



NUCLEAR ENERGY INSTITUTE

Ellen Ginsberg
Vice President, General Counsel
and Secretary

June 4, 2010

BY EMAIL AND U.S. MAIL

Mr. Stephen Burns
Office of the General Counsel
United States Nuclear Regulatory Commission
Mail Stop: 15D21
Washington, DC 20555-0001

Dear Mr. Burns:

In December 2009, the Nuclear Energy Institute (NEI)¹ submitted comments on the future role of the Committee to Review Generic Requirements (CRGR). As stated in our comment letter, NEI believes a healthy backfitting program promotes an orderly, disciplined, and predictable regulatory process. The rigorous analysis required by the backfit rule also serves to optimize allocation of NRC staff and licensee resources by ensuring that NRC's regulatory efforts are focused on activities that are required for adequate protection, compliance, or will result in a cost-justified, substantial increase in public health and safety or common defense and security.

Given the importance of an effective backfitting program and the current consideration being given to the role of the CRGR, I am writing to call your attention to an area in which the NRC's current backfitting practices seem to be inconsistent with the guidance provided in the Supplementary Information published with Commission's 1985 final backfitting rule (1985 Final Rule) and NUREG-1409. Specifically, the area of concern is the application of the backfitting process to interpretive guidance.²

The Commission has long recognized the importance of guidance in implementing a meaningful backfitting program. Specifically, in its 1985 Final Rule amending 10 CFR § 50.109, the Commission stated:

Many of the most important changes in plant design, construction, operation, organization, and training have been put in place at a level of detail that is expressed in

¹ 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, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

² As used in this letter, the term "interpretive guidance" means guidance that interprets the Commission's regulations and recommends specific action by licensees.

staff guidance documents which interpret the intent of broad, generally worked regulations. The NRC has determined that the correct focus for backfit regulation is the establishment of effective management controls on existing staff processes for the interpretation of regulations that are known to result in valuable upgrades in industry safety performance. Thus, the Commission opts to adopt a management process not only for the promulgation of regulations as backfit instruments, but also for the lower tier staff review and inspection processes known to result in reactor plant changes.³

This passage acknowledges the practical, action-forcing nature of NRC's interpretative guidance. Given that guidance often spurs changes at nuclear power plants, the Commission determined that the agency's process for managing backfits should focus not only on regulations, which actually "impose" agency positions, but also on "lower-tier" processes that result in plant changes.

This principle was carried forward in NUREG-1409, which contains the NRC's primary guidelines on backfitting.⁴ NUREG-1409 explicitly recognizes that the NRC has issued a number of guidance documents, including regulatory guides that were considered backfits. A footnote expanding upon this recognition explains:

As a legal matter, the backfit rule does not strictly apply until the point at which a backfit is required by, for example, a rule or an order. However, for the purpose of this discussion, that legal distinction is not important. *The NRC backfit process, including the CRGR Charter and NRC Manual Chapter 0514, is defined on the principle that new positions or requirements are to meet the standards of the rule before they are issued to licensee(s). New generic positions in documents, such as generic letters, bulletins, and regulatory guides, as well as plant-specific positions, are to be considered and justified as backfits before they are issued.* For this reason, they often are discussed in the same way as legally required backfits.⁵

Later in NUREG-1409, the NRC reiterates this point in response to a question asking why certain bulletins and generic letters that requested or required actions were not accompanied by a backfit analysis. On this point, NUREG-1409 states:

Many of the bulletins and generic letters issued in 1988 and 1989 were not justified by a backfit analysis simply because they were determined to fall under the compliance exception listed in 10 CFR § 50.109. When action is needed to ensure compliance with existing regulations or to ensure that an adequate level of protection is maintained, a backfit analysis is not required. However, a documented evaluation is needed to support the use of the exception.

³ "Revision of Backfitting Process for Power Reactors: Final Rule," 50 Fed. Reg. 38,101 (Sept. 20, 1985).

