PR 50 and 53
(71FR26267)

NUCLEAR ENERGY INSTITUTE

(9)

DOCKETED
USNRC

December 28, 2006 (4:30pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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December 28, 2006

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

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)*

PROJECT NUMBER: 689

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)[1] offers the following 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. These comments amplify the initial industry comments submitted on September 8, 2006.

The NRC has provided a good start to a technology-neutral, risk-informed regulatory framework. The essential elements of have been captured, yet the framework needs further development. It should be evaluated against a non-LWR design certification and licensing proceeding prior to finalizing the new regulations. We will continue to support the development of these regulations.

The Enclosure provides our detailed comments and responses to the questions listed in the *Federal Register*. If there are questions on these comments, please contact me at 202-739-8094; aph@nei.org or Biff Bradley at 202-739-8083; reb@nei.org.

Sincerely,

Ap. Heymer

Adrian P. Heymer

Enclosure

c. Mr. William Borchardt, NRC
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[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.

Template = SECY-067 SECY-02

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 risk-informed and performance based revisions to 10 CFR Part 50. Also, 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 would be premature to finalize a new rule such as a new Part 53 until more experience is available in the licensing of new reactors, especially new non-LWRs. We believe that going forward there should be a five-step approach:

1. Develop a preliminary draft rule based on the responses to the Advanced Notice of Rulemaking questions.
2. Once an application is received for a non-LWR design approval/certification, publish the draft for information.
3. Review and approve a non-LWR design using a Part 50-Part 52 approach
4. Evaluate the preliminary rule and comments against the non-LWR design that is being approved in step 2 for comments.
5. Update and publish the draft rule for comment

In the assessment approach above, 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 assess the draft rule and 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-technology specific basis. Qualitative principles are more appropriate for inclusion in rule language. Surrogates to QHOs and guidance for implementing QHOs on a design-technology 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 assessment 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 for 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, Defense-in-Depth (DID), and confinement) would better be addressed in technology-specific rules or guidance. Before deciding on technology-neutral or technology-specific regulations, assessment and amendment of both the technical basis and draft rule language should be performed.

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 neutral or specific rules could commence. Policy statements relating to retention of fission products (containment/retention functional performance) and other DID considerations need to be developed to prior to prototype licensing under Part 52. Regarding the last question, 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 their sufficiency and effectiveness, before finalizing the rule language. Guidance can be developed based on the experience gained in the assessment process.

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: The industry 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: The approach for dealing with safety and security should be based on the experience in developing regulations and implementation for the existing reactors. For current reactors, adjustments are being made to the existing regulations to better integrate security, emergency preparedness and safety provisions. At this point, we believe that some security and EP requirements would need to be developed exclusive of the framework. The reasons include:

1. 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.

2. Security is the subject of ongoing rulemakings; five security rulemakings are currently in progress. Until these rulemakings are complete, it would premature to attempt integration of security into the proposed framework.

3. 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 <u>insights</u> 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?

We believe the existing requirements developed for Part 73 and Part 52 should be applied, rather than an integration of security and safety into the same framework. Features of advanced designs, such as smaller source terms, may lend themselves to inherent improvement relative to potential impacts from security events. See point 3 in the response to question 8 above.

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?

See response to question 9 above.

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, and is unnecessary. As discussed above, risk insights need to be incorporated in a general sense. Also, the inherent safety benefits of the new designs should be factored into the security requirements.

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. Risk insights could be used to establish a new risk informed basis, and margin for an EPZ, and to re-evaluate the level of EP offsite response required recognizing the probability of the events. Risk insights should be used to define smarter protective action strategies e.g., evacuation, sheltering in certain situations, improved traffic control.

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 next to 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 possibly 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.

Quantitative Health Objectives (QHOs) and a Frequency-Consequence (F-C) function (dose vs. frequency of an event sequence or event sequence group) are key quantitative criteria for determining safety adequacy in the NRC framework. The F-C function is based on the principle that the frequency of an event sequence should decrease as the consequences of the event sequence increase. The F-C function and process for using the function can be viewed as a subsidiary risk objective, if the function and process can be demonstrated to meet the QHOs and the intent of the Safety Goal Policy Statements. As we discuss further in response to Question 30 we recommend NRC consider development of a CCDF for frequency versus consequences.

