# RULEMAKING ISSUE (Notation Vote)

| <u>June 14, 2007</u> | <u>SECY-07-0101</u>  |
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| FOR:                 | The Commissioners  |
| FROM:                | Luis A. Reyes<br>Executive Director for Operations /RA/  |
| <u>SUBJECT</u> :     | STAFF RECOMMENDATIONS REGARDING A RISK-INFORMED AND<br>PERFORMANCE-BASED REVISION TO 10 CFR PART 50<br>(RIN 3150-AH81) |

#### PURPOSE:

To request Commission approval of the staff's recommendations regarding a risk-informed and performance-based (RI/PB) revision to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and to inform the Commission of the results of the staff's review of stakeholders' comments on the various topics in the advance notice of proposed rulemaking (ANPR).

#### SUMMARY:

This paper provides the Commission (1) background information on the issuance of the subject ANPR, (2) a summary of the staff's actions to facilitate stakeholder comment on the issues in the ANPR, (3) an overview of the staff's analysis of the stakeholders' comments on the issues in the ANPR, and (4) the staff's recommendation to defer rulemaking to make 10 CFR Part 50 risk-informed and performance-based. The enclosure to this paper provides a more detailed analysis of the stakeholders' comments.

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#### BACKGROUND:

In SECY-06-0007, "Staff Plan to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," issued January 9, 2006 (ML053420012), the staff asked for Commission approval to publish an ANPR to solicit stakeholder input on a RI/PB revision to 10 CFR Part 50 and to supplement the ANPR, as needed, with additional information. In addition, the staff committed to (1) provide recommendations for Commission direction and approval on the two policy issues regarding the level of safety and integrated risk; (2) provide a path forward for Commission approval on the resolution of containment functional performance standards and on incorporation of a definition of defense-in-depth into the Commission's probabilistic risk assessment (PRA) policy statement; (3) inform the Commission of stakeholders' views on the ANPR; (4) provide the Technology-Neutral Framework (Framework) to the Commission, for information, after considering stakeholders' comments on the ANPR and having incorporated any additional guidance received from the Commission on the issues identified above; and (5) request Commission approval to initiate formal rulemaking on a new 10 CFR Part 53 and to initiate efforts to revise other regulations in 10 CFR Part 50, if any are identified.

In the Staff Requirements Memorandum (SRM), "Staff Plan to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," to SECY-06-0007 issued March 22, 2006 (ML060810277), the Commission approved the staff's recommendation to publish an ANPR. The Commission also directed the staff to (1) include questions in the ANPR on the Framework being developed by the Office of Nuclear Regulatory Research (RES); (2) publish the ANPR in the *Federal Register* with a comment period closing in December 2006; (3) place the latest working draft of the Framework on the RuleForum website no later than the date of publication of the ANPR; and (4) provide the Commission, at the end of the ANPR stage, with the staff's recommendation on whether and, if so, how to proceed with rulemaking having considered the Advisory Committee on Reactor Safeguards (ACRS) views and including any differing stakeholder views for the Commission's benefit when deliberating on the recommendation. Further, to facilitate stakeholder participation, the Commission directed the staff to hold public meetings and workshops starting soon after issuance of the ANPR and to keep stakeholders informed of progress throughout the public comment period.

#### DISCUSSION:

This paper provides a summary of (1) the staff's actions in response to the Commission's SRM; (2) the staff's analysis of the stakeholders' comments in response to the ANPR on the staff's plan regarding a RI/PB revision to 10 CFR Part 50, the Framework, and the policy issues included in the ANPR; and (3) the staff's progress on the commitments in SECY-06-0007.

#### Staff's Actions in Response to the SRM

The staff published the ANPR in the *Federal Register* with a comment period that closed December 29, 2006 (71 FR 26267; May 4, 2006) (ML060670055). The staff requested comments on the issues discussed in SECY-06-0007 and raised by the Commission in the associated SRM. These issues were included in the ANPR as ten separate topics (with corresponding questions) that addressed rulemaking, the Framework, and the policy issues. On April 27, 2006, the staff placed the Framework on the RuleForum website and the staff added an update of the Framework to the RuleForum website on August 1, 2006.