⁴ "Backfitting Guidelines," NUREG-1409 (July 1990).

⁵ NUREG-1409, at 3 (emphasis added).

The backfit analyses or documented evaluations are available in the Public Document Room. However, this was not readily apparent in the past because they were not cited in the generic letters and bulletins themselves. *In the future, backfit analyses or documented evaluations will be cited in the generic communications.* An example is provided in Appendix F to this report.⁶

A footnote supporting the first paragraph of the above-quoted passage states:

As was stated earlier, generic letters and bulletins do not impose backfits. Therefore, they are not required by regulation to be accompanied by backfit analyses or documented evaluations. *Nonetheless, it is NRC practice to justify them as backfits, if appropriate, before issuing them.*⁷

Both 1985 Final Rule and NUREG-1409 indicate that the NRC will, as a policy matter, analyze new positions issued in interpretive guidance in the same manner as backfits that are "imposed" by regulation or order. As the NRC recognized in its 1985 final rule, this policy position is vital to maintaining a meaningful backfitting program because important changes to nuclear power plants are often spurred by new or amended staff positions issued in interpretive guidance.

Despite the relatively clear policy direction on this subject, a review of recently issued Regulatory Guides⁸ reveals that the NRC staff is not routinely performing backfit analyses upon issuing new or revised guidance. Instead, the staff appears to be relying on the following stock language to avoid performing a backfit analysis:

The purpose of this section is to provide information to applicants and licensees regarding NRC's plans for using this draft regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

In some cases, applicants or licensees should propose an alternative or use a previously established acceptable alternative method for complying with specified portions of the NRC's regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.⁹

⁶ NUREG-1409, at 12 (emphasis added)(footnotes omitted).

⁷ *Id.* (emphasis added).

⁸ We focus on Regulatory Guides in this letter because they are one of the primary guidance documents used to interpret Commission regulations. Although our focus is on Regulatory Guides, our concerns are relevant to all interpretive guidance, regardless of the type of guidance document that the NRC uses to communicate a new or modified position.

⁹ See, e.g., Draft Regulatory Guide DG 1242 (Proposed Revision 2 of Regulatory Guide 1.54, dated July 2000), Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants; Regulatory Guide 1.11, Rev. 1, Instrument Lines Penetrating the Primary Reactor Containment (March 2010); Regulatory

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In taking this position, the NRC staff seems to have adopted a policy that unless or until a backfit is actually imposed – e.g., by rule or order – no backfit analysis will be performed. As explained above, this approach is inconsistent with the 1985 Final Rule, as well as NUREG-1409. Under the staff's current approach, if a licensee believes that the NRC is attempting to *require* action through its interpretive guidance, the licensee and the NRC would get the benefit of a backfit analysis only if the licensee forced the agency to issue an order "imposing" the action in question. Further, if a backfit analysis is not performed when the guidance is issued, both the NRC and licensees lose the benefit of knowing whether the proposed changes will result in a cost-justified, substantial increase in public health and safety or common defense and security.

Consistent with the 1985 Final Rule and NUREG-1409 NEI believes that requiring licensees to provoke "imposition" of a new position in order to reap the benefit of a backfit analysis is inefficient, and clouds the clarity and reliability of the agency's regulatory program. Instead, NEI believes that performing a backfit analysis upon issuance of interpretive guidance provides a more transparent and stable regulatory program by clarifying, through analysis, whether the positions taken in interpretive guidance *may be imposed*, rather than relying on statements focused on whether the NRC staff's *intends to impose* such positions.

Based on the discussion provided above, NEI respectfully requests that the NRC staff abide by the agency's stated policy and provide backfit analyses upon issuing interpretive guidance. Specifically, the backfit analysis should be provided when the interpretive guidance is issued for public comment in draft form. In the alternative, if the NRC has changed its policy in this area, NEI requests that the agency provide a reasoned basis for implementing this change.

Please feel free to contact me if you have any questions regarding this issue.

Very truly yours,



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