

PR 50 and 53  
(71FR26267)



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DOCKETED  
USNRC

Ms. Annette L. Vietti-Cook  
Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

September 12, 2006 (12:23pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

**ATTN:** Rulemakings and Adjudications Staff

**SUBJECT:** Comments on Advance Notice of Proposed Rulemaking for 10 CFR Parts 50 and 53 – *Approaches to Risk-Informed and Performance Based Requirements for Nuclear Power Reactors* (71 Federal Register 26267, May 16, 2003)

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)<sup>1</sup> offers the following initial comments on the subject *Federal Register* notice, which solicited public comments on the advance notice of proposed rulemaking for a proposed 10 CFR Part 53. We would note the following with respect to the enclosed comments:

1. These initial comments were developed in advance of an NRC public meeting to be conducted on September 14 and 15, and are intended to facilitate dialogue. The final comments are due on December 29, 2006 and will represent the official position of NEI on this rulemaking.
2. These comments are based on the April 2006 version of the NRC proposal (reflected in the subject *Federal Register* Notice), and do not reflect consideration of the revised version of NUREG 1860 and appendices that were published by NRC on July 31.

<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.

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3. These comments do not address all 67 questions posed in the subject *Federal Register* Notice. A complete response will be provided following the September public meeting.

Please contact Biff Bradley at (202) 739-8083; [reb@nei.org](mailto:reb@nei.org) or me if you have any questions regarding these comments.

Sincerely,



Adrian P. Heymer

Enclosure

c: Document Control Desk

## **Initial Responses to Questions in ANPR for 10 CFR Part 53**

### **A. Plan**

**Question 1: Is the proposed plan to make a risk-informed and performance-based alternative to 10 CFR Part 50 reasonable? Is there a better approach than to create an entire new 10 CFR Part 53 to achieve a risk-informed and performance-based regulatory framework for nuclear power reactors? If yes, please describe the better approach?**

**Response:** NEI supports the continued development of a risk-informed and performance based revisions to 10 CFR Part 50. We also support the NRC's development of a Technology-Neutral Framework (TNF) to guide the development of regulatory requirements for new reactors. However, we believe that it is premature to write a new rule such as a new Part 53 until more experience is available in the licensing of new reactors, especially new non-LWRs. Rather than commencing with a new Part 53, it would be preferable to first gain experience with a design certification of new non-LWRs under Part 52 in which case the TNF could be used as guidance for deciding which parts of Part 50 to apply and which parts need exemptions. For licensing new reactors, especially non-LWRs, it is better to license one or more reactors under the current regulations and under the guidance of the TNF before developing a new rule. Drafts of technology-neutral rules could be developed and tested against non-LWR power reactor licensing and operational projects.

**Question 2: Are the objectives, as articulated above in the proposed plan section, understandable and achievable? If not, why not? Should there be additional objectives? If so, please describe the additional objectives and explain the reasons for including them.**

**Response:** The objectives are understandable, and should be achievable if the risk-informed and performance based alternative to 10 CFR Part 50 is not prescriptive, and properly balances the content of the rule language with regulatory guidance.

The Quantitative Health Objectives (QHOs) set an appropriate industry-wide level for safety performance expectations. The need for, and approach to developing surrogate goals, and the specific approach to addressing margins and defense-in-depth is best addressed on a design-specific basis. Qualitative principles are more appropriate for inclusion in rule language. Surrogates to QHOs and guidance for implementing QHOs on a design-specific basis (e.g., using a Frequency-Consequence function combined with DID and margin principles) are more appropriate for guidance documents (such as regulatory guides and standards). These guidance documents would provide a means to address design-specific

characteristics efficiently and reduce the undesired effect of developing requirements which are unnecessary, and possibly adverse, for a specific design.

**Question 3:** Would the approach described above in the proposed plan section accomplish the objectives? If not, why not and what changes to the approach would allow for accomplishing the objectives?

**Response:** See responses to questions 1 and 2. Before the technical basis can be completed, extensive testing is needed to confirm and/or modify, as appropriate, the technical bases. The approach would accomplish the objectives if Task 1 included the licensing of at least one new reactor that is not based on existing LWR technology because, until then, the generic versus reactor-specific requirements cannot be effectively determined..