The staff met with stakeholders on June 15, 2006, to discuss the topics and questions in the ANPR. On September 14 and 15, 2006, the staff held a public workshop to provide an opportunity for a detailed discussion of the topics and questions in the ANPR and to obtain early stakeholder feedback. On March 7 and 8, 2007, the staff met with the ACRS in a round table discussion of the technical issues in the Framework. The staff offered to meet with the ACRS for further technical discussion prior to publishing the Framework report. On April 20, 2007, in response to an SRM from the Commission, the ACRS provided a letter (ML071100303) to the Commission regarding the Framework. On May 3, 2007, the staff met with the ACRS on its recommendation for rulemaking and on May 16, 2007, the ACRS provided a letter (ML071360076) to the Commission regarding the staff's recommendation.

#### Stakeholder's Comments

The staff received comments from ten stakeholders (including four preliminary sets). Comments were received from the Nuclear Energy Institute (NEI), the American Society of Mechanical Engineers, the American Nuclear Society, the Institute of Electrical and Electronics Engineers, Areva NP, General Electric Company, Westinghouse, Pebble Bed Modular Reactor (Pty) Ltd., the Strategic Teaming and Resource Sharing Alliance, and an individual associated with the Nuclear Equipment Forum. Some commenters only provided general comments on the ANPR plan or indicated that they agreed with the comments submitted by NEI.

The staff has categorized the stakeholders' comments into the following three groups: rulemaking, the Framework, or policy issues. An overview of the comments is provided below with a brief staff analysis. A more detailed analysis of the comments is provided as an enclosure to this paper.

# Rulemaking Comments (ANPR Topics A, I, and J)

<u>A. Plan to Risk Inform 10 CFR Part 50</u> – In general, all stakeholders were supportive of the plan to develop RI/PB requirements for future reactors but indicated that the NRC should not begin rulemaking immediately. Most stakeholders suggested that before initiating rulemaking, draft requirements using the Framework as the technical basis should be developed and made available for discussion and that the draft requirements should be tested against the licensing of a non-light-water reactor (LWR) under 10 CFR Part 50 and Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," as a pilot. Most stakeholders stated that the NRC needs to maintain a high priority on completing the licensing of the next generation of near-term LWRs and review of design certifications.

Stakeholders had mixed views as to whether requirements should be technology-neutral or technology-specific and thought a "test case" applying draft requirements would inform this topic.

I. Single Failure Criterion – Stakeholders supported replacing the Single Failure Criterion with an approach in which the frequency and consequences of each licensing basis event are taken into account and there are no arbitrary redundancy requirements. Stakeholders recommended that this approach be undertaken as part of the plan to risk inform 10 CFR Part 50 and be supported by the Framework. <u>J. Continue Individual Rulemaking to Risk Inform 10 CFR Part 50 Requirements</u> – Almost all stakeholders supported completing current rulemaking efforts to risk inform 10 CFR Part 50. Regarding initiating new rulemakings, many stakeholders indicated that the best candidates for risk-informed rulemaking had already been revised.

The staff agrees with the stakeholders that new rulemakings are not warranted at this time. For LWRs, the staff agrees that the NRC should not undertake new risk-informed and performance-based revisions of 10 CFR Part 50 until specific rules are identified as needed. This approach will allow industry and the NRC to focus resources on maintaining the safety of existing reactors and on the expedient licensing of new reactors to existing requirements. The staff will propose candidate rulemakings after the staff and industry have had time to identify appropriate candidates. For non-LWRs, the staff believes that the results of the development of the licensing strategy for the Next Generation Nuclear Plant (NGNP) and the Pebble Bed Modular Reactor (PBMR) pre-application review will help determine how to proceed to rulemaking. The staff believes this approach is appropriate, in part, because rulemaking is not needed for the near-term LWR licensing applications expected in the 2007-2010 time frame.

#### Framework Comments (ANPR Topic G)

<u>G. The Framework</u> – In general, stakeholders agreed with the top down approach used in developing the Framework and agreed that the next step should involve testing the Framework on a specific reactor design. Stakeholders gave specific comments on the criteria in the Framework. For example, stakeholders considered the approach for the selection of licensing basis events (LBE) and their acceptance criteria reasonable but some specific changes were suggested, e.g., the use of a 95% confidence level for the rare frequency category (i.e., <10<sup>-5</sup>/reactor year to  $\ge 10^{-7}$ /reactor year) is overly restrictive, and mean values should be used in the Framework. Stakeholders also requested clarification of certain criteria and guidance in the Framework.

