

February 12, 1999

Dr. Carl A. Paperiello, Director  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Two White Flint Center  
Washington, D.C. 20555-0001

**REFERENCE:      Backfit Provision for 10 CFR 70**

Dear Dr. Paperiello:

The Nuclear Energy Institute (NEI)<sup>1</sup> has through its September, 1997 *Petition for Rulemaking* requested the Nuclear Regulatory Commission (NRC) to include a backfit provision in revisions to 10 CFR 70. The NRC response indicated that a backfit provision would be included in Part 70 at a future date. A backfit provision is necessary to ensure that new regulatory requirements imposed on a Part 70 licensee are soundly based on public health and safety considerations and are appropriately cost-justified. Given the Staff's schedule to complete revisions to 10 CFR Part 70 by February 15, 1999, we believe it imperative to now consider inclusion of a backfit provision in the Rule.

NEI's *Petition for Rulemaking* (PRM-70-7) outlined the need for an immediately effective backfit provision that would generally require NRC analysis of any backfit<sup>2</sup> imposed on a licensee. NEI originally proposed that, in order for a backfit to be implemented, it must substantially increase overall protection of the public health and safety and its cost must be justified by the increased protection it affords.

Dr. Carl A. Paperiello

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<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

<sup>2</sup> Backfit analysis would *not* be required for any changes the NRC deemed (through a documented evaluation) to be necessary to ensure compliance with applicable license requirements or to ensure that adequate protection to the public health and safety, common defense and security is afforded by the facility.

Most recently the Commissioners issued a Staff Requirements Memorandum (SRM) in December, 1998 supporting the inclusion of a backfit provision that permits backfits to be imposed if they will provide "...modest increases in safety at minimal or inconsequential cost..." NEI is encouraged with the Commission's support for a Part 70 backfit provision and believes that the 'modest increase/minimal or inconsequential cost' standard is worthy of further consideration in a proposed rule.

With respect to the timing of effectiveness of the backfit provision, Commissioner Diaz in his September 29, 1998 vote sheet on SECY-98-185 specifically stated that "*the proposed rule should provide for an appropriately formulated [backfit] provision that would be immediately effective.*" (Emphasis added). The other Commissioners did not specifically address this issue.

NEI explained its basis for believing that making a backfit provision 'immediately effective' is essential in, among other places, its July 7, 1998 'Nuclear Energy Institute White Paper on Part 70 Regulation' which was previously provided to the Staff. We are enclosing for your reconsideration, the relevant excerpts from that document. NEI strongly recommends that the proposed rule reflect the advice of Commissioner Diaz and include an immediately effective backfit provision.

Finally, NRC's proposed use of a qualitative, non-monetary methodology to derive the safety benefit of a backfit modification is inconsistent with NUREG/BR-0058 Rev. 2 ('Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission'), which requires use of quantitative analyses to the maximum extent possible.

NEI is concerned that a wide range of costly new NRC Staff positions resulting from new or different NRC requirements, expectations or perceptions could be imposed without any site-specific consideration of whether they are needed for regulatory compliance or whether they can be justified on a cost-benefit basis.

NEI, therefore, encourages the NRC to include a backfit provision in the Part 70 revisions. This provision should be immediately effective. It should require a documented, quantitative analysis of any proposed modification to demonstrate that the proposed backfit: (i) will increase the overall protection of the public health and safety, and (ii) will have a cost of implementation that can be justified by the increase protection the modification affords. Within the context of this formulation, the backfit provision would permit modest increases in safety if they result only in minimal or inconsequential cost increases. The backfit provision would include a 'compliance exception' clause that would state that a backfit analysis would not be

required if the NRC determines that a backfit modification is necessary to bring the facility into compliance with its license commitments or that it is needed to protect the health and safety of the public, common defense and security.

NEI seeks to have an immediately effective backfit provision included in the Part 70 Rule. The Commissioners' directives and guidance on this issue should be reflected in the proposed rule. We would be pleased to discuss the need for this provision with your staff and, if desired, to assist in revising the proposed backfit provision language which NEI provided to the NRC in its September 1996 *Petition for Rulemaking* (PRM-70-7).