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. In addition, such as approach creates unnecessary uncertainty in the definitions for prevention and mitigation. Although there is considerable experience in establishing common terminology for LWRs, the approach to defining prevention and mitigation for use in characterizing latent and acute effects for non-LWRs is unclear.

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. Also see our response to Question 30.

Question18: 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: No. A mitigation goal is too restrictive. Application of the QHOs combined with DID and margin are sufficient. Also see our response to question 16.

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: No. 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 analyses 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 should be considered based a technology-specific basis.

Consequence analyses would still be required to demonstrate acceptance limits are met (e.g. 10 CFR Part 100 and the F-C function limits).

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. Due to the potential for staggered construction times of the modules, we would propose a "hybrid" license that has two parts: 1) license provisions applicable to all modules; and 2) license provisions (such as duration) that are applicable to each individual module.

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.

Subject to addressing our comments and additional testing and refinement, the approach in the draft framework (using QHOs, an F-C function and process, LBE identification and DID (including margins)) to establish the safety case appears able to address the level of safety views raised in the ACRS letter. See our response to Question 21 for integrated risk.

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.

The industry 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.

We recommend 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?

For some designs, containment can perform two functions; the pressure retention function, as well as a barrier to external challenges, such as intentional events. For other designs, these functions could be accomplished through independent means. For example, some designs may locate plants below grade to address specific physical security functions.

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: The approach described for LBE identification and deterministic defense-in-depth (see Table 6-3 of the draft framework document) is a reasonable starting point as this approach addresses the complete design capability, in addition to containment functional performance. Subject to the limitations of F-C functions and the process for using them, the frequency categories are judged to be reasonable. The frequency categories are also reasonably consistent with existing practices. We view the DID criteria in the draft framework as example acceptance criteria. Additional effort is needed to formally develop a comprehensive set of acceptance criteria and fully document the technical basis for them. Subject to this perspective, our review concluded the example DID criteria are reasonably consistent with current practices. However, specific features for DID and safety margin are most likely best addressed on a design-specific basis. Please see our response to Questions 42 for additional comments on LBEs.

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 cannot be answered without first defining the term "event." In addition this question can not be addressed without providing our perspective on the F-C function and process included in the draft framework, so this perspective is provided here. A definitive response to this question cannot be provided until the issues raised below are addressed.

The use of an F-C function could improve upon the practices used for currently operating plants, and perhaps on the practices used for the certified ALWR designs. The limitations of an F-C function, however, appear to have not been fully addressed in the draft framework. If an F-C function will be employed to serve as a licensing basis, the limitations associated with the development of the F-C function and the process for using it must be addressed. Issues and limitations identified include the following:

- Developing a basis for the frequency for a specific consequence level.

  It is unclear how an F-C function can be developed independent of the process for using the function and without reliance on an acceptable risk profile. The F-C function included in the draft framework appears reasonable, and can most likely be improved by considering the capabilities of currently operating plants. The consequence values have a basis but the frequency values are based on judgment. Since an objective of advanced nuclear power plants will be to demonstrate they will operate at a level of safety that meets or exceeds that of current LWR technology, future work should develop a revised F-C function and process that possess these characteristics.

- Event sequence definition.

  In the draft framework, the requirements for event sequence definition are not entirely clear. For example, for a specific initiating event there are several means to display a sequence which results in a comparable consequence level. A sequence displayed at the basic event level would have a lower frequency than if aggregated at the system or function level. For the framework to serve as an acceptable licensing basis, this issue needs to be addressed. The development of an F-C function must consider the process for using the function. Event sequences should be defined consistent with their use in the F-C process and on the basis of the F-C function. The draft framework recognizes this issue, and states that "The specific level of detail... will be determined in the technology specific Regulatory Guides."

- Initiating event definition.

  Defining an initiating event has challenges similar to the definition of event sequences. In particular, the question of to what level of detail should any IE be defined needs to be addressed. As an explicit example, the process should provide a method of specifying how many fire initiating events should be used (e.g. one representing the total plant fire frequency, frequency by room, etc.). As another example, the process should provide guidance on specifying how many transient IEs should be used (e.g. define at system level, train level, etc.) As another example, how would external hazards, such as earthquakes and tornadoes be addressed? This is likely to be technology-specific.