The staff is reviewing the stakeholders' comments to determine where and if the Framework needs to be revised. In addition, as noted above, on March 7 and 8, 2007, the staff met with the ACRS (subcommittee and full committee, respectively) in a round table discussion of the technical issues in the Framework. The staff has offered to meet with the ACRS for further technical discussion prior to publishing the Framework report. On April 20, 2007, the ACRS issued a letter to the Chairman with its views on the value of the Framework approach. The ACRS recommended that the staff should complete the technology-neutral Framework and that the staff should test it on the PBMR design. On May 16, 2007, after meeting with the staff on its recommendation, the ACRS issued a second letter supporting the staff's recommendation not to initiate rulemaking at this time and recommending additional interaction with the staff on resolution of the technical issues in the Framework.

The Framework's primary objective is to demonstrate the feasibility of a possible risk-informed and performance-based approach that would serve as the technical basis for licensing a reactor employing any technology. The staff believes that this objective will be accomplished with publication of the Framework. The staff plans to publish the Framework in 2007.

The staff agrees that the PBMR pre-application and licensing activity is a logical choice on which to test the concepts presented in the Framework. At the time of licensing, the staff will have the applicant's PRA available, and the staff anticipates that the Framework concepts could

be used in the review of the PBMR design. This licensing activity would be in addition to the testing already completed for a LWR, which is documented in Appendix E of the Framework report.

## Policy Issue Comments (ANPR Topics B, C, D, E, F and H)

<u>B. Integration of Safety, Security, and Emergency Preparedness</u> – Stakeholders overall expressed concerns for integrating safety, security, and emergency preparedness. The general concern raised was that integration of security would limit public participation. Some stakeholders believed integration was premature, not beneficial, or not practical.

<u>C. Level of Safety, D. Integrated Risk, and E. ACRS Views</u> – Stakeholders agreed that the quantitative health objectives (QHO) established in the Commission's Safety Goal Policy should be used to establish the minimum level of safety for new plants. Most stakeholders questioned the need to establish subsidiary risk objectives for accident prevention and accident mitigation; rather, it was expressed that both preventive and mitigative measures should be considered when evaluating a plant's ability to meet the QHOs. There was no consensus concerning the consideration of integrated risk. Regarding the ACRS views, in general, stakeholders believed the ACRS had raised important and relevant points about these issues.

<u>F. Containment Functional Performance Standards</u> – In general, stakeholders did not agree with the staff's proposed containment performance standards as documented in the Framework. Philosophically, industry stakeholders believed that defense-in-depth for protection against unacceptable fission product release could be achieved in ways different from relying on the performance of a specific (containment) barrier, whose functional performance requirement is specifically established to accommodate unknowns.

The staff believes that further insights which are expected to be gained through additional deterministic sensitivity analyses and review as part of a pre-application review for the NGNP reactor design and/or PBMR will help to better define a path forward for resolving these technical policy issues and toward resolving the differences between external stakeholder and staff views.

<u>H. Defense-in-Depth</u> – Stakeholders supported development of a separate policy statement on defense-in-depth, rather than a revision of the PRA policy statement because it is believed that defense-in-depth is broader than, and not limited to, PRA. Regarding the definition for defense-in-depth provided in the Framework, stakeholders were generally supportive but indicated a desire to have further interaction with the NRC prior to the development or finalization of a defense-in-depth policy statement to better understand the definition, principles, etc., described in the Framework. Further, some stakeholders recommended that the definition be "tested."

The staff will continue to interact with stakeholders in the development of a policy statement on defense-in-depth and will examine the merit of a test and what this test would entail.

#### COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper.

- 1. The staff will publish the Framework as a NUREG after considering stakeholders' comments from the ANPR and any additional comments from the ACRS.
- 2. The staff will initiate efforts to develop a policy statement for Commission consideration on defense-in-depth. As part of this effort, the staff will interact frequently with stakeholders to facilitate their participation and to inform them of staff progress.

#### **RECOMMENDATION:**

The staff recommends that the Commission approve deferring rulemaking for risk-informed and performance-based 10 CFR Part 50 reactor requirements for advanced reactors until after the development of the licensing strategy for the NGNP or receipt of an application for design certification or a license for the PBMR. The staff will provide the Commission a recommendation on initiating rulemaking 6 months after the licensing strategy for the NGNP is finalized.