Sincerely,

Marvin S. Fertel  
Enclosure

cc: The Honorable Shirley A. Jackson, Chairman, NRC  
The Honorable Greta J. Dicus, Commissioner, NRC  
The Honorable Nils J. Diaz, Commissioner, NRC  
The Honorable Edward McGaffigan, Jr., Commissioner, NRC  
The Honorable Jeffrey S. Merrifield, Commissioner, NRC  
Dr. William D. Travers, Executive Director for Operations, NRC

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ENCLOSURE

**EXCERPT FROM THE  
NUCLEAR ENERGY INSTITUTE WHITE PAPER  
ON PART 70 REGULATION  
(July 7, 1998)**

**IV. Timing and Implementation of the Backfit Provision**

NEI's Rulemaking petition also proposed the inclusion of a backfit provision in Part 70 that would apply immediately on the effective date of the other Part 70 rule changes. In SECY-97-137, the Staff stated:

*Staff proposes that a qualitative "backfit" mechanism, similar in purpose to a 10 CFR 50.109 provision, be considered after the safety bases, including the results of the ISA, are established and incorporated in the license, and after licenses and staff have gained a few years of experience with implementation of the ISA requirement. This mechanism would not apply to modifications identified as a result of the initial ISAs that are needed to assure protection of public health and safety; these modifications would be required for compliance with the revised Part 70. [SECY-97-137, Attachment 1, p.11]*

The Staff's proposed resolution raises two significant issues: (1) the "timing" of applicability of the backfit provision; and (2) the adoption of a "qualitative" vs. "quantitative" backfit provision.

**A. The Backfit Provision Must Be Immediately Effective**

It is critical that the backfit provision apply immediately upon the effective date of the rule change. The Staff's basis for concluding that its effectiveness should be delayed is that Part 70 licensees do not have the "well-defined licensing bases" which reactor licenses possess, and that "quantitative...PRAs" (which the industry does not believe are necessary) would be required to provide such bases. SECY-97-137 at Attachment 1, p.11. Thus, the Staff proposes to "consider" a backfit provision "after the safety bases, including the results of the ISA, are established and incorporated in the license, and after the licenses and staff have gained a few years of experience with the implementation of the ISA requirement." *Id.* at pp. 11-12.

There is no reason to delay application of the backfit provision on this basis. The NRC possesses an ample basis to have licensed the Part 70 facilities in the past and to have permitted their continued operation. The backfit provision would require the NRC to determine, based upon analysis, that an imposed backfit will provide a "substantial increase in the overall protection of the public health and safety or the common defense and security...and that the direct and indirect costs of implementation...are justified..." An analysis is not required if, through a documented evaluation, the NRC concludes that the backfit is necessary for regulatory compliance or adequate protection.

Findings of this type are often made by the Staff and it does not appear necessary for the NRC to

possess the detailed safety basis documentation provided only in the context of reactor licensees. The staff should be able to determine whether a proposed new requirement to be imposed on a Part 70 licensee would “:substantially increase” protection of the public health or safety or the common defense and security, whether the costs of such a new requirement are justified, and whether the new requirement is needed for compliance to assure “adequate protection.”

The Staff has stated that the backfit rule would not apply to:

*modifications identified as a result of the initial ISAs that are needed to assure protection of public health and safety; these modifications would be required for compliance with the revised Part 70. [see SECY-97-137, Attachment 1, p.11]*

There is no reason to delay implementation of the backfit rule on this basis. Once the ISAs are complete, if the licensee concludes that plant or program modifications are needed, it will make those changes and no backfit issue arises. On the other hand, if the Staff believes such changes are needed and proposes to require them through license amendments, orders or otherwise, it should be required to consider such changes under the backfit rule. It is important to recognize, of course, that under the rule, a backfit analysis is “not required” if the Staff concludes that the changes are required to provide compliance with applicable requirements or to ensure that the plant provides adequate protection to the public health and safety and the common defense and security. But this is very different from the Staff’s position that the backfit rule itself should not apply to plant changes based on the initial ISAs. Thus, the fact that some modifications may be necessary to ensure regulatory compliance or “adequate protection” provides no justification for delaying the effectiveness of the backfit rule.

The Staff previously proposed delaying the effectiveness of a backfit provision in another context – the certification of the Gaseous Diffusion Plants (GDPs) under 10 CFR Part 76. The history of that provision is very instructive on the Commission’s position on this issue in the past. When the Staff developed a draft, proposed backfit provision under Part 76, it recommended an approach very similar to the approach it is now advocating for Part 70. It proposed to delay application of the backfit rule until the time of “the first annual certification following the initial certification...” [SECY-93-285A, November 24, 1993 at p.2 (emphasis added)]. In explaining this provision, the Staff stated:

*In recognition of Commission interest, the Staff has further considered a backfit requirement in the proposed rule and concluded that such a provision could be included. However, because the Staff has no experience with backfit provisions appropriate for the two gaseous diffusion plants, the backfit provision recommended by the staff in the rule reflects provisions contained in 10 CFR Part 50, with the baseline to be established after the first annual certification following the initial certification. Other options with respect to the baseline include the first certification, certification after several years, or even the existing plant configuration prior to the first certification, (Emphasis added).*

In the actual proposed Part 76 rule later published in the Federal Register, the words “at the time of issuance of the first annual certification following the initial certification” were excluded in

accordance with the Commission's explicit directive in an SRM dated January 7, 1994, that "the backfit criteria should go into effect when the final rule goes into effect." (Emphasis added). In the Statements of Consideration accompanying the proposed rule, former Commissioner Rogers sought comments on whether section 76.76 should become effective immediately when 10 CFR Part 76 became final, as would happen were the proposed section to remain unchanged. [Fed. Reg. 6792, 6797-98 (February 11, 1994)].

