ASME
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CODES & STANDARDS

Three Park Avenue
New York, NY
10016-5990 · U.S.A.

tel 1.212.591.8500
fax 1.212.591.8501
www.asme.org

PR 50 and 53
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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

(11)

December 27, 2006

Secretary, U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Subject: Comments on Advanced Notice of Public Rulemaking to Make 10 CFR 50 Requirements Risk-Informed and Performance-Based

References:
1. Proposed Rules, *Federal Register, Vol. 71, No. 86, pp. 26267-26275*, May 4, 2006.
2. Letter from Kenneth R. Balkey, Vice President, ASME Nuclear Codes and Standards, to Secretary, U.S. Nuclear Regulatory Commission, dated August 25, 2006.

Dear Secretary:

The ASME Codes and Standards Board of Directors recognizes the benefit of performance-based standards and has had an initiative for a number of years to replace prescriptive codes and standards with performance-based codes and standards. As stated in our previous letter (Reference 2), ASME believes that the U.S. Nuclear Regulatory Commission should move forward with developing a new risk-informed performance-based Part 53 as an alternative to 10 CFR Part 50 for licensing future nuclear power plants. ASME submitted its general comments to the subject Advanced Notice of Public Rulemaking (ANPR) per Reference 2. The enclosure to this letter provides detailed comments on behalf of the ASME Board on Nuclear Codes and Standards and its Standards Committees to address specific questions within each subject area of the ANPR. The body of this letter summarizes our most significant comments.

1. The U.S. Nuclear Regulatory Commission (NRC) should maintain a high priority on supporting the licensing and certification of the next generation of light water reactors (LWRs). Development of the new Part 53 should not detract from development of standards and timely, technically sound decisions needed to support the nuclear steam supply system vendors and nuclear plant owners who are committed to building the next fleet of plants.

2. The NRC should allow the use of the existing 10 CFR 50.69 risk-informed regulations and related codes & standards to be applied, where appropriate, to

Template = SECY-067

SECY-02

designs of the next generation of advanced LWRs within the existing licensing process.

3. Although these proposed new rules are likely to be reactor technology neutral, applicability of the new Part 53 should be focused on the early Gen IV designs such as the High Temperature Gas Cooled Reactors and should be benchmarked against the safety levels of LWRs.

4. A phased approach to development of the new Part 53 should be considered. Development of a plan that integrates Part 53 development activities with on-going licensing and certification activities over a multi-year timeline is recommended. The plan should be prioritized to support industry and regulatory needs.

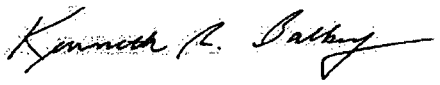
5. ASME does not agree with the treatment of Safety Margin as the sum of Design Margin + Regulatory Margin. In addition, the distribution curves being used to explain this concept address the tails and not the intersections of the probability curves. This proposed treatment is not consistent with the ASME codes and standards approach for addressing margins.

6. ASME has been working with the developers of new reactor technologies to determine changes in ASME Nuclear Codes & Standards to address their needs.
   (1) Several of ASME Nuclear Codes and Standards are technology neutral and can be directly applied to all types of reactor systems with little or no change including: (a) nuclear quality assurance, (b) cranes for nuclear facilities, (c) nuclear air and gas treatment, (d) nuclear accreditation, and (e) qualification of mechanical equipment.
   (2) Several ASME Nuclear Codes and Standards will require significant new technical additions including design approaches, material additions, inspection rules & criteria, and operating standards to address new reactor needs including: (a) Section III of the ASME Boiler & Pressure Vessel (B&PV) Code for nuclear components, (b) Section XI of the ASME B&PV Code for in-service inspection, (c) risk assessment standards, and (d) operation and maintenance codes.
   (3) There are significant additional areas that will require close interaction between NRC, other standards development organizations and ASME to determine where some specific rules and guidance would best be defined including: (a) definition of required safety goals, (b) risk objectives to achieve safety goals, (c) safety classification of components, and (d) defense-in-depth and single failure criterion rules.

ASME is working with stakeholders to address items (1) and (2) above. For item (3), ASME is prepared to work with the NRC and other standards development organizations on a concept for the new rules that will be required and to determine where best those rules should reside (Federal Regulations, NRC Requirements, NRC guidance documents or National Codes or Standards). It is ASME's opinion that detailed technical and programmatic requirements should be in national standards while rules and policy belong in the regulations and regulatory guidance documents.