#### RESOURCES:

For FY 2008, the staff budgeted the following resources for this rulemaking: 1 FTE and 25k for NRR, .1 FTE for NRO, and .1 FTE for OGC. The staff plans to reallocate these resources using the Planning, Budgeting, and Performance Management process. The staff will provide the Commission resource estimates for technical basis development and rulemaking in FY 2009 and FY 2010 in its recommendation for rulemaking that will be provided after the licensing strategy for NGNP is developed. Resources for development of the NGNP licensing strategy are already budgeted.

#### COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

# /RA Martin J. Virgilio Acting For/

Luis A. Reyes Executive Director for Operations

Enclosure:

Stakeholder Comments in Response to the Advance Notice of Proposed Rulemaking

# STAKEHOLDER COMMENTS IN RESPONSE TO ADVANCE NOTICE OF PROPOSED RULEMAKING

In its advance notice of proposed rulemaking (ANPR) regarding risk-informing reactor requirements, the staff requested comments on the issues discussed in SECY-06-0007, "Staff Plan to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," issued January 9, 2006 (ML053420012), and raised by the Commission in the associated Staff Requirements Memorandum (SRM), "Staff Plan to Make a Risk-Informed and Performance-Based Revision to 10 CFR Part 50," issued March 22, 2006 (ML060810277). These issues were included in the ANPR under 10 separate topics (with corresponding questions) that addressed rulemaking, the staff's Technology-Neutral Framework (Framework), and policy issues. The topics included the following:

- A. Plan to Risk Inform 10 CFR Part 50
- B. Integration of Safety, Security, and Emergency Preparedness
- C. Level of Safety
- D. Integrated Risk
- E. Advisory Committee on Reactor Safeguards (ACRS) Views
- F. Containment Functional Performance Standards
- G. The Framework
- H. Defense-in-Depth
- I. Single Failure Criterion
- J. Continue Individual Rulemaking to Risk Inform 10 CFR Part 50 Requirements

The staff received comments from ten stakeholders (including four preliminary sets). Comments were received from the Nuclear Energy Institute (NEI), the American Society of Mechanical Engineers (ASME), the American Nuclear Society (ANS), the Institute of Electrical and Electronics Engineers (IEEE), Areva NP, General Electric Company, Westinghouse, Pebble Bed Modular Reactor (Pty) Ltd., the Strategic Teaming and Resource Sharing (STARS) Alliance, and an individual associated with the Nuclear Equipment Forum.

Although detailed comments on each topic were provided by groups such as NEI, ASME, ANS, and Areva NP; some stakeholders only provided comments on the ANPR plan or indicated that they agreed with the comments submitted by NEI.

In the analysis below, the topics from the ANPR are grouped under rulemaking, the Framework, or policy issues. A summary of stakeholder comments with staff perspectives is provided for each topic. In the ANPR, a short introduction of the issue was provided with each topic and those introductory remarks are included below to provide background and context for the topic.

RULEMAKING TOPICS (ANPR Topics A, I, and J)

#### A. Plan to Risk Inform 10 CFR Part 50

#### Issue –

The NRC proposed a plan to develop an integrated risk-informed and performance-based (RI/PB) alternative to 10 CFR Part 50, "Domestic Licensing of Production and Utilization

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Facilities," that would cover power reactor applications including non-light-water reactor (LWR) designs. Safety, security, and preparedness will be integrated into this effort to provide one cohesive structure. This structure will ensure that the reactor regulations and staff processes and programs are built on a unified safety concept and are properly integrated so that they complement one another. Based on the above, the overall objectives of a RI/PB alternative to 10 CFR Part 50 are to (1) enhance safety and security by focusing NRC and licensee resources in areas commensurate with their importance to public health and safety, (2) provide the NRC with a framework that uses risk information in an integrated manner, (3) use risk information to provide flexibility in plant design and operation while maintaining or enhancing safety and security, (4) ensure that risk-informed activities are coherently and properly integrated such that they complement one another and continue to meet the Commission's 1995 PRA Policy Statement, and (5) allow for different reactor technologies in a manner that will promote stability and predictability in the long term. The proposed plan addresses risk-informed power reactor activities and the associated guidance documents. Risk-informed activities addressing non-power reactors, nuclear materials, and waste are not addressed.