In response, both USEC and DOE submitted comments stating that section 76.76 should be made effective as soon as the rule became final. In endorsing the proposed backfit provision as written, USEC stated that the "backfit provision should apply to any plant changes necessitated by NRC rules or interpretations after Part 76 becomes final...DOE stated that there was "no need to...delay the effectiveness of §76.76."

When the final rule was published, the NRC agreed with these comments and left the language of the rule unchanged. In particular, in adopting the final rule, the NRC discussed Commissioner Rogers' inquiry as follows:

*Commissioner Rogers was particularly interested...[w]hether the provisions of §76.76 should become effective immediately when 10 CFR Part 76 becomes final, as would happen were the proposed section to remain unchanged... A number of commentators agreed that the provisions of §76.76 should be made effective when the rule becomes final. There were no comments received in support of a delay in the implementation of the backfit provisions...*

The final rule is unchanged.

In spite of the clear record described above, the Part 76 backfit provision was not made effective when the rule became final. Thus, it was not applied to the many changes required to be made through the initial Certification Applications and the NRC-approved Compliance Plans. These changes resulted in very costly plant, program and procedural changes. Requirements contained in the Certification Applications and Compliance Plans were driven by individual NRC Staff expectations and perceptions without the benefit of a rigorous analysis against backfit rule criteria. Had the backfit rule been applied to determine the costs and benefits of those changes, it seems likely that a number of the modifications that were required might not have been necessary.

Therefore, NEI believes that it is essential that the backfit provision in Part 70 apply immediately upon the effective date of the Part 70 rule change and that the Commission should make that expectation clear and unambiguous.

### **B. There is No Basis for Adopting a "Qualitative" Backfit Provision**

SECY-97-137 states:

*Staff proposes that a qualitative "backfit" mechanism...be considered...*  
[SECY-97-137, Attachment 1, p.11]

The Staff has also previously proposed adopting a "qualitative" backfit standard in another context, again in connection with the certification of GDPs. On March 26, 1997, the NRC

published a Federal Register notice regarding “Criteria for Staff Implementation of ‘Backfitting’ Requirements for Gaseous Diffusion Plants,” 62 Fed. Reg. 14456 (March 26, 1997) to implement the backfit provision set forth in 10 CFR §76.76. In Appendix 3 of that document, the Staff proposed to use “a qualitative non-monetary methodology to derive the safety /safeguards benefit...” under the backfit rule. However, use of such a qualitative standard is not consistent with NUREG/BR-0058 Rev. 2 “*Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission*,” nor does it place a sufficiently high burden on the Staff to justify a finding that a proposed backfit will meet the “substantial increase” requirement. Throughout NUREG/BR-0058, the Staff has made it clear that quantitative analyses are much preferred over qualitative ones, even if values and impacts can not be expressed in “monetary” terms (i.e. \$2,000 per person-rem). In particular, NUREG/BR-0058, Rev. 2 (pp. 20-21) states:

- ⇒ *Estimated values and impacts should be expressed in monetary terms whenever possible;*
- ⇒ *Consequences that cannot be expressed in monetary terms should be...quantified in appropriate units to the extent possible;*
- ⇒ *[For materials licensees] the staff needs to make every reasonable effort to apply alternative tools that can provide a quantitative perspective...concerning the value of the proposed action;*
- ⇒ *Even inexact quantification with large uncertainties is preferable to no quantification*
- ⇒ *[Where PRAs or other statistics-based analyses are not available] the generally recommended approach is to utilize whatever data may be available within a simplified model to provide some quantitative perspective;*
- ⇒ *[Where quantification is not possible] reliance on the qualitative approach should be a last resort, to be used only after efforts to develop pertinent data or factual information have proved unsuccessful; [emphasis added] and*
- ⇒ *Certain issues, such as those involving emergency preparedness, security, and personnel requirements, tend to fall into [the] category [of issues requiring qualitative analyses].*

Contrary to the above statements, the Staff now proposes again to utilize qualitative analyses to assess any backfit at Part 70 facilities, regardless of whether reasonable, quantitative data can be obtained and regardless of the nature of the backfit. This is a significant departure from NUREG/BR-0058 Rev. 2 and it is not justified in SECY-97-137. Its effect is to substantially reduce the reasonable burden on the Staff to base proposed backfits on quantifiable grounds where it is practicable to do so. Therefore, the Commission should specify that backfit analyses performed under Part 70 will use quantitative analyses to the maximum extent possible, consistent with existing guidelines in NUREG/BR-0058.