**Question 4:** Would existing licensees be interested in using risk-informed and performance-based alternative regulations to 10 CFR Part 50 as their licensing basis? If not, why not? If so, please discuss the main reasons for doing so.

**Response:** At this stage, it is unlikely that there would be benefit for existing Part 50 licensees to convert to the alternative regulations. Success first needs to be demonstrated less comprehensive risk-informed rules, such as 10 CFR 50.69 and 10 CFR 50.46a, to enable confidence in these approaches.

**Question 5:** Should the alternative regulations be technology-neutral (i.e., applicable to all reactor technologies, e.g., light water reactor or gas cooled reactor), or be technology-specific? Please discuss the reasons for your answer. If technology-specific, which technologies should receive priority for development of alternative regulations?

**Response:** It is premature to develop a conclusion on the technology-neutral aspects of alternative regulations. See our response to question 2. We expect that areas where technology-specific design and operational features could significantly impact rule language (such as margins, DID, and confinement) would better be addressed in technology-specific rules or guidance. Before deciding on technology-neutral or technology-specific regulations, testing and modification of both the technical basis and draft rule language is appropriate.

**Question 6:** When would alternative regulations and supporting documents need to be in place to be of most benefit? Is it premature to initiate rulemaking for non-LWR technologies? If so, when should such an effort be undertaken? Could supporting guidance be developed later than the alternative regulations, e.g. phased in during plant licensing and construction?

Response: As we stated in response to question 2, once a draft set of rules has been evaluated against non-LWR licensing and operations, the rulemaking to finalize technology rules could commence. Policy statements relating to retention of fission products (containment/retention functional performance) and other DID considerations need to be developed to support prototype licensing under Part 52. Regarding the last question, the contents of the supporting guidance should be available before the end of the rulemaking. In addition, the rule language and draft guidance should have been tested, as a demonstration of the sufficiency and effectiveness or before finalizing the rule language. Guidance can be developed based on the experiences gained in the testing of the prototype.

Question 7: The NRC encourages active stakeholder participation through development of proposed supporting documents, standards, and guidance. In such a process, the proposed documents, standards, and guidance would be submitted to and reviewed by NRC staff, and the NRC staff could endorse them, if appropriate. Is there any interest by stakeholders to develop proposed supporting documents, standards or guidance? If so, please identify your organization and the specific documents, standards or guidance you are interested in taking the lead to develop?

Response: We believe stakeholders would support such participation.

#### **B. Integration of Safety, Security, and Emergency Preparedness**

Question 8: In developing the requirements for this alternative regulatory framework, how should safety, security, and emergency preparedness be integrated? Does the overall approach described in the technology-neutral framework clearly express the appropriate integration of safety, security, and preparedness? If not, how could it better do so?

Response: We do not believe the overall approach does an adequate job at describing the integration of security and emergency planning. For several reasons, we believe that some security and EP requirements would need to be developed exclusive of the framework. These reasons include:

Integration of security into the framework would appear to render public participation difficult, as the reactor safety and security provisions would be intertwined and subject to safeguards control.

Security is subject to ongoing rulemakings, five security rulemakings are currently in progress for operating reactors following 9-11. Integration of security into the framework would complicate this situation even further.

PRA methods are used primarily to address known accident initiators that can occur randomly and are amenable to statistical methods. Use of PRA methods to

address willful human misconduct would be premature, experimental, and subject to large uncertainties. Risk insights should be integrated into security but not through development of "security PRAs".

Question 9: What specific principles, concepts, features or performance standards for security would best achieve an integrated safety and security approach? How should they be expressed? How should they be measured?

Response: This question will be addressed in the final response to the ANPR.

Question 10: The NRC is considering rulemaking to require that safety and security be integrated so as to allow an easier and more thorough understanding of the effects that change in one area would have on the other and to ensure that changes with unacceptable impacts are not implemented. How can the safety-security interface be better integrated in design and operational requirements?

Response: This question will be addressed in the final response to the ANPR following discussion at the NRC workshop.