Thank you for the opportunity to comment on this initiative. If there are any questions regarding these comments, please direct them to Mr. Kevin Ennis, ASME Director, Nuclear Codes and Standards by phone (212-591-7075) or e-mail (ennisk@asme.org).

Very Truly Yours,



Kenneth R. Balkey
Vice President
Nuclear Codes and Standards

cc: Members, ASME Board on Nuclear Codes and Standards
Members, ASME BNCS Risk Management Task Group
Members, ASME Committee on Nuclear Risk Management
Members, Nuclear Risk Management Coordinating Committee

ENCLOSURE

ASME Response to NRC ANPR for Risk-Informed Performance-Based 10 CFR Part 53

ANPR Question	ASME BNCS Response
A. Plan	
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?	The proposed approach for establishing a risk-informed performance-based (RI-PB) alternative to 10 CFR Part 50 for the design and licensing of new reactor designs is reasonable. ASME does not have a better approach to suggest. However, in our response to Question 2, we believe there is benefit in developing a side-by-side comparison of Part 50 to the new Part 53.
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.	The objectives are reasonable and achievable. An additional objective would be to establish means to demonstrate that an equivalent level of safety is achieved. A useful tool for establishing equivalency would be a matrix with three columns. Column 1 would be paragraphs from Part 50. Column 2 would identify changes to each paragraph of Part 50 appropriate for RI-PB provisions for advanced light water reactors (LWRs). Column 3 would identify generic RI-PB changes appropriate for Gen IV advanced reactors. This approach would illustrate what is retained, what is to be changed, and what is to be added. The tool would help identify benefits as well as avoid deletion of important considerations. It also could help establish equivalent level of safety to better achieve understanding and acceptance, and perhaps identify improvements for Part 50.
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?	It is possible to achieve the goal using a variety of approaches. ASME recommends development in phases so that review and acceptance is performed in a stepwise fashion. A stepwise approach is more effective because the relationship to the current practice is easier to demonstrate. See our response to Question 5 for description of phases.
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.	ASME cannot speak for existing licensees. However, ASME believes that existing licensees would not be interested because they already have risk-informed initiatives through the current licensing process. ASME has worked with a number of licensees in development of risk-informed inservice inspection, inservice testing, and repair/replacement initiatives through the current Part 50 and 50.69 processes. In addition, ASME has ongoing initiatives for risk-informed safety classification and probabilistic design methods that would be applicable to construction of new nuclear facilities.

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?	Technology-neutral is a good ultimate objective. It can support and build on near term RI-PB applications. While the near term gas cooled reactor (GCR) designs are advanced over previously licensed GCR's, the previous designs provide a base from which advanced design safety requirements can evolve. In turn, these near term GCR designs form a basis for developing a technology specific RI-PB licensing basis that could then be extended as a technology neutral framework for other design concepts.
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?	ASME does not believe that currently certified advanced LWR designs and those expected to be certified in the next few years will apply to use the alternative process. Therefore, and as discussed in our response to both Questions 3 and 5, ASME recommends a phased approach with near term focus on pebble bed modular reactor (PBMR) and GCR designs. Alternative regulations and supporting documents, including codes and standards, should be in place prior to docketing of any license application. Changes during construction should be avoided.
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?	ASME has been working with the developers of new reactor technologies to determine changes in ASME Nuclear Codes & Standards to address their needs. (1) Several ASME Nuclear Codes & Standards are technology-neutral and can be directly applied to all types of reactor systems with little or no change including: (a) nuclear quality assurance, (b) cranes for nuclear facilities, (c) nuclear air & gas treatment, (d) nuclear accreditation, and (e) qualification of mechanical equipment. (2) Other ASME Nuclear Codes & Standards will require significant new technical additions including design approaches, material additions, inspection rules & criteria, and operating standards to address new reactor needs including: (a) Section III of ASME Boiler & Pressure Vessel (B&PV) Code for Nuclear Components, (b) Section XI of ASME B&PV Code for in-service inspection, (c) risk assessment standards, and (d) operation and maintenance codes. (3) There are significant additional areas that will require close interaction between NRC, other standards development organizations (SDOs), and ASME to determine where some specific rules and guidance would best be defined including: (a) definition of required safety goals, (b) risk objectives to achieve safety goals, (c) safety classification of components, and (d) defense-in-depth and single failure criterion rules. ASME is working with its stakeholders to address Items (1) and (2) above. For item (3), ASME is prepared to work with the NRC and other SDOs on a concept