The NRC's proposed approach is to create a new Part in 10 CFR (10 CFR Part 53) that can be applied to any reactor technology as an alternative to 10 CFR Part 50. The following two major tasks are proposed: (1) develop the technical basis for rulemaking for 10 CFR Part 53 and (2) develop the regulations and associated guidance for 10 CFR Part 53. As part of the ANPR, stakeholders were asked to provide input on the merit of a new 10 CFR Part 53, whether it should be technology neutral, when would it be needed, and whether they would be willing to develop needed guidance.

#### Stakeholder Comments -

In general, all the stakeholders were supportive of the plan to develop RI/PB requirements for future reactors, but the stakeholders indicated that the NRC should not begin rulemaking immediately. Stakeholders suggested that, before initiating rulemaking, draft requirements based on the Framework should be developed and made available for information and discussion and that the draft requirements should be tested against the licensing of a non-LWR under 10 CFR Parts 50 and Part 52, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants," as a pilot. Most stakeholders indicated that the NRC needs to maintain a high priority on supporting the licensing and certifications of the next generation of near-term LWRs. Stakeholders had mixed views as to whether requirements should be technology neutral or specific and thought a "test case" applying draft requirements would help inform this topic.

# Staff Perspectives -

The staff agrees with stakeholders that it would be beneficial for draft requirements to be developed and made available for information and discussion before initiating rulemaking. The staff also agrees that the draft requirements would benefit from being applied as a test case against the licensing of a non-LWR. This approach would provide an opportunity to determine if the scope and detail of the requirements are sufficient for licensing a non-LWR. Further, applying the requirements to a technology where the approaches for fuel failure prevention, reactor vessel confinement, core cooling, and mitigation of off-site radiological release are distinctly different from the approaches for existing LWRs will better test the requirements to

ensure that application of risk measures and performance-based requirements are appropriate. Additionally, such an application will provide valuable insights for the integration of safety, security, and emergency preparedness to be applied to later reactor designs. However, until such time that there is a demonstrable need for conducting rulemaking to support licensing of advanced reactors, the staff believes this decision should be deferred. The staff believes that insights gained through the evaluation of the various options being considered in the licensing strategy for the Next Generation Nuclear Plant (NGNP) and the Pebble Bed Modular Reactor (PBMR) pre-application review will help determine whether, and if so, how to proceed to rulemaking.

### I. Single Failure Criterion (SFC)

### Issue –

In SECY-05-0138, "Risk-Informed and Performance-Based Alternatives to the Single-Failure Criterion," dated August 2, 2005 (ML051950619), the staff forwarded to the Commission a draft report entitled "Technical Report to Support Evaluation of a Broader Change to the Single Failure Criterion" and recommended to the Commission that any followup activities to risk-inform the SFC should be included in the activities to risk-inform the requirements of 10 CFR Part 50. The Commission directed the staff to seek additional stakeholder involvement. The report provides the following options: (1) maintain the SFC as is, (2) risk inform the SFC for design bases analyses, (3) risk inform the SFC based on safety significance, and (4) replace the SFC with risk and safety function reliability guidelines. As part of the ANPR questions, stakeholders were also asked to discuss any other options for risk-informing the SFC that they wished to be considered.

# Stakeholder Comments -

With one exception, all stakeholders agreed that the SFC should be eliminated and/or risk informed as part of the broader effort to risk-inform the regulations. Some stakeholders indicated that the general approach of using the probabilistic risk assessment (PRA) along with the frequency-consequence (F-C) curve and licensing basis events eliminates the need for any kind of arbitrary redundancy requirement like the SFC. Another stakeholder felt that the use of PRA to risk-inform based on safety significance was also an acceptable approach to eliminating the SFC. However, one stakeholder felt that the SFC should be preserved and maintained until such time as standards committees revised their current nuclear codes and standards based on risk insights. There were no additional options for risk-informing the SFC offered by stakeholders. Some stakeholders indicated that changes to the SFC should be carried out as part of the effort to develop the proposed 10 CFR Part 53 while others felt that these efforts should be pursued separately (i.e., a separate 10 CFR Part 50 rulemaking).

# Staff Perspectives -

A risk-informed approach for SFC has been addressed in the Framework, which could be implemented if a separate Part 53 is pursued. With regard to changing the SFC in the current Part 50, this should be considered once the ongoing rulemaking efforts are completed (see response to Topic J).