Question 11: Should security requirements be risk-informed? Why or why not? If so, what specific security requirements or analysis types would most benefit from the use of Probabilistic Risk Assessment (PRA) and how?

Response: Risk-informing of security requirements using PRA would be difficult due to uncertainties and issues of quantification. As discussed above, risk insights need to be incorporated in a general sense.

Question 12: Should emergency preparedness requirements be risk-informed? Why or why not? How should emergency preparedness requirements be modified to be better integrated with safety and security?

Response: Emergency preparedness should be made more risk-informed. The degree of emergency planning should be commensurate with the risk to public health and safety.

### C. Level of Safety

Question 13: Which of the options in SECY-05-0130 with respect to level of safety should be pursued and why? Are there alternative options? If so, please discuss the alternative options and their benefits.

Response: The Quantitative Health Objectives set an appropriate industry-wide level for safety performance expectations. The working draft report comments that the Level of Safety is anchored in the QHOs "embedded in the NRC's safety goal

(SG) policy statement.” Further, the Policy statement on “Regulation of Advanced Nuclear Power Plants” is referenced as expecting that advanced designs will provide enhanced margins of safety and will comply with the SG policy statement. The last paragraph of section 3.2.1, also comments, “All of these factors argue for the need to compensate for the significant uncertainties encountered in comparing the plant safety profile to the QHOs via the ‘margins’ implied in Figure 3-2 between adequate protection and the safety goals, and by the application of DID as discussed in Chapter 4 of this report.” We agree that margins and DID should be considered. However, the specific application of margins and DID to address uncertainties is better addressed on a design-specific basis, rather than by explicit elements and features in a technology-neutral framework of regulations. Regulatory guides will provide a means to address design-specific characteristics efficiently and reduce the undesired effect of developing requirements which are unnecessary for a specific design. Thus, the framework can address the need to consider these areas on a design-specific basis.

Question 14: Should the staff pursue developing subsidiary risk objectives? Why or why not? Are there other uses of subsidiary risk objectives that are not specified above? If so, what are they?

Response: Development of subsidiary objectives should be considered, as appropriate, when developing technology-specific guidance. The development of technology neutral subsidiary objectives, other than perhaps development of a complementary cumulative distribution function (CCDF) representing frequency versus consequence, provides challenges which are better addressed on a technology-specific basis. For example, CDF and LERF are not appropriate surrogates for certain designs using gas as a coolant, and there are no obvious, comparable performance measures for designs using gas as a coolant.

Question 15: Are the subsidiary risk objectives specified above reasonable surrogates for the QHOs for all reactor designs?

Response: No. In its SRM on SECY 03-0047, *Policy Issues Relating to Non-Light-Water Reactors*, the Commission approved the NRC staff’s recommendation on how to ensure that future non-light-water reactors would meet the safety expectations described in the Commission’s Advanced Reactor Policy Statement. The staff’s proposal mirrored the way the issue had been successfully addressed for light-water reactors. As a result, the industry remains confused as to why the issue is being raised again, almost 3 years after the Commission approved the NRC staff proposal in SECY 03-0047.

The proposed non-LWR surrogates for accident prevention and mitigation of  $10^{-5}$ /year and  $10^{-6}$ /year respectively are not consistent with the NRC staff’s 2003 proposals or the Commission’s directives on level of safety. It constitutes a

substantial departure from the Commission's directives on how to ensure an improved level of safety without specifically imposing such a level through regulation.

The industry supports the establishment of subsidiary objectives for non-light-water reactors based on the Safety Goals and Quantitative Health Objectives. Yet, until there is greater experience in operating and regulating non-light-water reactors, the framework should describe subsidiary objectives in plain language, rather than specific numerical values. Once we have more experience at operating non-light-water reactors and with advances in knowledge and technology, we may be able to evolve towards including specific probability numbers in the regulation.

Question 16: Should the latent fatality QHO be met by preventive measures alone without credit for mitigative measures or is this too restrictive?

Response: No, this approach is too restrictive and unnecessary.

Question 17: Are there other subsidiary risk objectives applicable to all reactor designs that should be considered? What are they and what would be their basis?