	for the new rules that will be required and to determine where best those rules should reside (Federal Regulations, NRC Requirements, NRC guidance documents or National Code or Standard). It is ASME's opinion that detailed technical and programmatic requirements should be national standards while rules and policy belong in the regulations and regulatory guidance documents.
B. Integration of Safety, Security, and Emergency Preparedness	
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?	New reactor designs need to address results and insights from safety risk analysis, security risk evaluations, and emergency preparedness planning. Because of uncertainties in probabilities for security risks, integration of safety and security risk models and calculations is premature, but close coordination of these evaluations is necessary. Integration of safety risk and security risk, at this time, would not be beneficial for two reasons: (1) the risk objectives are different and (2) the current rule making for site security is very active and needs to be followed through to completion to have a stable set of security requirements for the future plants. Efforts should continue to link emergency planning with both safety risk and security risk.
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?	As stated in our response to Question 8, ASME believes it is premature to integrate safety and security from a probabilistic risk assessment (PRA) perspective but, the two should be closely coordinated so that plant features and operational and administrative controls addressing these risks are compatible and complimentary. See also our response to Question 10.
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 changes 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?	The safety-security interface can be better integrated in design and operational requirements by incorporating features from safety risk analysis models into security risk evaluations. Furthermore, physical and procedural modifications that are made for new reactor designs for security considerations can be factored into safety enhancements as well. Plant design and operational features should evolve as an iterative process between the safety and security evaluations. Criteria need to be established, however, to determine how to address conflicts that may arise from the safety and security evaluations.
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?	Security requirements should be risk-informed particularly to delineate certain incredible, low probability threat events from further consideration. Vulnerability assessments of new reactor designs benefit much from use of results and insights from PRAs performed specifically to address security considerations. However, PRAs for security risks with large uncertainty in probability are mainly beneficial in a comparative sense for risk ranking and prioritization.

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?	Emergency preparedness requirements should be risk-informed, particularly to plan for credible low or moderate probability events with modest to large consequences. Emergency preparedness requirements should be modified in a similar fashion as for physical and procedural plant modifications - i.e., an iterative process between the safety and security evaluations. Once again, criteria need to be established, however, to determine how to address conflicts that may arise in modifying emergency preparedness requirements from the safety and security evaluations.
C. Level of Safety	
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.	The existing NRC Quality Health Objectives (QHOs) are an appropriate basis for establishing the minimum level of safety, and thereby, the objectives for design requirements are also appropriate for new reactors regardless of technology. Hence, ASME concurs with the NRC Staff's selection of Option 2 in SECY-05-0130 as a reasonable approach for establishing a framework for the design and licensing of new reactor designs. As new technologies are considered, it may be appropriate and necessary to define technology-specific risk strategies and subsidiary risk objectives for use within this framework.
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?	Use of QHOs to define an acceptable level of safety implies, in the absence of a technology- or applicant-specific alternative safety case, development of a full PRA capable of estimating offsite consequences (e.g., equivalent to an LWR Level 3 PRA). However, it may be difficult to effectively use a full PRA directly in making design, licensing, and, ultimately, operational decisions. Therefore, an approach for establishing appropriate margins to the QHO will need to be established, implying the need for subsidiary risk objectives. Further, it may be difficult to establish technology-neutral subsidiary risk metrics. Given the difficulties in communicating risk in terms of public fatalities and in making safe operational decisions on this basis, development of either technology-specific subsidiary risk objectives or technology-neutral subsidiary objectives (and some means for relating them across technologies) should be a high priority for a RI-PB technology-neutral regulatory process. NRC establishing appropriate subsidiary risk objectives is a necessary part of establishing appropriate Nuclear Codes and Standards for use in developing new reactor designs.
15. Are the subsidiary risk objectives specified above reasonable surrogates for the QHOs for all reactor designs?	Please refer to ASME's response to Question 14. Either NRC technology-specific subsidiary risk objectives or technology-neutral risk objectives, including a framework for relating these objectives to various technologies, will likely be needed. Once established, the subsidiary risk objectives can be used to define new-technology design criteria that reflect appropriate safety margins to ensure that new plants meet the QHOs.