# J. Continue Individual Rulemaking to Risk Inform 10 CFR Part 50 Requirements

# Issue –

The NRC has for some time been revising certain provisions of 10 CFR Part 50 to make them more RI/PB. Examples are (1) a revision to 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants;" (2) a revision of 10 CFR 50.48, "Fire Protection," to allow licensees to voluntarily adopt National Fire Protection Association (NFPA) Standard 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants, 2001 Edition" (NFPA 805); and (3) issuance of 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," as a voluntary alternative set of requirements. These actions have been effective but they required extensive NRC and industry efforts to develop and implement. The NRC plans to continue the current ongoing risk-informed rulemaking actions (e.g., 10 CFR 50.61, "Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events," and 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors") and would undertake new risk-informed rulemaking only on an as-needed basis.

# Stakeholder Comments -

The majority of the stakeholders who responded to this topic were in general agreement that the priority focus should be on completing ongoing efforts on specific 10 CFR Parts 50 and 52 rulemakings. With regard to future endeavors, stakeholders provided views in the following three areas:

• Future rulemakings on select regulations in 10 CFR Part 50.

Some stakeholders commented that it was not cost-beneficial to undertake new rulemakings and that NRC should wait on the completion of the first reviews on the combined construction and operating licenses, other stakeholders thought it was too difficult to make a recommendation until successful implementation of the 10 CFR 50.69 and 10 CFR 50.46a actions.

• Revising the supporting regulatory guides to be RI/PB.

Some stakeholders suggested NRC should complete including RI/PB considerations in the ongoing revisions to the regulatory guides, others suggested that NRC should make no RI/PB changes as long as the underlying regulation is deterministic, and others suggested developing a policy statement for achieving a RI/PB regulation.

• Time frame for initiating any new endeavors.

Some stakeholders suggested NRC should start new endeavors immediately while other stakeholders suggested waiting until successful implementation of ongoing efforts had been demonstrated.

## Staff Perspectives –

The staff agrees that the NRC should not undertake new RI/PB revisions of 10 CFR Part 50 until specific rules are identified, which will allow industry and NRC to focus resources on maintaining the safety of existing reactors and on the expedient licensing of new reactors to existing requirements. The staff will propose candidate rulemakings after time allows the staff and industry to identify any requirements appropriate for revision.

### FRAMEWORK TOPIC (ANPR Topic G)

### G. The Framework

### Issue –

In support of determining the requirements for these alternative regulations, the NRC is developing a technology-neutral framework. This Framework provides one approach in the form of criteria and guidelines that could serve as the technical basis for 10 CFR Part 53 that is technology-neutral and RI/PB. A working draft of this Framework was issued for public review and comment in SECY-05-0006, "Second Status Paper on the Staff's Proposed Regulatory Structure for New Plant Licensing and Update on Policy Issues to New Plant Licensing," dated January 7, 2005. The latest working draft of the Framework document was placed on the RuleForum website in April 2006. An updated version with additional information was placed on the following: safety, security, and emergency preparedness expectations; licensing basis events (LBE) identification and selection; safety classification of structures, systems, and components; and PRA technical acceptability.

In the ANPR, stakeholders were asked to provide feedback regarding the structure, organization, and objective of the Framework; the use of the Commission's Safety Goals as the basis for requirements; the usefulness of testing the Framework using an actual reactor design; the incorporation of defense-in-depth and emergency preparedness into the Framework; the process used for selection of licensing basis events, their acceptance criteria, and safety classification of equipment; the Framework guidance on the scope, quality, and use of the PRA; and the process used to determine the need for requirements for a RI/PB 10 CFR Part 53.

# Stakeholder Comments -

Stakeholders generally agreed that the structure, organization, and objective of the Framework was reasonable and clear and that the use of the Commission's Safety Goals was a reasonable basis from which to derive the requirements. Stakeholders also agreed that the next step should be to test the Framework using an actual non-LWR design prior to conducting any rulemaking.

Stakeholders suggested that the way defense-in-depth is presented in the Framework is not clear and should be modified to integrate the five Framework protective strategies that are, in effect, a high-level defense-in-depth structure, with the Framework defense-in-depth principles. The stakeholders indicated that this would be a more logical and comprehensive way to implement defense-in-depth into the Framework.

The stakeholders also suggested that design-specific risk information should be allowed to be used in implementing the defense-in-depth measures.