Response: Subsidiary risk objectives, based on a CCDF, as noted in our response to question 14, could be considered and may be able to be developed for applicability to all reactor designs.

Question 18: Should a mitigation goal be associated with the early fatality QHO or should it be set without credit for preventive measures (i.e., assuming major fuel damage has occurred)?

Response: A mitigation goal is too restrictive. Application of the QHOs combined with DID and margin are sufficient.

Question 19: Should other factors be considered in accident mitigation besides early fatalities, such as latent fatalities, late containment failure, land contamination, and property damage? If so, what should be the acceptance criteria and why?

Response: This would represent a departure from the approach of the current safety goal policy for operating plants and would fundamentally impact the risk informed process.



Question 20: Would a level 3 PRA analysis (i.e., one that includes calculation of offsite health and economic effects) still be needed if subsidiary risk objectives can be developed? For a specific technology, can practical subsidiary risk objectives be developed without the insights provided by level 3 PRAs?

Response: This depends on the subsidiary risk objectives and their corresponding bases. It appears possible that subsidiary risk objectives could be developed such that a level 3 PRA analysis would not be required. A level 3 PRA could then be used as a refinement to the subsidiary risk objectives on a plant-specific basis if needed, as appropriate. As we have noted in our other responses, technology-neutral subsidiary risk objectives do not exist and the development of subsidiary risk objectives might be better addressed on a technology-specific basis.

#### D. Integrated Risk

Question 21: Which of the options in SECY-05-0130 with respect to integrated risk should be pursued and why? Are there alternative options? If so, what are they?

Response: Option 2, "Quantification of integrated risk at the site from new reactors", should be pursued. NRC staff has typically considered risk on a per reactor basis, regardless of the number of reactors on a site, except for instances where a substantial number of common systems are associated with several reactors at a single site.

We agree with the staff position that for a site with several modular reactors, the assessment of public risk is more realistically determined by assessing the risk of all modules at the site. The risk from this group of reactors must be consistent with the Commission's Safety Goal Policy. Consequently, we agree that the integrated risk for multiple modules, where several small reactors are used to generate the electrical output equivalent to that of one large reactor, should be characterized by treating accident prevention independent of reactor power, while allowing reactor power to be considered in the assessment of risk measures related to accident mitigation. Applying this approach, modular reactor characteristics are realistically accounted for and safety requirements for each reactor are not more stringent than implied by the Safety Goal Policy, when considered on a per plant basis.

Consistent with the above statements, NEI believes that a single license should be issued for plants having multiple modules, where the definition of a plant is based on the language proposed in the Price-Anderson legislation, which would allow a set of modular reactors to be treated as a single unit with a combined rated capacity of up to 1300 MW.

Question 22: Should the integrated risk from multiple reactors be considered? Why or why not?

Response: See response to Question 21.

Question 23: If integrated risk should be considered, should the risk meet a minimum threshold specified in the regulations? Why or why not?

Response: See response to Question 21.

#### **E. ACRS Views on Level of Safety and Integrated Risk**

Question 24: Should the views raised in the ACRS letter and by various members of the Committee be factored into the resolution of the issues of level of safety and integrated risk? Why or why not?

Response: We note that some of the proposals contained in the ACRS letter are in conflict with our comments above on the use of CDF and LERF for new reactor designs. Further, the ACRS letter included the suggestion of elevation of CDF and LRF as fundamental goals, which we do not believe is necessary or appropriate. Additional details will be provided later, in the NEI final set of comments, following the NRC workshop and public interactions.

#### **F. Containment Functional Performance Standards**

Question 25: How should containment be defined and what are its safety functions? Are the safety functions different for different designs? If so, how?

Response: The industry believes that functional performance requirements and criteria for containment should be developed on a technology-neutral basis. Consequently, the fission product barrier function should be viewed as a plant wide function and not necessarily limited to a pre-determined set of physical barriers or SSCs. The fission product barrier may not necessarily manifest itself as a pressure-retaining structure. In other words, the differences in performance requirements among plant designs should reflect differences in designers' integrated approaches, but reach the same end point in regard to fission product retention.

