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WINSTON & STRAWN

1400 L STREET, N.W., WASHINGTON, DC 20005-3502
202-371-5700

35 W. WACKER DRIVE
CHICAGO, IL 60601-9703
312-558-5600

200 PARK AVENUE
NEW YORK, NY 10166-4193
212-294-6700

444 FLOWER STREET
LOS ANGELES, CA 90071-2911
213-615-1700

43 RUE DU RHONE
1204 GENEVA, SWITZERLAND
41-22-317-75-75

21 AVENUE VICTOR HUGO
75116 PARIS, FRANCE
33-1-53-64-82-82

October 16, 2000

David L. Meyer, Chief
Rules and Directives Branch
Division of Administrative Services
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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**Re: Comments on NRC's Proposed Guidelines for Including Industry
Initiatives in the Regulatory Process (65 Fed. Reg. 53,050 (2000))**

Dear Mr. Meyer:

The following comments are submitted on behalf of the Nuclear Utility Backfitting and Reform Group ("NUBARG")¹ on NRC's proposed guidelines for including industry initiatives in the regulatory process. 65 Fed. Reg. 53,050 (2000). NUBARG endorses comments submitted by the Nuclear Energy Institute ("NEI") in its letter dated October 16, 2000. Furthermore, while we concur with NRC efforts to better ensure that industry initiatives are appropriately considered by the NRC, we are concerned that the subject guidelines may result in the use or application of these initiatives for unintended purposes.

Specifically, we believe it is more appropriate that the use of particular industry initiatives be addressed on a case-by-case basis and that generic guidelines not be developed by the NRC. In the alternative, however, if the NRC continues to believe that formal guidelines are

¹ 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 and NRC regulatory reform efforts. Accordingly, these comments are being submitted from the perspective of regulatory reform.

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Add: J. Foster (JWF)

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appropriate, we offer several comments for consideration. We have categorized our comments into three key areas: (1) definitions; (2) adequate protection and NRC endorsement, and (3) inspection and enforcement.

Definitions

A number of terms are used in the guidelines that may have different meanings to different users. We believe that the final guidelines should define these important new terms to avoid confusion in their implementation. These terms, and our suggested definitions, are provided below.

Applicable Industry Group ("AIG") - An industry group that undertakes action to prepare an "industry initiative" or a "voluntary initiative." It is acceptable for the AIG to represent a subset of operating reactors, and therefore, not represent the entire industry. An AIG would include an Owners' Group, NEI, a Codes and Standards group, EPRI, or a group of licensees established formally for an intended purpose applicable to that group of reactors, or a group of licensees who have reached a mutual agreement to speak to an issue as a single entity.

Cost-Beneficial Safety Enhancement Initiative - An AIG action, which is undertaken in response to an issue that provides a potential cost-beneficial safety enhancement, with the specific intent to establish generic guidance. (Note that this term relates to a "Type 1(b)" initiative in the proposed guidelines.)

Industry Initiative - An action by an AIG that is undertaken in response to an actual or anticipated issue, with the specific intent to establish formalized guidance for endorsement by the NRC as an acceptable method of achieving a specific regulatory purpose. (Note that this term relates to a "Type 1(a)" initiative in the proposed guidelines.)

Stakeholder - The NRC, licensees, AIGs, vendors, consulting companies, State and local governments, the general public, and any other group that may be directly impacted by NRC decisions in the specific area of consideration.

Voluntary Initiative - An AIG action that is undertaken for issues that are outside of existing regulatory requirements or is used as an information gathering mechanism. A voluntary initiative does not always represent a cost beneficial safety enhancement. (Note that this term relates to a "Type 2" initiative in the proposed guidelines.)

