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PROPOSED RULE PR

Chapter 1

NEI

NUCLEAR ENERGY INSTITUTE

(68 FR 19162)

July 2, 2003 (11:23AM)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

James W. Davis  
DIRECTOR, OPERATIONS  
NUCLEAR GENERATION DIVISION

July 2, 2003

Ms. Annette L. Vietti-Cook, Secretary  
U.S. Nuclear Regulatory Commission  
ATTN: Rulemakings and Adjudications Staff  
Washington, DC 20555-0001

Dear Ms. Vietti-Cook:

**SUBJECT:** Regulatory Analysis Guidelines: Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis, 68 FR 19162, April 18, 2003

The Nuclear Energy Institute<sup>1</sup> (NEI) submits the following response to the subject Federal Register Notice. The issue in question is the treatment of individual requirements in a regulatory analysis. NEI continues to have concerns on the proposed aggregating or "bundling" different requirements in a single analysis which could potentially mask the inclusion of an inappropriate individual requirement.

#### I. NRC Preliminary Criteria

In February 2002, the NRC published a Federal Register Notice<sup>2</sup> containing proposed criteria for "bundling" multiple items into a single regulatory analysis. The proposed criteria attempted to incorporate Commission guidance contained in three staff requirements memoranda (SRM):

<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> Federal Register, 67 FR 6663, "Criteria for the Treatment of Individual Requirements in a Regulatory Analysis; Meeting, February 13, 2002.

Template = SECY-067

SECY-02

A. SRM,<sup>3</sup> January 19, 2001

*“ ... a disciplined, meaningful, and scrutable process needs to be in place to justify any new requirements that are added as a result of the development of risk-informed alternative versions of regulations. ... The Commission challenges the staff to establish such a criterion in a manner that adds fairness and equity without adding significant complexity. The staff should develop a proposed resolution for this issue and provide it to the Commission for approval.” [emphasis added]*

B. SRM,<sup>4</sup> October 3, 2001

*“ ... the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4).” [emphasis added]*

C. SRM,<sup>5</sup> December 31, 2001

*“ ... provide the Commission with recommendations for revising existing guidance in order to implement a disciplined, meaningful, and scrutable methodology for evaluating the value-impact of any new requirements that could be added by a risk-informed alternative rule.” [emphasis added]*

## II. Public Meeting on Preliminary Criteria

A public meeting was held on March 21, 2002, to obtain stakeholder input on the preliminary NRC criteria. The public comments provided at the meeting were not seriously considered as seen in the NRC staff's disposition of the comments, in Attachment 3 to SECY-02-0225.<sup>6</sup> Issues of remaining concern to NEI fell into two categories. The first category addressed criteria necessary to evaluate the bundling of individual requirements into a single regulatory analysis. The second category addressed the use of subjective judgment in making bundling decisions.

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<sup>3</sup> Staff Requirements – SECY-00-0198 – Status Report on Study of Risk -informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-informed Changes to 10 CFR 50.44 (Combustible Gas Control),” January 19, 2001.

<sup>4</sup> Staff Requirements – SECY-01-0134 – Final Rule Amending the Fitness-for-duty Rule, October 3, 2001.

<sup>5</sup> Staff Requirements – SECY-01-0162 – Staff Plans for Proceeding with the Risk-informed Alternative to the Standards for Combustible Gas Control Systems in Light-water-cooled Power Reactors in 10 CFR 50.44, December 31, 2001.

<sup>6</sup> SECY-02-0225, “Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis,” December 27, 2002.

### III. NRC Proposed Criteria

The staff has republished the preliminary criteria as proposed criteria<sup>7</sup> for comment by July 2, 2003. As discussed below, NEI continues to have the same type of concerns about the proposed criteria as we had about the preliminary criteria. In brief, the proposed criteria do not incorporate adequately the Commission guidance cited in Section I of this letter.

#### A. Criteria for Evaluating the Bundling of Individual Requirements

1. At the March 2002 public meeting, NEI commented that, for rules that provide risk-informed voluntary alternatives to current regulations, an individual requirement should have to be cost-justified and integral to the purpose of the rule rather than cost-justified or integral to the purpose of the rule.

In the Discussion section of the Federal Register Notice (FRN) that published the proposed criteria, the NRC staff dismisses this comment and concludes that "if an individual requirement is integral to the purpose of the rule, then that alone is a sufficient basis for its inclusion, and in fact, a decision on its inclusion or exclusion is not discretionary." Further, "the staff finds that if a requirement is not deemed integral, it should be included if it is cost-justified." The staff also replaced the phrase "integral to the purpose of the rule" with the word "necessary" and included (minimal) explanation of what constitutes "necessary."