16. Should the latent fatality QHO be met by preventive measures alone without credit for mitigative measures, or is this too restrictive?	A truly risk-informed regulatory approach requires the consideration not only of the possible adverse consequences of an endeavor (e.g., latent fatalities) but also the likelihood of occurrence of those potential consequences. Specifically, with respect to latent fatalities, some consideration should be given by NRC to address the likelihood that extremely low levels of exposure pose little or no risk, contrary to the linear dose/response assumptions. While separate subsidiary risk objectives may be defined for accident prevention (e.g., core damage frequency for LWRs, which essentially measures prevention) and mitigation (e.g., large early release frequency for LWRs, which essentially measures mitigation), it is possible that for a particular technology a more integrated subsidiary measure may be defined. In any case, these measures are necessarily related. Given that the QHO are the ultimate criteria, there is no need to establish a general requirement that no credit be taken for mitigation or prevention in meeting the QHO in a risk-informed approach. Failure to account for the expected response of a design to the events that challenge normal operation implies a deterministic rather than a risk-informed approach. Further, this could lead to irrational design requirements, and impractical codes and standards.
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?	As noted in other ASME responses, it may be possible for NRC to define technology-neutral subsidiary risk objectives. However, from a practical perspective, it should be expected that technology-specific subsidiary risk objectives will need to be developed based on technology-specific, scientific and engineering considerations.
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)?	See ASME response to Question 16.
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?	The NRC QHO and subsidiary measures provide the appropriate metrics for risk-informed regulatory attention. Imposing objectives for land or property damage does not add to the ability to achieve minimal public health and safety risk. While it would be interesting to know how the risk to land or property from a given industry (e.g., commercial nuclear power) measures up against the risks from other industries (e.g., chemical processing, transportation, commercial agriculture), there is currently no meaningful way to make such comparisons and no valid means for setting limits of acceptability. Therefore, additional risk metrics for land contamination or property damage should not be established until an appropriate context is available for their use. Other regulatory approaches are available for protection of land and property. Establishing appropriate subsidiary risk objectives for early and late fatalities provides the requisite safety relationship to the QHO, and an appropriate set of criteria on which to base codes and standards for design and operation of facilities.

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?	As noted in the ASME response to Question 19, calculation of offsite economic effects should not be an objective until such time as meaningful comparisons can be made relative to economic effects of other human endeavors. In a technology-neutral context, it will be difficult for NRC to establish universally applicable subsidiary risk metrics. A Level 3 PRA provides a least common denominator in relation to the QHOs, and such an analysis for health effects will likely be needed, at least for each technology, to help define the subsidiary objectives. However, given the difficulties in communicating risk in terms of public fatalities, development of technology-specific subsidiary risk objectives should be a high priority objective within the regulatory process.
D. Integrated Risk	
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?	See ASME response to Question 22.
22. Should the integrated risk from multiple reactors be considered? Why or why not?	The overall risk to the public for multiple reactors at a given site cannot be ignored if there are significant events that could cause simultaneous severe accidents. However, this overall risk evaluation should not include the contributions from existing reactors at the same site, unless the licensee desires to reduce existing emergency planning or exclusion boundaries. Including these plants would essentially require backfit of a full scope PRA on the existing plant.
23. If integrated risk should be considered, should the risk meet a minimum threshold specified in the regulations? Why or why not?	See ASME response to Question 22.
E. ACRS Views on Level of Safety and Integrated Risk	
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?	See ASME responses to questions in Parts C and D.

F. Containment Functional Performance Standards	
25. *How should containment be defined and what are its safety* functions? Are the safety functions different for different designs? If so, how?	*The containment system safety function, for any technology, is to prevent the* release of fission products to the environment. The performance rules should address the containment "system" not just the containment structure. The enclosure building around the reactor is only one component of the system. The 10CFR50 rules have always dealt with the containment system as a whole. The safety function of the containment system is to prevent the dispersion of radiological releases. The safety function of the reactor enclosure building containment for LWRs are likely different for other plant designs.
26. Should the containment functional performance standards be design and technology specific? Why or why not?	Containment functional performance standards should reflect performance *sufficient to ensure that NRC QHO and subsidiary objectives are met, with* appropriate defense-in-depth features and safety margins applied. The design specifications of the enclosure building would vary depending on the design of the reactor type and the containment system functional expectations of the enclosure building. ASME would publish standards for steel or concrete enclosures buildings that would define specifications for the design and fabrication to meet the functional performance required (leak tightness and strength).
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?	The radiological release level probabilities should be technology-neutral. The containment system for each reactor design relies on a number of components and system performance, and the performance expectations for the enclosure building will be unique to each reactor design. For example, some designs may rely more on a predefined level of leak tightness and structural reliability while other designs rely on system or fuel performance and others on component performance. The enclosure building performance criteria should reflect a defense-in-depth philosophy. But within that context, criteria should be developed in an integrated manner that focuses on performance of the overall system of barriers rather than specifying criteria for individual barriers within the overall system. ASME can provide standards to provide the rules for design and fabrication of pressure components such that the leak tightness or structural integrity functional performances are met.
28. What plant physical security functions should be associated with containment and what should be the related functional performance standards?	ASME Nuclear Codes and Standards should not define the security functions required for the containment (enclosure building). Those functions should be established based on licensing Design Basis Threat (DBT) rules. ASME Nuclear Codes and Standards would define rules (design, fabrication and construction) of how to provide the structural integrity (functional performance) against those threats in addition to all other design requirements for the containment building.