With respect to emergency preparedness, the stakeholders suggested that the Framework include criteria that would allow the emergency planning zone (EPZ) to be adjusted based upon plant characteristics and that risk information be used to optimize protective measures. These inclusions were suggested because it is expected that future plants will have enhanced safety characteristics over current plants.

Stakeholders felt that the approach to selecting LBEs is conceptually reasonable but needs clarification with respect to how to aggregate event sequences and how to establish a cut-off frequency for events that need to be considered. Stakeholders did not agree with using a 95% confidence level for assessing consequences for rare events selected as LBEs. Again, the addition of a complementary cumulative distribution function (CCDF) curve to the Framework was suggested because the stakeholders felt it would be useful in establishing a cutoff frequency for events that need to be considered as LBEs. Likewise, stakeholders felt that the process for safety classification needs to be clarified. With respect to the Framework proposed acceptance criteria for LBEs, the stakeholders viewed the deterministic criteria as examples but generally agreed with the dose criteria expressed by the F-C curve.

The Framework contains guidance on the scope and quality of the PRAs to be used in implementing the Framework. Stakeholders suggested that not everything needs to be analyzed using a PRA and that the Framework should acknowledge this. Examples included using a screening process to eliminate low consequence events from PRA analysis and allowing methods other than PRA (e.g., seismic fragility analysis) in certain areas.

Stakeholders indicated that the process to select topics that need requirements based on the Framework guidance was reasonable and that the resulting list of topics was reasonable. The process for performing a completeness check was also considered reasonable.

#### Staff Perspectives -

The staff agrees that a reasonable next step would be to test the concepts in the Framework against an actual design; that the PBMR pre-application and licensing activity is a logical choice on which to test the concepts presented in the Framework. At the time of licensing, the staff will have the applicant's PRA available and the staff anticipates that the Framework concepts could be used in the review of the PBMR design. This licensing activity would be in addition to the testing already completed for a light water reactor, which is documented in Appendix E of the Framework report.

The staff does not agree with combining the defense-in-depth principles with the protective strategies. The defense-in-depth principles provide a definition of defense-in-depth and ensure consistency and uniformity in addressing uncertainties. The protective strategies are an element of defense-in-depth and also address completeness at a high level in developing requirements for design, operation, and construction.

The comments on emergency preparedness will be evaluated by the staff and factored into any future recommendations in this area.

Prior to publication of the Framework; the staff will consider clarification of the Framework description of the LBE selection process, safety classification processes, and PRA scope and quality in order to address the comments received from stakeholders.

POLICY ISSUE TOPICS (ANPR Topics B, C, D, E, F, and H)

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

# Issue –

The Commission believes that safety, security, and emergency preparedness should be integrated in developing a RI/PB set of requirements for nuclear power reactors (i.e., in this context, 10 CFR Part 53). The NRC has proposed to establish security performance standards for new reactors (see SECY-05-0120, "Security Design Expectations for New Reactor Licensing Activities" July 6, 2005, ML051100233). Under the proposed approach, nuclear plant designers would analyze and establish, at an earlier stage of design, security design aspects so that there would be a more robust and effective (intrinsic) security posture and less reliance on operational (extrinsic) security programs (guns, guards, and gates). This approach takes advantage of making plants more secure by design rather than by adding security components on after the design is complete. As part of the ANPR questions; stakeholders were asked to provide feedback on the proposed approach for integration, views on principles for security standards, and if security and emergency preparedness should be risk-informed.

# Stakeholder Comments -

A majority of stakeholders expressed concern with the integration of safety, security, and emergency preparedness. One concern expressed was that the public exchange of information on a new reactor's safety design philosophy could lead to compromising its protection against threats to physical security and vice versa. It is believed that, full integration of safety and security could conflict with the need to limit public discussion of strategies to protect against threats to security so that the inherent security in a given plant design is not compromised. Most stakeholders indicated that application of PRA methods to the issue of security risk was premature because of the large uncertainties involved. Stakeholders indicated that insights derived from risk assessments on safety should be used to develop a coordinated approach to safety and security. One stakeholder argued that security requirements should credit future designs that have low intrinsic risks and that there was a need to risk-inform security. Another stakeholder stated that it is premature to integrate safety and security until the several ongoing rulemakings on security are complete. All stakeholders, however, agreed that emergency preparedness should be risk-informed based on all available risk information and insights using a graded approach.

