

October 12, 2006

Thomas C. Houghton
Director, Strategic Regulatory Programs
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, NW, Suite 400
Washington, DC 20006-3708

Dear Mr. Houghton:

I am responding to your August 25, 2006, letter requesting U.S. Nuclear Regulatory Commission (NRC) feedback on the Nuclear Energy Institute (NEI) draft document entitled "The Nuclear Regulatory Process." The NRC staff performed a limited scope review of the document and identified several aspects of the document that should be clarified, corrected, or enhanced. A listing of the NRC's high-level comments based on this review is enclosed.

The NRC recognizes the importance of training and knowledge transfer activities. As such, the NRC staff is available to meet with the NEI to discuss the enclosed comments and additional detailed comments from the NRC staff. To coordinate such a meeting, please contact Stacey L. Rosenberg of my staff at 301-415-2357 or slr1@nrc.gov. Thank you for the opportunity to review and comment on the document.

Sincerely,

/RA/

J. E. Dyer, Director
Office of Nuclear Reactor Regulation

Project No. 689

Enclosure: As stated

cc w/encl: See next page

NRC High Level Comments on the

Nuclear Energy Institute's draft document entitled "The Nuclear Regulatory Process"

General Comments

- The document does not discuss licensee responsibility with respect to safety, i.e., the licensee is primarily responsible. This should be incorporated throughout the document, especially in Section 7.0.
- The document mixes factual information about regulatory process with commentary about NEI's opinion on how the process should work (as an example, see page 11, 3rd paragraph).
- Some issues and processes are missing from the document (e.g., topical report process and the fee recovery formula for the NRC budget).
- The document does not discuss the treatment of proprietary and safeguards information.
- The document omits discussion of public meetings and when they are required versus drop-in meetings.

Section 2.3, "NRC's Relationships with Other Entities"

- The document does not thoroughly and correctly characterize the role of State and local governments or other federal agencies in the regulation of nuclear materials and power reactors, such as the Department of Transportation, the Environmental Protection Agency, the Occupational Safety & Health Administration, the Federal Emergency Management Agency, Department of Homeland Security, etc.

Section 3.0, "NRC Requirements"

- The document needs to make the point that NRC regulations apply to licensees and vendors.
- The document should stress that Rulemaking is required to be an open process.
- Page 9 - The set of orders issued to address security concerns following the events of September 11, 2001, are both Safety Orders and Common Defense and Security Orders.

Section 4.0, "NRC Regulatory Guidance and Staff Interpretations"

- Licensee commitments to adhere to regulatory guidance and industry codes and standards become binding on the licensee when incorporated into license conditions.
- Page 14 - Interim Staff Guidance (ISG) documents are more like Regulatory Guides than Regulatory Information Summaries. 10 CFR 54.37(b), "Additional Records and Record Keeping Requirements," allows for scope backfits to the aging management program. These backfits are communicated through the use of ISG documents.

Section 5.0, "NRC Generic Communications"

- The writeup on the generic communications inadequately describes the process. For example, it does not relay that generic communications are a vehicle for the NRC staff to obtain information concerning compliance with existing regulations.

ENCLOSURE

Section 6.0, "NRC Reactor Oversight and Enforcement Process"

- The document should discuss that Non-Cited Violations involving significant conditions adverse to quality have additional requirements.
- With respect to inspection, the document states that the NRC inspects to ensure that licensees comply with the regulations. This statement is not accurate. Ensuring compliance is the licensee's responsibility. The NRC inspection efforts use a sampling approach to provide reasonable assurance of protection of public health and safety.
- The document does not capture the concept that adequate protection is the lowest threshold at which a plant remains safe to operate.
- The document does not mention that some regulations are based on safety enhancements while others are based on adequate protection. Furthermore, it oversimplifies the process describing what happens when "non-compliance occurs."

Section 7.0, "The Licensee Role in the Regulatory Process"

- The document does not emphasize licensee's role in enhancing the regulatory process (e.g., page 28 discusses expectations of NRC reviewers regarding minimizing requests for additional information, but there is no discussion regarding expectations for licensees to provide quality submittals in the first place).
- The document does not mention the acceptance review performed by the NRC for quality and completeness.
- The document does not mention that licensees must explain why the emergency situation could not have been avoided when requesting emergency license amendments.
- Additionally, the NRC staff will be providing detailed comments in response to the NEI request for comment dated July 27, 2006, to draft NEI 06-02, "License Amendment Request Guidelines."

Section 8.0, "NRC Management and Control of the Regulatory Process"

- The document does not make it clear that a new NRC staff position needs to be imposed to be considered a backfit. Taking an initial position is not a backfit.

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***No legal objection**

NRC-001

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