  The NRC draft framework recognizes this issue and includes a provision for cumulative limits on IE frequency for each LBE event sequence category. However, this does not fully address the issue. Similar to defining an event sequence, research needs to be performed to develop a consensus process to define IEs.

- Aggregate risk.

  Since the F-C function treats sequences, or groups of sequences, and not the aggregate risk profile resulting from the sequences, a method of evaluating the aggregate risk profile is required. Sole reliance on the QHOs is not sufficient to achieve this objective. The draft framework recognizes this feature of the QHOs and applies other integrated risk acceptance criteria. A CCDF, or other means, should be considered. A simple table top exercise would demonstrate that if the number of sequences which populate the F-C function is not limited then an unacceptable risk profile would be allowed.

- Requiring every sequence to meet the F-C function limits does not appear to be a reasonable approach to providing a licensing basis that assures adequate plant safety.

  In the framework, if any one sequence is above the F-C limit (regardless of its postulated frequency), the design is considered unacceptable, whereas, if the same event is just below the limiting value of the F-C function, the design is acceptable. This application of a "hard acceptance threshold" provides limited flexibility to both the regulatory authority and reactor designers. Rather than treating individual, or groups of, sequences, as needing to always meet the F-C limits, a CCDF should be used. In this manner the benefits of an F-C function are preserved, but an unnecessary limitation is removed. Use of a CCDF would also address event sequence, initiating events and external hazard modeling issue. In addition, it could address several of the views raised by ACRS.

A new, reference F-C function and process should be developed that integrates and improves on the example F-C function in the framework. The F-C function developed should consider the issues and actions discussed above, to reach a consensus framework that addresses the interests of all stakeholders. Such a function should also address one of the ACRS views on the limits on the use of the QHOs.

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: Yes, Figure 2-6 is reasonable.

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: The approach in the draft framework has the potential to achieve regulatory coherence. However, the issues we have raised in our responses to the questions in this ANPR must first be addressed. After these issues are addressed and draft rule language and guidance documents have been developed and fully tested, we will be able to provide a definitive response to this question.

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?

All of the above factors could play a role in integrating EP requirements into the framework. New designs are likely to have enhanced defense in depth, and smaller source terms, both of which could lead to margin relative to EPZ considerations. Risk insights could form the basis for defining smarter protective action strategies (PAS) that have the potential to significantly reduce public risk from a range of accidents

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

See response to Question 35 above. We do not believe that technology-specific emergency preparedness requirements would be practical, and that these requirements should be maintained on a generic level.

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.

The industry acknowledges that DID is a fundamental concept for treating uncertainties. 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.

We conducted a review and a simple table top exercise to identify an alternative means to discuss DID. Below is a summary. We believe that additional dialogue is necessary before a practical, technology-neutral approach and description of DID requirements can be developed.

The structure of the draft NRC framework is based on the following:

- A set of safety/security/preparedness expectations, which are ensured
- By Defense-in-Depth expectations, which are fulfilled
- By a set of protective strategies and certain design criteria and guidance, which are used
- In a process for the development of licensing requirements.

In the draft NRC framework, the following Defense-in-Depth principles were established:

1. Consideration of intentional (e.g. security-related) as well as inadvertent (e.g., random failure of SSCs and human error) events,
2. Providing both accident prevention and mitigation capability,
3. Ensuring key safety functions (KSFs) are not dependent upon a single element of design, construction, maintenance or operation,
4. Consideration of uncertainties in equipment and human performance,
5. Providing for alternative capability to prevent unacceptable releases, and
6. Siting considerations.