Containment functional performance requirements should be stated at a high level in the framework, with codified design specific functional performance requirements in design specific Regulatory Guides.

NEI further believes that risk informed insights for each design type will determine the level of risk to be protected against. Design-specific risk considerations will eliminate costly technology solutions based on non-mechanistic events that result in

unnecessary plant design features which could be counterproductive to more realistic accident mitigation. Options proposed in the framework should not impose solutions which result in additional technology to support source term calculations and design related enhancements involving incremental costs.

NEI recommends that the criteria for containment performance specify that functions must adequately reduce exposures to the public to meet onsite and offsite radionuclide dose acceptance criteria for the events selected in the event categories.

The issue of how to best define fission product retention functions emphasizes the need to evaluate draft technology neutral requirements and guidance against actual non-LWR designs during the licensing and initial prototype operation.

**Question 26:** Should the containment functional performance standards be design and technology specific? Why or why not?

**Response:** See response to Question 25.

**Question 27:** What approach should be taken to develop technology-neutral containment performance standards that would be applicable to all reactor designs and technologies? Should containment performance be defined in terms of the integrated performance capability of all mechanistic barriers to radiological release or in terms of the performance capability of a means of limiting or controlling radiological releases separate from the fuel and reactor pressure boundary barriers?

**Response:** See response to Question 25.

**Question 28:** What plant physical security functions should be associated with containment and what should be the related functional performance standards?

**Response:** Will respond in final comment package.

**Question 29:** How should PRA information and insights be combined with traditional deterministic approaches and DID in establishing the proposed containment functional performance requirements and criteria for controlling radiological releases?

**Response:** Will respond in final comment package.

Question 30: How should the rare events in the range  $10^{-4}$  to  $10^{-7}$  per year be considered in developing the containment functional performance requirements and criteria? Should events less than  $10^{-7}$  per year in frequency be considered in developing the containment functional performance requirements and criteria?

Response: This question can not be answered without first defining the term "event."

#### G. Technology-Neutral Framework

Question 31: Is the overall top-down organization of the framework, as illustrated in Figure 2-6 a suitable approach to organize the approach for licensing new reactors? Does it meet the objectives and principles of Chapter 1? Can you describe a better way to organize a new licensing process?

Response: Will respond in final comment package.

Question 32: Do you agree that the framework should now be applied to a specific reactor design? If not, why not? Which reactor design concept would you recommend?

Response: Yes, the framework should be tested using a design for which the calculated risk profile, margin, and DID characteristics are well established, or can be readily established. The testing should consider the full spectrum of potential initiating events and sequences. This includes normal operation, AOOs, DBEs, BDBEs, and severe accidents. We would recommend the following order for testing:

- First, an operating LWR, as the preponderance of experience, models, and results exists for these reactors;
- Second, if possible, a gas cooled reactor, as this type is more likely to benefit from an alternative to Part 50.

Question 33: The unified safety concept used in the framework is meant to derive regulations from the Safety Goals and other safety principles (e.g., DID). Does this approach result in the proper integration of reactor regulations and staff processes and programs such that regulatory coherence is achieved? If not, why not?

Response: Will respond in final comment package.

Question 34: The framework is proposing an approach for the technical basis for an alternative risk-informed and performance-based 10 CFR Part 50. The scope of 10 CFR Part 50 includes sources of radioactive material from reactor and spent fuel pool operations. Similarly, the framework is intended to apply to this same scope. Is it clear that the framework is intended to apply to all of these sources? If not, how should the framework be revised to make this intention clear?

Response: Yes, this is clear.

Question 35: What role should the following factors play in integrating emergency preparedness requirements (as contained in 10 CFR 50.47) in the overall framework for future plants:

- The range of accidents that should be considered?
- The extent of DID?
- Operating experience?
- Federal, state, and local authority input and acceptance?
- Public acceptance?
- Security-related events?

Response: Our responses regarding integration of emergency preparedness into the framework will be provided as part of our final comment package.

Question 36: What should the emergency preparedness requirements for future plants be? Should they be technology-specific or generic regardless of the reactor type?

Response: Our responses regarding integration of emergency preparedness into the framework will be provided as part of our final comment package.

