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October 16, 2000

Chief, Rules and Directives Branch
Division of Administrative Services
U.S. Nuclear Regulatory Commission
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Subject: Proposed Guidelines for Including Industry Initiatives
in the Regulatory Process (65 FR 53050, August 31, 2000)

The Nuclear Energy Institute (NEI)¹, on behalf of its industry members, is submitting these comments in response to the subject proposing guidelines for the use of industry initiatives in the nuclear regulatory framework published in the *Federal Register Notice* on August 31.

We offer general comments on the proposed process. Additionally, comments on specific provisions of the proposed guidelines are provided in the Enclosure.

The nuclear industry has historically developed programs and guidelines that effectively addressed operational, technical and regulatory issues. It is noteworthy that the NRC staff and industry recognize that past initiatives have generally been quite successful and that the process has been effective. Key reasons for this success are and should continue to be early and frequent communications, involvement of all affected stakeholders, and flexibility in resolution development.

NEI has commented in the past that the proposed guidelines are not necessary. We continue to believe that there is little value in developing a formalized, structured process on interactions that have historically worked well. We believe such a process would do nothing more than become a burdensome obstacle to open, candid and necessary interactions between the NRC and its stakeholders.

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including 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.

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Programs and guidelines developed by industry are intended for voluntary use. They may be utilized by a number of licensees, but not all unless a formal industry position is adopted. The approval and implementation of such a position results in agreement among nuclear utilities to take specific actions. Individual licensees may choose to commit to implement industry-developed guidance in response to regulations, orders and license conditions relating to specific technical or regulatory issues, or take other actions, as they deem appropriate.

The guidelines outlined in the subject *Federal Register Notice* describe that industry initiatives could be employed to respond to potential regulatory concerns that are outside existing regulatory requirements. As noted in our February 17, letter to Dr. Brian W. Sheron, we believe that industry initiatives should not be used in lieu of or as a substitute for required regulatory actions. The NRC has the authority and responsibility to promulgate new or revised requirements necessary to ensure adequate protection of public health and safety. The NRC must continue to do so in order to maintain its standing as an objective and credible regulatory agency. Deferring to industry organizations or "applicable industry groups," or creating the perception of doing so under the auspices of the proposed guidelines will quickly erode public confidence and trust.

Please contact me (202-739-8080 or am@nei.org) or Fred Madden (202-739-8114 or fwm@nei.org) if you have any questions or wish to further discuss these comments.

Sincerely,



Alexander Marion

Enclosure

**Nuclear Energy Institute
Comments Regarding Proposed NRC Guidelines
For Including Industry Initiatives in the Regulatory Process**

1. The proposed guideline adopts the term “applicable industry group (AIG)” as the entity proposing initiatives. The definition of AIG within the proposed guidelines could permit virtually any organization, and as few as two licensees, to be considered an AIG. This term is ill-defined and suggests the NRC staff will leverage two or more utilities to undertake an activity that cannot otherwise be pursued by the NRC.
2. The proposed guidelines define two types of initiatives and two sub-types within Type 1. There is sufficient difference between the two sub-types to warrant the guidelines reflect the three distinct types of initiatives as follows:
 - **Type 1** – An initiative developed in response to an issue of potential safety concern that would complement regulatory actions within existing regulatory requirements.
 - **Type 2** – An initiative developed in response to regulatory concern that is a potential cost beneficial safety enhancement outside existing regulatory requirements.
 - **Type 3** – An initiative developed to address issues of concern to the applicable industry group(s), but are outside existing regulatory requirements and are not cost beneficial safety enhancements or are used as an information gathering mechanism.

Regardless of how initiative “types” are defined, the fundamental tenant is for the NRC to pursue rulemaking for adequate protection issues, for cost-beneficial safety enhancements, and for imposing new regulatory requirements – all within the discipline of the Backfitting Rule (10 CFR 50.109).

3. The discussion regarding inspection, monitoring, and enforcement (Step 9) should be segregated by initiative type as delineated above. There are two ways in which implementation of industry initiatives may be subject to the NRC inspection and enforcement:
 - When implementation guidance associated with an industry initiative is endorsed by the NRC via a regulatory guide as one way of meeting an explicit provision of a regulation, or
 - When the implementation guidance affects programs or processes within the framework of current regulations, typically through a docketed commitment.

ENCLOSURE

4. Step 1, "Issue Identification," of the proposed process delineates a number of factors to be considered in the NRC staff's preliminary evaluation of the technical and policy implications of the emerging issue. This part of the process should involve the industry and other affected stakeholders to a greater extent than what is suggested by the proposed guidelines. Early involvement and interaction in a public forum provides an opportunity to discuss an emergent issue and achieve an understanding of its technical and regulatory implication. This will aid in determining generic applicability, or applicability to class of licensees or whether the issue has a more limited scope.
5. The policy guidance provided in Step 2, "NRR ET Approval to Pursue Issue," describes the content of the NRC staff's issue evaluation to be provided to the Nuclear Reactor Regulation Executive Team. This guidance should be more specific with regard to industry involvement. Information from the industry on the subjects of safety significance and limitations in the amount of information available or the ability to characterize the issue would be valuable input to the Executive Team's deliberations. Therefore we recommend a Federal Advisory Committee Act panel be established to engage affected stakeholders in the Executive Team's preliminary assessment of an emergent issue.
6. A NRC management escalation process, designed to resolve issue impasses between the NRC Staff and industry, should be explicitly recognized in the process guidelines. This escalation process should designate responsibility for resolving disagreements that may arise in the development and implementation of industry initiatives.
7. The proposed guidelines recognize that effective and continuing communication between the NRC, industry and other interested stakeholders is an essential underpinning of the process. We believe that an excellent example of an effective communication model is the one employed for the new Reactor Oversight Process. As noted above, the use of a Federal Advisory Panel Act panel would be appropriate.
8. The proposed guidelines contain a section on "Communications Plan" which includes provisions for public meetings and stakeholder participation in deliberations on industry initiatives. Although the NRC has a responsibility to openly communicate its regulatory decision making and, in this case, how it applies industry initiatives in the regulatory process, internal industry deliberations are generally not conducted in open, public forums.