The report notes that DID principles would be applied regardless of the level of safety determined using a PRA. This approach provides a (qualitative) means to address uncertainties and corresponds to good engineering practice developed over several decades of LWR operation. Since an underlying principle of the NRC framework is that accident prevention alone cannot be relied upon to reach an acceptable level of safety, capabilities to mitigate accidents (item 5 above) are also required in this framework. This resulted in the identification of the following protective strategies:

1. Provide physical protection from hazards (e.g., radiological and chemical) for workers and public,
2. Ensure stable operation by limiting the frequency of events that can upset plant stability and challenge safety functions,
3. Provide adequate protective mitigation systems (by providing sufficiently available, reliable and capable SSCs, including human actions, on the basis of the frequency of challenge and the significance of the challenge),
4. Ensure barrier integrity (by providing adequate barriers for workers and public),
5. Develop effective protective actions (by providing accident management capability and emergency planning)

The two principle deterministic DID elements of the framework are implementation of the protective strategies and the DID principles. The probabilistic Defense-in-Depth element of the framework is the use of PRA techniques and other logical processes to search for and identify unexpected scenarios, to address uncertainty, and to further assure adequate DID, including adequate safety margin.

The above description of DID in the draft framework is understandable, but appears to refer to all aspects of design and operation as DID. Here modest changes are identified for consideration. The result retains all of the relevant features but reorganizes the description of DID.

First, we tabulated protective strategies and DID elements. Next, by grouping protective strategies and DID elements, an alternative view to Design Principles and DID Principles was established. In this view the Protective Strategies and DID elements have been grouped into nine Design and Defense-in-Depth Principles.

- **Design Principle and DID:** Barrier integrity (adequate barriers for workers and public - physical and chemical[1]).
- **Design Principle:** Physical protection (workers and public).
- **Design Principle:** Stable operation (limit frequency of events that can upset plant stability and challenge safety functions).
- **Design Principle:** Siting considerations.
- **Design Principle:** Accident prevention and mitigation capability (Includes Protective Actions - emergency procedures, accident management and emergency preparedness).

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[1]Regulation relative to barriers for chemicals should be limited to "chemicals involving licensed materials or produced from licensed materials" similar to the provisions in 10 CFR 70.61. NRC has no legal jurisdiction over chemical hazards per se (which are the responsibility of OSHA and EPA).

- **Design Principle:** Consideration of uncertainties in equipment and human performance.
- **Design Principle:** Monitoring and Feedback.
- **DID:** Ensuring key safety functions (KSFs) are not dependent upon a single element of design, construction, maintenance or operation.
- **DID:** Alternative capability to prevent unacceptable releases consistent with the inherent characteristics of the design.

The expectations, defense-in-depth principles and protective strategies in the draft framework are addressed by the above nine principles. With the above organization there are two DID principles; one principle, which includes both design and DID principles; and 6 design principles.

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: The discussion in Chapter 6 is sufficient. Additional guidance would be appropriate for technology-specific regulatory guides.

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 the first question. No, to second question. The NRC draft framework is based on development of a set of safety expectations (e.g. QHOs and an F-C function); which are ensured by application of defense-in-depth (DID) principles using a set of protective strategies and corresponding design criteria. As we have noted there is interdependence in the elements of this approach, so we recommend NRC consider combining the expectations, principles and corresponding criteria into fundamental technology neutral safety and associated design principles (FSPs and FDPs).

This distinction is intended to establish and apply common terminology which addresses each of the above elements. FSPs and FDPs provide the underlying basis on which the proposed licensing framework ensures adequate plant safety. In this structure, FSPs provide the nuclear safety objective which is to be achieved. Associated with each FSP is a corresponding FDP that provides mechanisms by which achievement of the FSP can be demonstrated. A table top exercise was conducted to develop a preliminary set of FSP / FDP combination. A review of these FSPs / FDPs demonstrates that they provide a structured and comprehensive set of candidate principles from which the proposed licensing process can ensure adequate nuclear safety levels.

Eleven preliminary, candidate FSPs with their corresponding FDP and relationship to similar elements contained in the draft NRC framework are discussed in Table 1. A list of the FSPs and an abbreviated description is provided below.