Question 37: Is the approach used in the framework for how DID treats uncertainties well described and reasonable? If not, how should it be improved?

Response: The approach lacks clarity. In this draft, the discussion on DID, design criteria, and protective strategies are interdependent. For example, both DID and protective strategies address prevention and mitigation, using different language. We suggest NRC develop a simple tabulation demonstrating the inter-relationship of these three elements of the framework document.

NEI acknowledges that DID is a fundamental concept for treating uncertainties in advanced reactor designs. In order to effectively determine DID requirements however, protective strategies should be analyzed both individually, as well as an integrated set so as to accurately determine overall DID requirements.

Furthermore, the framework model should be tested against a licensed LWR design to determine its overall effectiveness.

NEI believes that additional dialogue is necessary before a practical, technology-neutral approach and description of DID requirements can be developed. We will provide more detailed comments in our final comment package.

**Question 38:** Are the DID principles discussed in the framework clearly stated? If not, how could they be better stated? Are additional principles needed? If so, what would they be? Is one or more of the stated principles unnecessary? If so, which principles are unnecessary and why are they unnecessary?

**Response:** See response to question 37.

**Question 39:** The framework emphasizes that sufficient margins are an essential part of DID measures. The framework also provides some quantitative margin guidance with respect to LBEs in Chapter 6. Should the framework provide more quantitative guidance on margins in general in a technology-neutral way? What would be the nature of this guidance?

**Response:** Will respond in final comment package.

**Question 40:** The framework stresses that all of the Protective Strategies must be included in the design of a new reactor but it does not discuss the relative emphasis placed on each strategy compared to the others. Are there any conditions under which any of these protective strategies would not be necessary? Should the framework contain guidelines as to the relative importance of each strategy to the whole DID application?

**Response:** Unlikely to first question. No to second question.

**Question 41: Are the protective strategies well enough defined in terms of the challenges they defend against? If not, why not? Are there challenges not protected by these five protective strategies? If so, what would they be?**

**Response:** Protective Strategies are straightforward and reasonable. In this draft, the discussion on DID, design criteria, and protective strategies are interdependent. For example, both DID and protective strategies address prevention and mitigation, using different language. We suggest NRC develop a simple tabulation demonstrating the inter-relationship of these three elements of the framework document.

**Question 42: Is the approach to and the basis for the selection LBEs reasonable? If not, why not? Is the cut-off for the rare event frequency at  $1E-7$  per year acceptable? If not, why not? Should the cut-off be extended to a lower frequency?**

**Response:** Conceptually the approach is reasonable. As discussed in our responses to previous comments, testing and comparisons to the results expected and achieved for existing and advanced LWRs is needed. The discussion on aggregating event sequences to develop LBEs is not clear. In addition, determining a cut-off frequency for the "rare event" can not be determined without first defining the terms "event" and "rare." Finally, as provided in our responses to previous questions a CCDF approach to frequency versus consequences should be considered before determining cut-off frequency values, if any, for "events", "events sequences", and "hazards."

**Question 43: Is the approach used to select and to safety classify structures, systems, and components reasonable? If not, what would be a better approach?**

**Response:** Conceptually, the approach appears reasonable but is not clear. For example, it would appear that SSCs needed to maintain the frequency of a sequence below the corresponding value on the frequency consequence (F-C) curve would be classified as risk significant and therefore equivalent to "safety class". This is expected to be more restrictive than the approaches used today.

**Question 44: Is the approach and basis to the construction of the proposed F-C curve reasonable? If not, why not?**

**Response:** The use of an F-C curve as a designer's aid is understandable and merits additional consideration. Sections 3.2.2 and 6 do not provide a complete, understandable basis for the frequency or consequence values and the points which define the curve. Further, without a defined process for using the curve, we do not understand how a basis for establishing the function and the values for the function can be developed. As discussed previously, a CCDF should be considered. A CCDF could also be used as a surrogate, similar to the use of CDF and LERF as surrogates for the QHOs for existing LWRs.

Question 45: Are the deterministic criteria proposed for the LBEs in the various frequency categories reasonable from the standpoint of assuring an adequate safety margin? In particular, are the deterministic dose criteria for the LBEs in the infrequent and rare categories reasonable? If not, why not?

