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Mr. Thomas L. King
Director, Risk Analyses & Applications
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Mail-Stop T-10E50
Washington, DC 20555-0001

SUBJECT: Industry Comments on:
a) Draft NRC Framework for Risk-Informing NRC Technical Requirements, and
b) Draft NRC report on, *Risk-Informing 10 CFR 50.44 "Standards for Combustible Gas Control Systems in Light-Water-Cooled Power Reactors"*

Dear Mr. King:

These comments are submitted by the Nuclear Energy Institute (NEI)[1] on behalf of the nuclear energy industry in response to a request made at the NRC February 24-25, 2000, workshop on risk-informing NRC technical requirements. The industry commends the NRC for making these draft documents available to the public and the willingness to enter into open public discussions on improving the regulatory process through a risk-informed approach. We appreciate the opportunity to provide early input to the development of NRC process for implementing improvements to NRC technical requirements.

The draft framework document, provided by the NRC at the February 2000 NRC workshop on risk-informing NRC technical requirements, is well formatted. It provides a starting point for developing the appropriate technical requirements for a risk-informed regulatory regime.

The industry strongly endorses the NRC strategy of linking the risk-informed approach to improving NRC technical requirements to the cornerstones of the NRC Reactor Inspection and Oversight Program. As with any draft document, there is a

[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 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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need for further clarification to reduce the apparent inconsistencies in the text relating to defense-in-depth, safety margin, single failure, and strategies. Consistent terminology and approach are essential elements in any regime and reduce the likelihood of future misunderstandings and misinterpretations.

At this time we do not believe that total quantification is necessary to implement Option 3 to SECY 98-300, *Risk-Informing NRC Technical Requirements*. The program is one of risk-informed approaches, not risk-based. We acknowledge that risk-insights are needed to implement some elements, but that does not necessarily require full scope PRA quantification.

When developing risk-informed improvements to the technical requirements, it is important to focus on those matters that are essential to the adequate protection of public health and safety. Incorporating "nice to have" features as part of a risk-informed regulation or regulatory guidance defuses the focus on those matters that have safety significance. It reduces the effectiveness of the regulatory process and is liable to be a significant disincentive for adopting, what is meant to be an improved regulatory process. We support the NRC proposal made at the NRC February 24-25, 2000 workshop on Option 3 to develop an internal NRC administrative process, modeled on Section 50.109, *Backfitting* rule, for assessing additions to NRC requirements and guidance in the development of optional risk-informed regulatory improvements.

Enclosure 1 and Enclosure 2 provide additional and more specific comments on the two draft NRC documents.

If you have any questions, please contact Biff Bradley (202-739-8083, e-mail **reb@nei.org)**, Adrian Heymer (202-739-8094, e-mail **aph@nei.org)**, or me.

Sincerely.

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Enclosure 1

Comments on Draft NRC Framework for Risk-Informing Regulations

The draft framework document provided by the NRC at the February 2000 NRC workshop on risk-informing NRC technical requirements is well formatted. It provides a starting point for developing the appropriate technical requirements for a risk-informed regulatory regime. The document is predominantly focused on the technical requirements, and as such the heading should be changed to reflect the prime emphasis, risk-informing NRC technical requirements.

We do not believe that total PRA quantification is necessary to implement Option 3. Risk-informing the regulations is not a risk-based (full quantification) project. Such an approach appears to be suggesting a regulatory regime solely based on quantification. The industry does not support such an approach for existing plants, and believes that there is significant uncertainty in regard to the near term attainment of safety and efficiency enhancements from such an approach.

We acknowledge that shutdown and low power events, external events, fire, and external events need to be considered and the risk-insights (qualitative and quantitative) from such studies should be used in the evaluation process for improving the regulations. We also acknowledge that the greater the level of detail and scope of a licensee's PRA the higher the degree of potential benefit.

Strategies

The industry strongly endorses the NRC strategy of linking the risk-informed approach to improving NRC technical requirements to the cornerstones of the NRC Reactor Inspection and Oversight Program.

We are confused by the apparent proposal in *Figure 2,* and the accompanying language in the Strategies section to include environmental protection in the cornerstones. The inclusion of such a term will only cause confusion and misunderstanding. It will result in resources being expended unnecessarily on regulatory interactions in attempts to resolve misinterpretations. We do not understand the rationale for introducing such statements at this stage. From the interactions on risk-informing NRC technical requirements, we agree that the existing radiation safety cornerstones, protect plant workers and protect the public from radiation exposures addresses the intent of the environmental protection phrase. As such, we recommend that references to environmental protection be deleted.