29. How should PRA information and insights be combined with traditional deterministic approaches and defense-in-depth in establishing the proposed containment functional performance requirements and criteria for controlling radiological releases?	The PRA should be used for establishing the credible conditions for which the containment system needs to perform. Therefore, the reactor enclosure buildings (a component of the system) design criteria would take into account the fragility (strength and leak tightness) of the enclosure building to contribute to the system performance. It would also be appropriate to establish defense-in-depth, such as a non-mechanistic capability that is desired for a given reactor design. For example, the doubled-ended guillotine pipe break used in the sizing of LWR containments may be a capability that should be retained in future LWRs.
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?	Rare events should be considered in containment system design. However, the design criteria reliability requirements (strength or leak tightness) of the system or component should be reflective of the probability of such an event occurring.
G. Technology-Neutral Framework	
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?	Yes, this is a suitable approach.
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?	See ASME responses to Questions 3 and 5.
33. The unified safety concept used in the framework is meant to derive regulations from the Safety Goals and other safety principles (e.g., defense-in-depth). 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?	This approach has the potential to achieve regulatory coherence. However, ASME responses to this ANPR need to be addressed.
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?	The framework is clear on applicability to other sources.

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 defense-in-depth? • Operating experience? • Federal, state, and local authority input and acceptance? • Public acceptance? • Security-related events?	For a general response, see ASME responses to questions in Part C and D. For more specific responses, ASME believes the Nuclear Energy Institute and other entities representing future nuclear power plants are in a better position to respond.
36. What should the emergency preparedness requirements for future plants be? Should they be technology-specific or generic regardless of the reactor type?	See ASME response to Question 35.
37. Is the approach used in the framework for how defense-in-depth treats uncertainties well described and reasonable? If not, how should it be improved?	See ASME response to Question 35.
38. Are the defense-in-depth 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? Are one or more of the stated principles unnecessary? If so, which principles are unnecessary and why are they unnecessary?	See ASME response to Question 35.
39. The framework emphasizes that sufficient margins are an essential part of defense-in-depth measures. The framework also provides some quantitative margin guidance with respect to licensing basis events (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?	See ASME response to question 35. In addition, ASME does not agree with the treatment of Safety Margin as the sum of Design Margin + Regulatory Margin. In addition, the distribution curves being used to explain this concept address the tails and not the intersections of the probability curves. This proposed treatment is not consistent with the ASME codes and standards approach for addressing margins.
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 defense-in-depth application?	See ASME response to Question 35.

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?	See ASME response to Question 35.
42. Is the approach to and the basis for the selection of 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?	See ASME response to Question 35.
43. Is the approach used to select and to safety classify structures, systems, and components reasonable? If not, what would be a better approach?	See ASME response to Question 35.
44. Is the approach and basis to the construction of the proposed frequency-consequence (F–C) curve reasonable? If not, why not?	See ASME response to Question 35.
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?	See ASME response to Question 35.
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?	See ASME response to Question 35.
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 and 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?	LBEs should be partly generic (e.g., ultimate heat sink, off-site power) and partly technology specific (e.g., natural circulation eliminates some safety related pumps and valves). The ASME PRA standard calls for review of the PRA as the design evolves and during operation. In this context, reassessment similar to the 50.59 process is reasonable.