FSP-1: Quantitative Health Objectives (QHOs) and the intent of the Safety Goal Policy Statement shall be met with margin.
FSP-2: Allowable consequences shall decrease as the frequency of events increases and shall be demonstrated to be equal to or better than the current generation of plants.
FSP-3: Stable plant operation shall be achieved.
FSP-4: The number of barriers and the integrity of each specific barrier shall be sufficient to meet the QHO, F-C and operational stability requirements specified in FSPs 1, 2 and 3, respectively.
FSP-5: Accident prevention and mitigation, consistent with inherent safety characteristics, shall be addressed to meet the QHO, F-C and operational stability requirements specified in FSPs 1, 2 and 3, respectively.
FSP-6: Key Safety Functions (KSFs), consistent with inherent safety characteristics, shall not be dependent on a single element of design, construction, maintenance or operation.
FSP-7: Site selection shall consider hazards, emergency response impediments and environmental considerations.
FSP-8: Uncertainties in analyses, in equipment and human performance, and in plant response shall be considered in the assessments that demonstrate the FSPs / FDPs are achieved.
FSP-9: Operating limits and practices shall be established to provide assurance that operating conditions are within the bounds of the plant design and corresponding analysis requirements and assumptions.
FSP-10: Emergency plans and procedures shall be developed and demonstrated to be effective in mitigating the potential impacts of events.
FSP-11: Operating experience shall be used to confirm design and analysis assumptions and modify plant design and/or operating practices as appropriate.

We recommend NRC develop consensus Fundamental Safety and Design Principles to improve interactions with all stakeholders and to assist in reaching agreement on the most challenging elements in the framework.

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. Please see our response to Questions 37 and 40.

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: Please see our response to Question 30 which addresses individual sequences. 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." 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."

Assuming the issue of cut-off frequency is addressed, the key uncertainty in using the approach is expected to be the decisions which will be required to determine event sequence groups. As discussed above the purpose and approach to grouping should be clarified.

Use of a 95% confidence level for consequence appears reasonable for the frequent and infrequent categories (NRC proposes quantitative definitions for these categories at a sequence level. We believe these specific values should not be designated at this point in rule development. Following further experience, appropriate values can be defined prior to issuance of the final rule.) The use of a 95% confidence level for consequence for the rare category appears to be overly restrictive. We propose that mean values be used for the rare event categories.

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 may be 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. The approach to identifying safety significant SSCs, which could cause an initiating event, is not fully developed, and is not specifically addressed. Instead, a living PRA is used and target frequencies for initiating event categories are considered in the NRC developed framework. It is recommended that an approach to evaluating initiating events be developed. The approach could consider practices that currently are applied to operating LWRs (e.g. in SSC classification for the Maintenance Rule 10CFR 50.65).

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

Response: Please see our response to Question 30. The use of an F-C curve to design decisions 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

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: The example deterministic criteria from the draft framework provide a reasonable initial approach. We view the criteria as examples, which are not necessarily applicable for all technologies. Specific deterministic criteria are not appropriate for a regulation. The criteria are best addressed in regulatory guidance. Additional development and testing is warranted to:

- Compare the results which would be achieved using this approach to those obtained from application of existing practices.
- Specifically address how other DID principles in the draft framework would be addressed.
- Address the broad range in the infrequent category where allowable consequences very significantly.
- Consider the implications of varying technologies.

The deterministic dose criteria are reasonable, but additional testing is needed.

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: Mean results are appropriate for comparison to the QHOs and F-C limits. However, conservative analyses should be permitted as an alternative when their application would not impact the conclusions obtained. This alternative could support more efficiency in both the analysis and regulatory review process.

For LBEs, use of a 95% confidence level for consequence appears reasonable for the frequent and infrequent categories (NRC proposes quantitative definitions for these categories at a sequence level. We believe these specific values should not be designated at this point in rule development. Following further experience, appropriate values can be defined prior to issuance of the final rule.) The use of a 95% confidence level for consequence for the rare category appears to be overly restrictive. We propose that mean values be used for the rare event categories.

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: As the LBEs are developed on the basis of PRA and deterministic practices, and subjected to both applicant and NRC review, we expect the potential for changes to "risk-significant events" over time to be small and manageable. A process, similar to the processes used to address 50.59, but based on the acceptance criteria applied in the risk-informed, performance based approach, will be appropriate. The metrics and process would need to be developed on the basis of the acceptance criteria established for a specific design and its application, and the definition of a LBE for a specific design. For example, CDF and LERF may not apply and certainly do not apply to 50.59. Assessments to demonstrate that the LBEs remain below the F-C limits and meet other deterministic criteria may be the metrics which are similar to the intent of 50.59.