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Adequate Protection and NRC Endorsement of Industry Initiatives

We agree with statements in the proposed guidelines that reiterate the NRC position that issues involving adequate protection of public health and safety must be addressed by regulatory processes already in place.² Other statements in the guidelines, however, seem to contradict this position. For this reason, NUBARG is concerned with the current NRC approach regarding this issue because it appears that the potential exists under these guidelines for the NRC to shift its responsibility for addressing generic adequate protection issues to the industry. Industry initiatives cannot substitute for regulatory actions when such actions are necessary to assure adequate protection or compliance with legally binding requirements, which presumptively assures adequate protection. Our concern stems from the guidelines which appear to indicate that a "Type 1(a)" industry initiative may "substitute for or complement regulatory actions for issues within existing regulatory requirements." 65 Fed. Reg. 53,051 (2000). NUBARG believes that the NRC must fully evaluate the issue of regulatory concern, and follow required processes for evaluating whether a change in regulations or staff positions is necessary to: (1) assure adequate protection, (2) change the standard of adequate protection, (3) maintain compliance, or (4) achieve a substantial increase in the overall protection of public health and safety. 10 C.F.R. § 50.109.

The proposed guidelines define a "Type 1(a)" industry initiative as an action in response to an issue of potential regulatory concern which substitutes for or complements regulatory action already addressed by existing regulatory requirements. A "Type 1(b)" industry initiative is defined as one which involves potential cost-beneficial safety enhancement issues outside existing regulatory requirements. 65 Fed. Reg. 53,051 (2000).

NUBARG recommends that the guidelines more clearly explain the NRC's intent behind and process for incorporating the industry initiatives into the regulatory process. For example, the NRC may endorse industry initiatives by incorporation by reference into NRC regulations, thereby making the industry initiatives legally binding requirements.³ Alternatively,

² In licensing facilities pursuant to Section 182 of the Atomic Energy Act of 1954, as amended, the Commission must assure that the facility will provide adequate protection of the public health and safety. 42 U.S.C. § 2232. In addition, Section 50.109 ensures that the Commission will always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public. 10 C.F.R. § 50.109(a)(5).

³ See, for example, 10 C.F.R. § 50.55a, "Codes and Standards," in which the American Society of Mechanical Engineers ("ASME") Boiler and Pressure Vessel Code, Sections III and XI, and the ASME Operations and Maintenance Code are incorporated by

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the NRC may endorse industry initiatives by referencing the initiatives in regulatory guides, thereby making the initiatives equivalent to NRC guidance and methods acceptable to the NRC for meeting particular regulatory requirements.⁴ Without addressing the means by which an industry initiative would be incorporated into a regulatory process, the guidelines appear to be incomplete.

Further, the guidelines should describe the NRC's reliance on the Type 1(b) industry initiatives as being complementary to, but not in lieu of, the regulatory process. For example, if initiatives incorporated into regulations represent a new NRC Staff position or a change in an NRC Staff position, the backfitting rule (10 C.F.R. § 50.109) appears to require application of its provisions before incorporating the initiative into the regulatory process as a requirement. Otherwise, implementation of the industry initiative should be left to a licensee's discretion, similar to the "Type 2" industry initiatives described in the proposed guidelines, and our suggested "voluntary initiative" above. We also would remind the NRC that the industry may develop voluntary initiatives without being guided by the NRC, so long as the initiative is not in conflict with regulatory requirements.

Additionally, we believe that the Type 1 (a) and (b) industry initiatives represent two distinct types of initiatives, as suggested in our definitions above. The Type 1(a) is the type of industry initiative meant to address a significant regulatory concern that must be resolved in a prompt manner. The Type 1(b) is the type of industry initiative aimed at providing a cost-beneficial safety enhancement. We recommend that the final guidelines separate these two types of initiatives.

reference into the regulations. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the *Federal Register* (5 U.S.C. § 552(a)).

⁴ See, for example, Regulatory Guide ("RG") 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," which endorses portions of NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Rev. 2 (April 1996). NUMARC 93-01 is an example of an industry initiative developed to provide a means to comply with 10 C.F.R. § 50.65. RG 1.160 specifies which portions of NUMARC 93-01 provide an acceptable means to comply with the applicable regulatory requirements.

