in the backfitting process readily accommodates the NRC's increased attention to the risk-significance of proposed rulemaking initiatives. An accurate assessment of risk reduction is at the heart of the backfit process. Such an accurate estimate of risk also supports the accurate estimate of regulatory costs, many of which are calculated as averted risks. These assessments are necessary for the Commission to "fully understand the effects of a proposed backfit before its imposition." (50 Fed. Reg. 38101).

This experience with the backfitting rule shows that there is substantial value in strictly adhering to it as an intrinsic component of the plans to risk-inform the regulatory process. In particular, the well-established benefits that flow from a rigorous application of the backfitting rule should not be avoided by characterizing regulatory changes as voluntary. Voluntary changes, on close examination, may include changes in NRC positions that cannot realistically be avoided by licensees that elect to implement the changes. Moreover, even where changes are truly voluntary, application of the backfit process will ensure that the NRC has carefully considered all of the factors which are important to cost-effective regulation.

Turning now to the ANPR, a careful review of it shows that several additional, potentially costly activities would be required of licensees. Among these activities are:

- additional controls on plant probabilistic risk assessment ("PRA") modeling and enhancements in the scope, quality, and updates in PRA data;
- establishment and implementation of an integrated decision-making panel ("IDP");
- changes to configuration control process procedures; and
- establishment of a monitoring program for SSCs.

Because these process changes could be resource intensive, the cost-benefit analysis required by the backfitting rule would clearly show whether it is necessary to apply the new requirements for relaxing special treatment requirements for SSCs. The analysis required by the backfitting rule will better achieve the NRC's strategies for the rulemaking plan because licensees will more readily accept risk-informed approaches, safety would be maintained while reducing unnecessary burden on licensees and the NRC, and public confidence in the process will be enhanced.

Moreover, these proposed process changes also appear to be inconsistent with the Commission's focus on regulatory reform. As discussed in the ANPR, one goal for risk-informing the regulations is to eliminate unnecessarily burdensome regulatory requirements. We are concerned that the categorization process for determining the safety significance category for SSCs in the new Appendix to 10 C.F.R. Part 50 does not achieve that goal. Because the proposed process is overly prescriptive and inflexible, it likely will discourage licensees from pursuing alternatives. To avoid this unintended consequence, we suggest that a disciplined application of the backfit evaluation process will help the NRC to identify alternatives which meet the regulatory reform objectives through a more performance-based, less prescriptive categorization process.

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Finally, consistent with the intent of the backfitting rule, the NRC Committee to Review Generic Requirements ("CRGR") has long included proposed relaxations or decreases in current requirements or Staff positions in its Charter for review of proposed changes.<sup>2</sup> According to the CRGR Charter, the Staff must explain its rationale that the public health and safety would be adequately protected if the proposed reduction were implemented (presumably, whether as an NRC initiative or as a voluntary licensee initiative), and that the cost savings attributed to the action would be substantial enough to justify taking the action.

We appreciate the opportunity to comment on the ANPR. We would be pleased to address any questions the NRC may have on our comments. Additionally, we endorse the comments prepared on behalf of the industry by the Nuclear Energy Institute.

Sincerely,



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Sheldon L. Trubatch  
Patricia L. Campbell  
Counsel to NUBARG

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<sup>2</sup> See NUREG-1409, "Backfitting Guidelines," Appendix C, "Charter, Committee to Review Generic Requirements (Revision 4, April 1987)," July 1990, at C-7.