A process and criteria should be developed and tested during the licensing application of a specific design.

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: PRA is used extensively. The acceptability of the guidance will best be determined by testing, possibly a limited test. Issues we identified are as follows:

- "Other Risk Evaluations": The NRC draft framework uses a full scope PRA. "Other risk evaluations" refers to risk evaluations which are not fully quantitative, such as the PRA-based seismic margins approach used for the certified, advanced designs. We believe that certain hazards and operating modes might be better, or sufficiently, addressed using approaches and methods other than PRA that are not fully quantitative. We recommend establishing approaches, similar to those used for ALWR designs certified using 10 CFR Part 52, for addressing hazards such as seismic and other external hazards where PRA is not needed to demonstrate an adequate safety case.
- PRA for AOOs: AOOs are anticipated events. All hazards at a plant site are to be addressed in the frameworks under development. Some hazards may have such minor potential consequences that the quantitative frequency of an AOO or DBE is not important. That is, the hazard can be treatment deterministically. Certain AOOs may have such small potential consequences that modeling with PRA techniques will be unnecessary. The framework should be enhanced to allow for such screening.

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: The process appears reasonable. The process needs to be tested on an actual design to identify where improvements are warranted.

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: The use of logic diagrams is reasonable. Note that the same logical process could be communicated in a list or tabulation.

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: The list appears reasonable. This question can be better addressed after testing.

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: The completeness check is reasonable. This question is also better addressed when the process is tested.

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: A justification should be provided. Again, as we have noted in our responses to previous questions, testing is needed to identify and address any issues with the process.

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: Please see our responses to Questions 37 and 45.

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: The development of a better description should be completed on a schedule which supports a pilot study in which a TNF is tested on an actual non-LWR design certification application.

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?

These changes should be pursued separately. Some changes to the SFC for existing plants have already been proposed through the 10 CFR 50.46a rulemaking, which would exempt SFC for certain improbable events (very large pipe breaks).

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?

It is difficult to identify new risk-informed rulemakings until success is demonstrated with the existing efforts (see response to question above). Once the implementation and benefits of existing efforts are realized and understood, clarification of future direction will be possible.

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: In general, it is difficult to provide risk-informed modifications to Regulatory Guides if the underlying regulations are deterministic. This was demonstrated through Regulatory Guide 1.175, which attempted to risk-informed 10 CFR 50 Appendix B. We have not identified further regulatory guides for consideration at this time. Again, this would be dependent on demonstration of success of current regulatory reform efforts.

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.

Table 1: Fundamental Safety and Design Principles

FSP-1: Quantitative Health Objectives (QHOs)

FSP: Quantitative Health Objectives (QHOs) and the Safety Goal Policy Statement shall be met with margin. In this framework, the QHOs provide one measure of nuclear safety risk. The objective is that plants licensed under this framework should possess equal or reduced levels of risk compared to the current generation of operating plants. In addition, the spectrum of hazards, sequences and consequences, shall be addressed, and not be limited to sequences that are beyond those specified in the design basis.

FDP: A PRA and other risk evaluations, of sufficient scope and quality that appropriately consider uncertainties shall be performed. This analysis shall evaluate a complete spectrum of hazards over all plant operating modes. The resulting spectrum of consequences shall be compared to the QHOs to demonstrate this FSP is achieved.

Relationship to NRC Framework: This FSP/FDP is equivalent to similar criteria in the proposed framework, with one exception. Here, we allow for the use of "other risk evaluations," rather than a full PRA. This change is intended to allow alternatives, such as a PRA-based margins approach for seismic events that are appropriate to assess hazards that are characterized by considerable uncertainty and for which a blended approach rather than a full PRA, might be preferable and adequate. This is consistent with the regulatory guidance which is anticipated to be issued in early 2007 for applying for a combined operating license (COL) using 10 CFR Part 52.

FSP-2: Frequency-Consequence (F-C) Relationship

FSP: Allowable consequences shall decrease as the frequency of events increases. Risk, as determined using consequences compared to the anticipated event frequency shall be demonstrated to be equal to or reduced compared to the current generation of operating plants. This analysis shall evaluate the complete spectrum of hazards, sequences and consequences. In particular, the analysis shall not be limited to sequences that are beyond those specified in the design basis.