Response: Will respond in final comment package.

Question 46: Is it reasonable to use a 95% confidence value for the mechanistic source term for both the PRA sequences and the sequences designated as LBEs to provide margin for uncertainty? If not, why not? Is it reasonable to use a conservative approach for dispersion to calculate doses? If not, why not?

Response: Will respond in final comment package.

Question 47: The approach proposed in the framework does not predefine a set of LBEs to be addressed in the design. The LBEs are plant specific. They are identified and selected from the risk-significant events based on the plant-specific PRA. Because the plant design and operation may change over time, the risk-significant events may change over time. The licensee would be required to periodically reassess the risk of the plant and, as a result, the LBEs may change. This reassessment could be performed under a process similar to the process under 10 CFR 50.59. Is this approach reasonable? If not, why not?

Response: Will respond in final comment package.

Question 48: The framework provides guidance for a technically acceptable full-scope PRA. Is the scope and level of detail reasonable? If not, why not? Should it be expanded and if so, in what way?

Response: Will respond in final comment package.

Question 49: Because a PRA (including the supporting analyses) will be used in the licensing process, should it be subject to a 10 CFR Part 50 Appendix B approach to quality assurance? If not, why not?

Response: Not all requirements of 10 CFR Part 50 Appendix B (as interpreted through subsidiary documents for operating plants) are practical or necessary for application to PRA. NRC Regulatory Guide 1.174 provides a discussion of the elements of Appendix B that would generally be applicable to the PRA.

Question 50: Is this process clear, understandable, and adequate? If not, why not? What should be done differently?



Response: Will respond in final comment package.

Question 51: Is the use of logic diagrams to identify the topics that need to be addressed in the requirements reasonable? If not, what should be used?

Response: Will respond in final comment package.

Question 52: Is the list of topics identified for the requirements adequate? Is the list complete? If not, what should be changed (added, deleted, modified) and why?

Response: Will respond in final comment package.

Question 53: A completeness check was made on the topics for which requirements need to be developed for the new 10 CFR Part 53 (identified in Chapter 8) by comparing them to 10 CFR Part 50, NEI 02-02, and the International Atomic Energy Agency (IAEA) safety standards for design and operation. Are there other completeness checks that should be made? If so, what should they be?

Response: Will respond in final comment package.

Question 54: The results of the completeness check comparison are provided in Appendix G. The comparison identified a number of areas that are not addressed by the topics but that are covered in the IAEA standards. Should these areas be included in the framework? If so, why should they be included? If not, why not?

Response: Will respond in final comment package.

#### H. Defense-in-depth (DID)

Question 55: Would development of a better description of DID be of any benefit to current operating plants, near-term designs or future designs? Why or why not? If so, please discuss any specific benefits.

Response: As discussed in our responses to other questions, there is interdependence in the draft framework among DID, protective strategies, and design criteria. We recommend that NRC first clarify this interdependence.

Question 56: If the NRC undertakes developing a better description of DID, would it be more effective and efficient to incorporate it into the Commission's Policy Statement on PRA or should it be provided in a separate policy statement? Why?

Response: This definition should be incorporated into a separate policy statement. The concept of DID is not limited to PRA applicability. Further, NRC has established de facto definitions of this concept and applied them to operating plants, so any such policy statement should either be consistent with past definitions or made applicable to Part 53 only.

Question 57: RG 1.174 assumes that adequate DID exists and provides guidance for ensuring it is not significantly degraded by a change to the licensing basis. Should RG 1.174 be revised to include a better description of DID? Why or why not? If so, would a change to RG 1.174 be sufficient instead of a policy statement? Why or why not?

Response: This question is not limited to Part 53. Changes to RG 1.174 would affect all operating plants. We do not believe it is necessary to revise RG 1.174 in this regard. See response to previous question.

Question 58: How should DID be addressed for new plants?

Response: Will respond in final comment package.

Question 59: Should development of a better description of DID (whether as a new policy statement, a revision to the PRA policy statement or as an update to RG 1.174) be completed on the same schedule as 10 CFR Part 53? Why or why not?