Events and activities associated with non-generating plant scenarios which do not result in core damage events are separate activities to those associated with risk-

informing Part 50. There are additional activities being planned to improve these requirements.

Radionuclide Release Criteria and Safety Goals

The need for, and practicality of producing specific quantitative criteria and guides on late releases with any degree of confidence is not understood. NUREG 1150 studies found that late releases are, at best, of second order effect in regard to latent fatalities. As such, we do not understand the basis for the proposed acceptance criteria of 0.1 for a large late release at this time.

The framework for risk-informing the technical requirements depicted in *Figure 2* links the risk-informed regulatory improvements to the NRC Safety Goals and to adequate protection of public health and safety. The safety goals are linked to the risk of early fatalities, and the risk of latent fatalities. The risk associated with a large early release is associated with a major release of fission products before the evacuation of the surrounding population. The risk from latent fatalities is associated with doses to the public, during or before the onset of evacuation, and which prove to be fatal in the long term.

While this topic may warrant further discussion and evaluation it should not delay the implementation of Option 2 to SECY 98-300, *Risk-Informing NRC Special Treatment Requirements,* (risk-informing the scope of structures, systems and components or Option 3 to SECY 98-300, *Risk-Informing NRC Technical Requirements*. NUREG 1150 conclusions when taken with the continuing monitoring of the licensee's emergency response plan provides the necessary and sufficient assurance that public health and safety is being adequately protected.

We acknowledge that a general qualitative assessment could be made, yet are uncertain as to the value of such an exercise, or the benefit since comparison against generic and realistic objective criteria is not feasible at this time. Long term actions relating to the prevention of late release are addressed in a licensee's severe accident management programs.

At this time, we do not believe there is sufficient information and knowledge to reach a definitive conclusion and understanding on a quantitative assessment of large late release with any certainty. Further, we do not believe there is an urgent need for expending significant resources on such a task when public health and safety is assured through the implementation, testing of existing licensee programs, and the NRC oversight of those programs, that include public evacuation.

Option 2/Option 3 Interface

The document needs to articulate the interface between Option 2 to SECY 98-300 and Option 3 to SECY 98-300. Ultimately, Option 2 defines those safety-significant SSCs (RISC-1 and RISC-2 SSCs) that will be governed by risk-informed NRC technical requirements in a manner consistent with the safety-significance of the activity.

While Option 2 is still under development, the existing NRC proposals for low safety-significant SSCs (RISC-3 SSCs) indicate that such SSCs probably will be subject of a regulatory commitment to satisfy a performance monitoring program. Such a program will be sufficient to provide reasonable assurance that the required function will be satisfied. The performance thresholds for such a program have already been defined by the maintenance rule. The regulatory commitment is necessary to satisfy: a) existing specific NRC deterministic technical requirements that directly reference specific SSCs, or b) the licensee's safety analyses elements that are required by the existing deterministic regulations. Option 3 is intended to assess and, where appropriate, offer an alternative and improved risk-informed set of design bases. On completion of Option 3, RISC-3 SSCs will become RISC-4 SSCs, and will not be subject to NRC requirements.

Defense-in-Depth

The location of the "Defense-in-Depth" box in figure 2 is not understood.

The proposed NRC philosophy for defense-in-depth in a risk-informed regime appears to be practical, although further clarification is needed. We support the approach which retains the high level principles, yet provides for implementation based on the uncertainties in the evaluation process. However, the summary section when discussing defense-in-depth, states that the regulations will retain deterministic requirements. We find this confusing and clarification is necessary to ensure that the implementation of defense-in-depth is based on risk-insights and not overly influenced by established deterministic practices.

The proposed working level definition for defense-in-depth should be amended to emphasize a balanced approach that incorporates the general philosophy for defense-in-depth, yet is focused on, and governed by risk-insights in its application.

Rare Initiators

The discussion on rare initiators suggests that risk-informed regulation will not require plant structures, systems and components to be designed to address rare initiating events. Risk-informed regulation embodies both defense-in-depth and risk insights. As such, rare initiating events will be considered and, depending on

their significance (probability of occurrence and potential consequence) may be included in design activities.