FDP: Frequency consequence relationship(s) and processes shall be developed. The results of the PRA and other risk evaluations shall be used to demonstrate this FSP is achieved on an aggregate basis, e.g., by using a complementary cumulative distribution function (CCDF) for frequency versus consequences.

Relationship to NRC Framework: This FSP/FDP also is equivalent to similar criteria in the NRC framework, with the following exceptions. We added "equal to or reduced compared to current generation of operating plants" and "...CCDF.." This language is included to provide assurance that a plant designed and licensed using a new framework has a defendable technical basis for concluding that the safety level is equal to or better than the current generation of operating plants. The NRC framework does not provide a clear basis for supporting this desired conclusion.

FSP-3: Operational Stability

FSP: Stable plant operation shall be achieved; the frequency of events that can upset plant stability and challenge safety functions shall be limited.

FDP: The design shall meet a total initiating event frequency goal that is determined to provide an adequate level of public safety. An initiating event which results in releases exceeding ALARA principles should not be expected during a plant's lifetime. Additionally, challenges to safety systems should be minimized consistent with the potential safety significance of the challenge.

Relationship to NRC Framework: This FSP/FDP is equivalent to similar criteria in the NRC framework, but has been expanded to include an ALARA criterion.

Table 1: Fundamental Safety and Design Principles

FSP-4: Barrier Defense in Depth (DID)

FSP: To assure sufficient DID, the number of barriers and the integrity of each specific barrier (when combined) shall be sufficient to meet the QHO, F-C and operational stability requirements specified in FSPs 1, 2 and 3, respectively. The capability of barriers designed to prevent radioactive material release shall increase as the frequency of events which could challenge the barriers increases.

FDP: Barrier failure leading to significant radioactive material release shall not be expected during the lifetime of a plant. At least one barrier shall be available to mitigate a potentially significant release for events that have a reasonable probability of occurring during the lifetime of a fleet of plants.

Relationship to NRC Framework: This FSP/FDP is equivalent to similar criteria in the NRC framework.

FSP-5: Accident Prevention and Mitigation

FSP: Accident prevention and mitigation, consistent with inherent safety characteristics, shall be addressed to assure FSPs 1-4 are achieved. Reliance on accident prevention alone is not sufficient; strategies and systems shall be put in place such that effective mitigation actions can be performed to maintain nuclear safety during abnormal plant conditions to a high degree of confidence. In the design of protective systems, plant response, including human actions, shall be demonstrated to be sufficiently available, reliable, and capable of ensuring adequate safety margins are maintained.

FDP: The plant design shall be demonstrated to have sufficient mitigation capability, consistent with inherent safety characteristics, with the assumption that the SSCs intended to prevent a BDBE have failed to perform their intended functions. The availability, reliability and capability of the SSCs intended to prevent and mitigate accidents shall be demonstrated to be acceptable with respect to meeting FSPs/FDPs 1–4. SSCs designed to provide accident prevention and mitigation capabilities shall receive treatment and monitoring appropriate to their safety significance. In selecting SSCs and developing monitoring and feedback processes, the potential causes of degraded reliability or capability (such as design errors, human errors and common cause failures) shall be addressed.

Relationship to NRC Framework: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework. We have included "consistent with inherent safety characteristics" to acknowledge that certain designs may have inherent characteristics which are significantly different than currently operating light water reactors.

FSP-6: Key Safety Function (KSF) Defense in Depth (DID)

FSP: Key Safety Functions (KSFs), consistent with inherent safety characteristics, shall not be dependent on a single element of design, construction, maintenance or operation.

FDP: To ensure sufficient DID is achieved, no KSF, consistent with inherent safety characteristics, shall be dependent on a single element (either physical SSC or associated human action). Additionally, hazards, such as fire, flooding, and seismic events, shall not prevent KSFs from achieving their intended objectives of ensuring FSPs 1-5.

Relationship to NRC Framework: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework. We have included "consistent with inherent safety characteristics" to acknowledge that certain designs may have inherent characteristics which are significantly different than currently operating light water reactors.

FSP- 7: Siting

FSP: Site selection shall consider hazards, emergency response impediments and environmental considerations.