Inspection and Enforcement

NUBARG believes that any discussion in these guidelines of enforcement relative to an industry initiative is inappropriate unless the industry initiative becomes a legally binding requirement. The NRC's authority to enforce legal requirements is well established. We agree that if the industry initiative becomes a legally binding requirement on a licensee, and is captured in a regulation promulgated consistent with the Administrative Procedures Act ("APA"),⁵ the NRC may take enforcement actions if the licensee fails to implement the requirements (*see* 64 Fed. Reg. 25,368 (2000)).⁶ Therefore, guideline statements regarding enforcement being available if violations of regulatory requirements occur do not appear to be necessary in this document. 65 Fed. Reg. 53,054 (2000).

For other industry initiatives (*e.g.*, cost-beneficial industry initiatives) or voluntary initiatives, it does not appear that the NRC would have the authority to consider enforcement action unless the initiatives were considered necessary to satisfy a regulatory requirement. If other administrative processes (*e.g.*, Order, Notice of Deviation) for a commitment are used, the NRC may be required to justify such actions according to the provisions of the backfitting rule. 10 C.F.R. § 50.109. We are concerned, however, with the potential "spill over" effects (*i.e.*, NRC expectations that licensees will implement so-called

⁵ 5 U.S.C. § 553.

⁶ Not all industry initiatives become legally binding requirements. Nevertheless, they may be the subject of a licensee commitment to the NRC. For these initiatives, administrative actions other than enforcement would apply, if NRC actions is deemed appropriate -- for example, Notices of Deviation, Notices of Nonconformance, Confirmatory Action Letters, Letters of Reprimand, and Demands for Information. 65 Fed. Reg. 25,381 (2000). The proposed guidelines note that, if the NRC considers it appropriate in instances when a licensee deviates from a commitment to an industry initiative, and if the backfitting criteria for a safety enhancement are satisfied (10 C.F.R. § 50.109), then the NRC may issue an Order to modify, suspend, or revoke a license in accordance with 10 C.F.R. § 2.202, or may undertake rulemaking. 65 Fed. Reg. 53,056 (2000). The final guidelines should discuss the various actions, depending on the significance of the issue, that the NRC may take (if appropriately justified) in instances when a licensee deviates from a commitment. The NRC recently issued Regulatory Issues Summary 2000-17, "Managing Regulatory Commitments Made by Power Reactor Licensees to the NRC Staff," September 21, 2000, which accepts NEI 99-04, "Guidelines for Managing NRC Commitment Changes," as an acceptable process for management of commitments.

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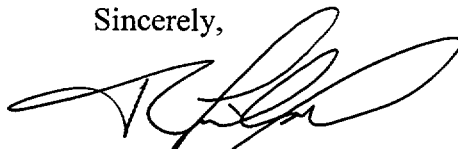
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voluntary initiatives) that could occur. It is imperative that the guidelines clearly distinguish between the types of initiatives, and that the guidelines are consistent with the NRC's enforcement policy. 65 Fed. Reg. 25,368 (2000).

NUBARG also suggests that the guidelines address how the different types of industry initiatives are to be treated in the significance determination process delineated in NRC Inspection Manual Chapter 0609. We recommend that the guidelines be explicit in this treatment and ensure consistency with the guidance in Manual Chapter 0609.⁷

In summary, NUBARG believes that there are a number of issues that should be addressed in more detail if the NRC determines that the guidelines are necessary. These issues would include ensuring that the guidelines methodology does not abdicate NRC's statutory authority and follows existing regulatory requirements, such as the backfitting rule. If you have any questions regarding these comments, please contact us.

Sincerely,



Thomas C. Poindexter
Patricia L. Campbell

Counsel for the Nuclear Utility Backfitting
and Reform Group

cc: J. Murphy, Chairman
Committee to Review Generic Requirements

⁷ For example, Inspection Manual 0609, Section 0609-11, discusses the use of the significance determination process to determine the significance of a licensee performance deficiency that does not constitute a violation of a regulatory requirement or a commitment. It states that agency follow-up for such issues determined to be significant "will be handled in accordance with the backfit rules of 10 CFR 50.109 as appropriate."