NEI strongly disagrees with the staff position. The proposed criteria would be a significant disincentive to implementation of voluntary alternative requirements developed by industry groups because of the lack of scrutable guidance regarding the addition of individual requirements by the NRC staff.

Voluntary initiatives should be encouraged because they are an effective way to standardize the resolution of technical and policy issues to the advantage of all stakeholders. Potential volunteers should be permitted to add/drop independent line items based on plant-specific cost/benefit decisions. Once committed to a voluntary initiative, licensees would manage changes in accordance with NRC-endorsed industry commitment-management guidance.<sup>8</sup>

2. If a proposed individual requirement is not cost-beneficial, is not required for compliance, and is not required for adequate protection (the fundamental regulatory tests of value and/or necessity), it is not "integral to the purpose of the rule." We also question the deletion of this phrase from the proposed criteria. It is the phrase used in the January 19, 2001, Commission SRM, and it was a key phrase in the February 2002 preliminary criteria.

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<sup>7</sup> Federal Register, 68 FR 19162, "Regulatory Analysis Guidelines: Proposed Criteria for the Treatment of Individual Requirements in a Regulatory Analysis," April 18, 2003.

<sup>8</sup> NEI 99-04, "Guidelines for Managing NRC Commitment Changes," July 1999.

**B. Guidance on Using Judgment to Make Bundling Decisions**

1. At the March 2002 public meeting, NEI commented that NRC analysts need more guidance on making bundling judgments to help ensure that individual requirements are bundled appropriately.

In the Discussion section of the Federal Register Notice (FRN) that published the proposed criteria, the NRC staff claims it has added more guidance regarding the appropriate level of disaggregation in an analysis. Specifically, the additional guidance states that "a decision on the level of disaggregation needs to be tempered by considerations of reasonableness and practicality, and that a more detailed disaggregation would only be appropriate if it produces substantively different alternatives with potentially meaningful implications on the cost-benefit results."

This statement is confusing and provides no meaningful standard. It makes it easier for staff to aggregate without explanation, whereas the greater use of individual subjective judgment should be held to a high standard.

2. A regulatory analysis cannot be "meaningful & scrutable," as prescribed by Commission SRM, unless there is some documented basis for disaggregation. A reviewer cannot comment absent information used by the NRC analyst. Regulatory analysis decisions must be supported by sufficient documentation of individual items to permit an independent peer reviewer to understand the reasons for bundling them together.
3. The subjective, undocumented nature of the proposed criteria is inconsistent with NUREG/BR-0058 as currently written. NUREG/BR-0058 already contains detailed guidance on the treatment of values and impacts and on the documentation of alternatives. It should be straightforward to add guidance on how to treat the "bundling" issue. This is not to say that a detailed objective basis is necessary for each individual proposed requirement. However, the proposed criteria should require more documentation of bundling than a simple statement citing the analyst's judgment.
4. The use of judgment in the proposed criteria relies too much on NRC management review and public comment to provide backstops against unnecessary regulatory burden. Subjective judgments, no less than objective criteria, warrant a scrutable basis. The burden should be on the NRC to provide sufficient information to evaluate regulatory analysis decisions.
5. The proposed criteria do not establish a common understanding of new requirements, do not establish a scrutable process for making regulatory decisions about voluntary initiatives, and do not provide sufficient documentation to inform future decisions.

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#### IV. Conclusion

NEI requests that NRC defer a final decision until previous public comments invading those made by NEI are properly addressed. Public input can be obtained through participation in accordance with NRR Office Instruction COM-204.<sup>9</sup> We believe it is worth additional effort to explain the assumptions and reasoning that underlie the NRC proposal. Further dialogue could resolve these concerns to the satisfaction of all stakeholders. An appropriate vehicle for dialogue would be NRC/NEI Licensing Action Task Force (LATF) meetings, which are held several times each year to discuss generic licensing issues.

By using public meetings with industry-sponsored groups as a discussion forum for shaping proposed regulatory actions, the NRC staff can enhance the documentation of assumptions made and sources of information used to prepare a regulatory analysis. As permitted by NUREG/BR-0058 [section 4, page 17], information obtained from outside the NRC, including any from parties interested in a proposed regulatory action, may be used in the regulatory analysis after the staff has been assured of the reasonableness of the information.

If you have questions or need additional information, please contact Mike Schoppman at (202) 739-8011 ([mas@nei.org](mailto:mas@nei.org)).

Sincerely,



James W. Davis

Enclosure

c: Leyard B. Marsh, NRC  
NEI Licensing Action Task Force

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<sup>9</sup> NRR Office Instruction, COM-204, "Interfacing with Owners Groups, Vendors and NEI," July 5, 2001.