FDP: Natural and man made hazards shall be considered and demonstrated to be acceptable with respect to meeting FSPs/FDPs 1-6. Siting decisions shall address emergency response capabilities and impediments and environmental considerations. In addition, siting decisions should consider the acceptability of routine operations, in addition to off-normal occurrences such as AOOs, DBEs and BDBEs.

Table 1: Fundamental Safety and Design Principles

Relationship to NRC Framework: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework.

FSP-8: Consideration of Uncertainties

FSP: Uncertainties in analyses, in equipment and human performance, and in plant response (e.g., lack of operational experience, type and magnitude of challenges, and physical, chemical and aging phenomena) shall be considered in the assessments that demonstrate the FSPs / FDPs are achieved.
FDP: To ensure sufficient safety margins, appropriate uncertainties shall be identified and explicitly addressed or bounded, so as to provide assurance that FSPs 1-6 are achieved. The margin appropriate to address applicable uncertainties shall be identified and included within the design and operating requirements.
Relationship to NRC Framework: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework.

FSP 9: Operating Limits and Practices

FSP: Operating limits and practices shall be established to provide assurance that operating conditions are within the bounds of the plant design and corresponding analysis requirements and assumptions, including allowances for analysis and monitoring uncertainties and response to conditions which could place the plant outside these bounds.
FDP: Operating limits (e.g., Limiting Conditions for Operation (LCOs)) shall be established which are based on plant design and corresponding analysis requirements and assumptions. Limits shall consider uncertainties in analyses and monitoring capability. Operating practices shall be established to implement these limits and to respond to conditions which could result in operating outside of them. These practices include operating procedures, abnormal response procedures, and emergency procedures.
Relationship to Frameworks Reviewed: This FSP/FDP is equivalent to similar requirements provided in the NRC framework, and is consistent with current practice.

FSP-10: Emergency Preparedness

FSP: Emergency plans and procedures shall be developed and demonstrated to be effective in mitigating the potential impacts of events.
FDP: Emergency plans and emergency procedures (such as accident management guidelines) shall be developed, which consider the comprehensive use of installed SSCs and human intervention, coordination with regulatory and government agencies, and access to resources (human and SSCs) outside the plant.
Relationship to NRC Framework: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework.

FSP-11: Monitoring and Feedback

FSP: Operating experience shall be used to confirm design and analysis assumptions and modify plant design and/or operating practices as appropriate.
FDP: The design shall provide for monitoring of SSCs at a level commensurate to their safety importance. Operating practices, including a reliability assurance program, shall be established so as to support effective monitoring and to provide feedback into decision making.
Relationship to Frameworks Reviewed: This FSP/FDP is equivalent to, and basically a summary of similar requirements provided in the NRC framework.

From: "HEYMER, Adrian" <aph@nei.org>
To: <avc@nrc.gov>
Date: Thu, Dec 28, 2006 3:25 PM
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)

December 28, 2006

Ms. Annette L. Vietti-Cook

Secretary

Rulemakings and Adjudications Staff

U.S. Nuclear Regulatory Commission

Washington, DC 20555-0001

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)

PROJECT NUMBER: 689

Dear Ms. Vietti-Cook:

The Nuclear Energy Institute (NEI)[1] offers the following 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. These comments amplify the initial industry comments submitted on September 8, 2006.

The NRC has provided a good start to a technology-neutral, risk-informed regulatory framework. The essential elements of have been captured, yet the framework needs further development. It should be evaluated against a non-LWR design certification and licensing proceeding prior to finalizing the new regulations. We will continue to support the development of these regulations.

The Enclosure provides our detailed comments and responses to the questions listed in the Federal Register. If there are questions on these comments, please contact me at 202-739-8094; aph@nei.org or Biff Bradley at 202-739-8083; reb@nei.org.

Sincerely,

Adrian P. Heymer

Senior Director, New Plant Deployment

Nuclear Generation Division

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Enclosure

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[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.

Mail Envelope Properties (45942826.155 : 19 : 4437)

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)
Creation Date Thu, Dec 28, 2006 3:27 PM
From: "HEYMER, Adrian" <aph@nei.org>

Created By: aph@nei.org

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