Safety Margin

We do not understand the discussion on relationship between uncertainty and safety margin in Section 4. The need for safety margin is not clear when PRAs quantify uncertainties as reflected in their mean estimates. Some safety margin exists due to conservatism in selected safety acceptance criteria as represented by QHOs. Also, such conservatism has been identified in the framework document, "...safety margin exists due to conservatisms placed in acceptance criteria and methods for demonstrating compliance with acceptance criteria...."

Single Failure Criteria

In a risk-informed regulatory regime, the continuing need for single failure criteria is not understood. PRAs go beyond single failure and single events by considering multiple failures including, common cause and human error.

Quantitative Goals for Risk-Informing the Regulations

The individual quantitative goals, see *Figure 3,* in the lower categories (anticipated initiators, infrequent initiators, and rare initiators) could be too restrictive, if the overall objective is to be $\leq 10^{-6}$/yr. There could be various combination of the four columns that would result in a product $\leq 10^{-6}$/yr. For example, there may be accident initiating events that would meet the overall safety goal of 10^{-6}/yr, but the individual safety goals (associated with the four elements in *Figure 3*) may not be met.

- Specific example: SGTR in PWRs may have the following risk attributes as an infrequent initiator: $<10^{-2}$/yr $<10^{-3}$/yr, <1, and <0.1. Although, the overall 10^{-6}/yr goal is met, the containment effectiveness criterion may not be met.

  In addition, there may be initiating events for which the product of the first three terms in *Figure 3* would be $>10^{-4}$/yr while the last risk measure, i.e., the conditional early fatality probability may be $<10^{-2}$/yr (e.g., mid-loop operation during plant outage/shutdown conditions).

The framework should cover those anticipated events with frequencies >1 /yr such as reactor trip and turbine trip. *Figure 3* and *Table 2* do not cover such events.

The recommended safety goals in *Figure 3* should be flexible enough to be applicable to plant shutdown/low power conditions.

Assessment of Plant Changes

The relationship to the risk acceptance criteria in terms of changes in CDF and LERF as described in Regulatory Guide 1.174 should be included in the document to provide additional clarification and avoid misunderstandings. Cumulative risk impact evaluations (qualitative and quantitative) should be performed at periodic intervals consistent with the periodic update of the PRA. As necessary, individual changes should be assessed per the guidelines described in Regulatory Guide 1.174.

The framework document should clarify that risk evaluations for changes to low safety-significant SSCs (RISC-3 SSCs or RISC-4 SSCs) are not necessary. The periodic updates of the risk-evaluation model and conclusions, together with the monitoring of equipment under the maintenance rule and the NRC oversight process provide adequate indication of the impact on safety-significant activities from low safety-significant SSCs.

Regulatory Amendments

Improving the regulations through a risk-informed approach will result in an improved management focus on those matters that have safety significance. This will involve changes to both requirements and guidance documents. We acknowledge that such changes may be additions to, or elimination of existing requirements and guidance.

While the industry acknowledges that additions to guidance documents and requirements may become necessary, we recommend that an understanding be developed on the criteria for determining when additions are necessary. We support NRC suggestions made at the NRC February 24/25, 2000, for the development of an internal NRC process for control of regulatory requirements and guidance in an optional, risk-informed regulatory regime. Such a process, similar to that described in Section 50.109, *Backfitting,* would significantly improve industry appreciation of the need for any additional requirements and guidance that emanate from risk-informed improvements to the regulatory process. Confidence that such internal controls are being used will eliminate unnecessary and often extended interactions on such issues.

Schedules

It is important to set defined and practical schedules to ensure a decision point is reached in regard to improving the specific regulation under review. The NRC has set an aggressive schedule for addressing Section 50.44. Once there is a better understanding on the scope of potential Section 50.46 improvements a schedule should be developed to drive §50.46 to conclusion and for addressing improvements to other regulations, with priorities based in part on the conclusions from the §50.46

evaluations. Such action is central to good project management and will assist in avoiding the expenditure of resources on attaining a goal of technical utopia with total certainty.

Enclosure 2

Comments on NRC Draft Document on Risk-Informing 10 CFR 50.44,
Standards for combustible gas control systems in
light-water-cooled power reactors

In general, the document provides a good summary of 10 CFR 50.44, and its evolution. The document provides a good discussion on the inconsistencies in the regulations and the associated guidance documents relating to combustible gas controls. The draft document supports the NRC decision to use Section 50.44 as a test case for Option 3.