Response: Will respond in final comment package.

## I. Single Failure Criterion

Question 60: Are the proposed options reasonable? If not, why not?

Response: We support Alternative 1 in which the SFC is effectively eliminated and replaced by a more general approach in which the frequency and consequences of each LBE are taken into account and there are no arbitrary redundancy requirements.

Question 61: Are there other options for risk-informing the SFC? If so, please discuss these options.

Response: Based on the above response, we do not believe the SFC should be maintained.

**Question 62: Which option, if any, should be considered?**

**Response:** Based on the above response, we do not believe the SFC should be maintained.

**Question 63: Should changes to the SFC in 10 CFR Part 50 be pursued separate from or as a part of the effort to create a new 10 CFR Part 53? Why or why not?**

**Response:** Will respond in final comment package.

#### **J. Continue Individual Rulemakings to Risk-Inform 10 CFR Part 50**

**Question 64: Should the NRC continue with the ongoing current rulemaking efforts and not undertake any effort to risk-inform other regulations in 10 CFR Part 50 or should the NRC undertake new risk-informed rulemaking on a case-by-case priority basis? Why?**

**Response:** If current rulemaking efforts (10 CFR 50.69, 10 CFR 50.46a) lead to successful implementation, additional efforts should be considered.

**Question 65: If the NRC were to undertake new risk-informed rulemakings, which regulations would be the most beneficial to revise? What would be the anticipated safety benefits?**

**Response:** Will respond in final comment package.

**Question 66: In addition to revising specific regulations, are there any particular regulations that do not need to be revised, but whose associated regulatory guidance documents, could be revised to be more risk-informed and performance-based? What are the safety benefits associated with revising these guides? Which ones in particular are stakeholders interested in having revised and why?**

**Response:** Will respond in final comment package.

**Question 67: If additional regulations and/or associated regulatory guidance documents were to be revised, when should the NRC initiate these efforts, e.g., immediately or after having started implementation of current risk-informed 10 CFR Part 50 regulations?**

**Response:** See response to Question 64 above.

**From:** "HEYMER, Adrian" <aph@nei.org>  
**To:** <avc@nrc.gov>  
**Date:** Mon, Sep 11, 2006 3:13 PM  
**Subject:** Comments on Advance Notice of Proposed Rulemaking for 10 CFR Parts 50 & 53

September 11, 2006

Ms. Annette L. Vietti-Cook

Secretary

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

**ATTN:** Rulemakings and Adjudications Staff

**SUBJECT:** Comments on Advance Notice of Proposed Rulemaking for 10 CFR Parts 50 and 53 - Approaches to Risk-Informed and Performance Based Requirements for Nuclear Power Reactors (71 Federal Register 26267, May 16, 2003)

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)[1] offers the following initial comments on the subject Federal Register notice, which solicited public comments on the advance notice of proposed rulemaking for a proposed 10 CFR Part 53. We would note the following with respect to the enclosed comments:

1. These initial comments were developed in advance of an NRC public meeting to be conducted on September 14 and 15, and are intended to facilitate dialogue. The final comments are due on December 29, 2006 and will represent the official position of NEI on this rulemaking.

2. These comments are based on the April 2006 version of the NRC proposal (reflected in the subject Federal Register Notice), and do not reflect consideration of the revised version of NUREG 1860 and appendices that were published by NRC on July 31.

3. These comments do not address all 67 questions posed in the subject Federal Register Notice. A complete response will be provided following the September public meeting.

Please contact Biff Bradley at (202) 739-8083; reb@nei.org or me if you have any questions regarding these comments.

Sincerely,

Adrian P. Heymer

Enclosure

c: Document Control Desk

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[1] 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.

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**From:** Annette Vietti-Cook  
**To:** Billie Champ; Evangeline Ngbea; Linda Mike  
**Date:** Mon, Sep 11, 2006 4:45 PM  
**Subject:** Fwd: Comments on Advance Notice of Proposed Rulemaking for 10 CFR Parts 50 & 53

Billie could you make sure this gets in RF, even though this is a docket item. Note there is a meeting Sept. 14-15 where they intend to discuss.

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