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?	In general, a full-scope PRA approach is reasonable. However, there are some minor events and specific hazards where PRA is not needed. To date the majority of risk-informed approaches have not relied on full scope PRAs, and it is anticipated that they may not be needed, at least to the same level of detail and certainty, to support risk-informed decision-making in the future.
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?	NRC Regulatory Guide 1.174 provides a valid interpretation of the appropriate quality assurance elements to be applied to risk-informed activities.
50. Is this process clear, understandable, and adequate? If not, why not? What should be done differently?	The process is reasonable. Adequacy needs to be measured against Part 50 as proposed in ASME response to Questions 1 and 2.
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?	The use of a logic diagram is valuable.
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?	See ASME response to Question 50.
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?	See ASME response to Question 50.
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?	See ASME response to Question 50.
H. Defense-in-Depth	
55. Would development of a better description of defense-in-depth 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.	A better description of defense-in-depth addressing interdependency between design criteria and mitigating strategies and specific to safety margins is needed. (see ASME response to Question 39)

56. If the NRC undertakes developing a better description of defense-in-depth, 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?	Defense-in-depth should be incorporated into a separate policy statement, as its applicability is not limited to PRAs.
57. RG 1.174 assumes that adequate defense-in-depth 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 defense-in-depth? Why or why not? If so, would a change to RG 1.174 be sufficient instead of a policy statement? Why or why not?	RG 1.174 should not be revised. See response to Question 56.
58. How should defense-in-depth be addressed for new plants?	See ASME response to Question 35.
59. Should development of a better description of defense-in-depth (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?	A better description of defense-in-depth should be developed in advance or as one of the first elements of Part 53. RG 1.174 has provided a foundation for risk-informed determinations made to date under the licensing rules of Part 50. There does not appear to be a compelling reason to modify this foundation. A modified and more comprehensive definition may be appropriate for use under Part 53, particularly as it may apply to advanced reactors.
I. Single Failure Criterion	
60. Are the proposed options reasonable? If not, why not?	ASME prefers Option 1, eliminating SFC, because use of PRA obviates need for SFC. Option 2, use of PRA to risk-inform the SFC concept (e.g., use the PRA to identify safety significant components and then apply the SFC) may also be acceptable.
61. Are there other options for risk-informing the SFC? If so, please discuss these options.	See ASME response to Question 60. ASME prefers elimination of SFC when risk-informed approaches are employed.
62. Which option, if any, should be considered?	See ASME response to Questions 60 and 61.
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?	Elimination of the SFC or risk-informing SFC should be pursued as part of the new 10CFR53. In either case, the basis for the changes to the SFC should be pursued as part of risk-informing the regulations.

J. Continue Individual Rulemakings to Risk-Inform 10 CFR Part 50	
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?	Since it will likely take several years to create 10 CFR Part 53, it is important to continue, as a priority, the risk-informed, performance-based initiatives for 10 CFR Part 50 for new LWRs. It is important to support emerging developments as risk-informed processes evolve. ASME has wrestled with this same challenge. While changes continue to be made to risk-informed ISI, IST, and repair/replacement activities, ASME is also addressing risk-informed design. Since the U.S. has 103 operating nuclear power plants that have many years of service life remaining; initiatives need to continue toward RI-PB regulations. Also, ASME experience in applying these concepts to the current generation of LWRs helps to apply this technology to new Gen III and Gen IV nuclear power plant designs.
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?	NRC should address those regulations that involve the expenditure of a great deal of public, regulatory and industry effort. Security would likely be an excellent example.
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?	IST of pumps, valves, and snubbers are excellent examples; although the NRC has a risk-informed regulatory guide (with accompanying ASME OMN Code Cases). Owners and the NRC, however, continue to spend an immense amount of effort implementing prescriptive programs.
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?	Having some experience in implementation is always beneficial (e.g., many licensees have experience in a wide variety of risk-informed programs). On the other hand, applying Improved and broader scope RI-PB principles to some degree to the next round of nuclear power plant orders would be beneficial.

From: Carol Gallagher
To: Evangeline Ngbea
Date: 01/03/2007 5:39:19 PM
Subject: Comment letter on Approaches to Risk-Inform & Performance-Base Requirements for NPRs

Attached for docketing is a comment letter on the above noted ANPR that I received via the rulemaking website on 12/28/06.

Carol

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Subject: Comment letter on Approaches to Risk-Inform & Performance-Base Requirements for NPRs
Creation Date 01/03/2007 5:39:13 PM
From: Carol Gallagher

Created By: CAG@nrc.gov

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Priority:	Standard
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Junk List is not enabled
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Block List is not enabled