Basis for Risk-Informing Section 50.44

The industry believes that the NRC Safety Evaluation Report, dated September 3, 1999, approving the Southern California Edison (SCE), San Onofre Nuclear Generating Station exemption request on hydrogen recombiners provides sufficient basis for implementing improvements to Section 50.44. We support the conclusion in the report that the licensing actions with respect to the San Onofre hydrogen control system provide the generic bases for other pressurized water reactors with large, dry (including subatmospheric) containments. We also believe that the SER and previous NRC and industry evaluations provide a supporting element for justifying similar actions for other NSSS designs. The San Onofre decision reinforces previous evaluations that suggest the hydrogen recombiners are of minimal or no benefit.

The document also contains proposed statements that question the basis of some specific benefits stated in the San Onofre SER on hydrogen recombiners. Such statements are confusing and introduce unnecessary uncertainty into the process, and diminishes confidence in the predictability of the regulatory process. The SCE and NRC evaluations and the reviews of the San Onofre Emergency Operating Instructions (EOIs) by experienced station operators and NRC staff reached the conclusion that there is a positive benefit in simplifying the EOIs and removing the hydrogen recombiners. We do not understand the draft statements that now question such conclusions and the SER.

Igniters

The document appears to ignore previous regulatory interactions and conclusions associated with "glow-plug igniters." We do not understand the draft statements that suggest that glow-plug igniters may be necessary in large dry containments. Also, we reinforce comments that were made at the recent NRC Option 3 workshop, that a number of ice-condenser plants do not rely on hydrogen monitoring to

energize its igniters. They rely on other indications as described in their accident management procedures.

We do not understand the statements made in the section on ice-condenser plants that suggests that existing PRA analyses has identified hydrogen combustion as being a significant contributor to early containment failure from station blackout sequences. To our knowledge the majority of existing licensee PRA analyses for such plants do not support such a contention. If there are unique circumstances relating to one specific plant, such circumstances should not become the basis for additional generic risk-informed requirements. If there are additional and specific NRC studies that support these statements, we request that these be made available to licensees to achieve a better understanding of the basis for the comments and statements in the report.

Power Operated Relief Valves (PORVs)

Not all PWRS have PORVs. The statement that hydrogen could be released through PORVs into containment needs to be clarified to reflect varying industry plant configurations.

Long Term Actions to Avoid Late Release of Radionuclides

NUREG 1150 studies found that late releases are, at best, of second order effect in regard to latent fatalities. We acknowledge that a general qualitative assessment could be made, yet are uncertain as to the value of such an exercise, or the benefit since comparison against generic and realistic objective criteria is not feasible at this time. Long term actions relating to the prevention of late release are addressed in a licensee's severe accident management programs. (*Additional comments provided in Enclosure 1)*

Metal/Water Reactions

Item #6 in the mitigation of severe core degradation accidents in operating plants identified the need for plant specific containment analyses to assess the impact of hydrogen generation from a metal/water reaction involving 75% of the cladding surrounding the active fuel region. *Table 7.5, Additional Requirements for Plants with Large dry Containments,* also suggests that additional analyses are required. We suggest that the existing generic containment studies linked to various plant designs may obviate the need for such additional analyses.

Issues

BWR Mk III and PWR Ice Condensers

The NRC appears to have answered the issue linked to BWR Mark III and PWR ice condenser containments in a station blackout scenario. Such a scenario is, in general of low safety-significance. As such we maintain a more definitive statement needs to be made in regard to the "no need for further action" conclusion.

More Risk Significant Design Bases Analyses

We do not understand the issue associated with the need for more risk-significant design basis or risk-based accident for combustible gas concerns. The NRC SER on the San Onofre exemption request, which provides a generic bases for improving §50.44, indicates that the system is not safety-significant from a design basis or severe accident perspective.

Voluntary and Selective

The Commission in response to SECY 98-300 recognized the need for risk-informing NRC requirements to be a voluntary option. Also, the Commission acknowledged that a licensee could be selective in its adoption of risk-informed regulations. The selective element is subject to review, following experience in implementing, adopting, and regulating risk-informed regulations.

The backfit rule applies only to requirements being imposed by the NRC. The adoption of risk-informed regulation is a voluntary regulatory initiative. The industry agrees with the NRC statements made at the February NRC workshop on Risk-Informing NRC Technical Requirements, that administrative process guidance similar to the backfit rule should be adopted for addressing the addition of regulatory requirements and guidance for implementing risk-informed regulation, a voluntary licensee option. Such a process will ensure that "nice to have but not essential to the adequate protection of public health and safety" requirements and guidance are appropriately addressed.