# Staff Perspectives –

The staff believes that additional insights on the integration of safety, security, and emergency preparedness, as well as the feasibility of risk-informing security, will be gained through the evaluation of the various options being considered in the licensing strategy for the NGNP and the PBMR pre-application review. These insights will help reconcile the diverse stakeholder

opinions for generically resolving these policy issues. With respect to risk informing emergency preparedness, development of a graded approach in a timely fashion appears reasonable.

# C. Level of Safety

# Issue –

The staff, in SECY-05-0130, "Policy Issues Related to New Plant Licensing and Status of the Technology-Neutral Framework for New Plant Licensing," issued July 21, 2005 (ML051670388), proposed options for establishing a regulatory standard that would be applied during licensing to enhance safety for new plants consistent with the Commission's policy statement, "Regulation of Advanced Nuclear Power Plants." Four options were evaluated which included (1) perform a case-by-case review, (2) use the Quantitative Health Objectives (QHO) in the Commission's policy statement on "Safety Goals for the Operation of Nuclear Power Plants," (3) develop other risk objectives for the acceptable level of safety, and (4) develop new QHOs. The NRC is soliciting stakeholder views on these options. In the ANPR, stakeholders were also asked to discuss any alternative options and their benefits. Subsidiary risk objectives could also be developed to implement the Commission's expectation regarding enhanced safety for new plants. These subsidiary risk objectives could be a useful way to focus more on plant design, provide quantitative criteria for accident prevention and mitigation, and provide high-level goals to assist in establishing plant system and equipment reliability and availability targets. Currently, subsidiary risk objectives of 10<sup>-5</sup>/plant year and 10<sup>-6</sup>/plant year that could be applicable to all reactor designs are being considered for accident prevention (i.e., preventing major fuel damage and accident mitigation) (i.e., preventing releases of radioactive material offsite such that no early fatalities occur from acute radiation doses).

As part of the ANPR questions, stakeholders were asked to provide feedback on staff options, subsidiary objectives, need for a Level 3 PRA, and whether the QHOs could be met by prevention or mitigation alone.

# Stakeholder Comments -

Stakeholders agreed that the QHOs established in the Commission's Safety Goal Policy should be used to establish the minimum level of safety for new plants. There were no alternative options brought up by the stakeholders. However, there was no consensus concerning the establishment of subsidiary risk objectives similar to core-damage frequency (CDF) and large early release frequency (LERF) for LWRs. Some stakeholders indicated that subsidiary risk objectives should be established to facilitate the development of industry standards and regulatory guidance and to provide an approach for demonstrating that a new plant meets the QHOs without performing a Level III risk assessment. Most stakeholders stated that subsidiary risk objectives should be established in technology-specific regulatory guidance. Two stakeholders argued that it is not technically possible to develop meaningful technology-neutral subsidiary risk objectives that could be successfully applied to gas-cooled reactors. Most stakeholders questioned the need to establish subsidiary risk objectives for accident prevention and accident mitigation; rather, it was expressed that both preventive and mitigative measures should be taken into account when evaluating the capability of a plant to meet the QHOs.

## Staff Perspectives -

The staff believes that insights gained through the evaluation of the various options being considered in the licensing strategy for the NGNP and the PBMR pre-application review will help reconcile the diverse stakeholder opinions for generically resolving this policy issue. There is no compelling reason to seek generic resolution of these policy issues at this time because all near-term combined license applications will be for LWRs and these can be licensed using the existing regulations and because the only non-LWRs that require near-term staff attention for potential licensing are the NGNP and the PBMR.

### D. Integrated Risk

# Issue –

For new plant licensing, potential applicants have indicated interest in locating new plants at new and existing sites. In addition, potential applicants have indicated interest in locating multiple (or modular) reactor units at new and existing sites. The NRC is evaluating the issue of integrated risk. The staff, in SECY-05-0130, evaluated three options that included (1) no consideration of integrated risk, (2) quantification of integrated risk at the site only from new reactors (i.e., the integrated risk would not consider existing reactors), and (3) quantification of integrated site risk for all reactors (new and existing) at that site. Another aspect of this issue is the level of safety associated with the integrated risk. The NRC is presently considering whether the integrated risk should be restricted to the same level that would be applied to a single reactor. If this approach were adopted, the integrated risk resulting from adding multiple reactors to an existing site would not be allowed to exceed the level of safety expressed by the QHOs in the Commission's Safety Goal Policy Statement. As part of the ANPR questions, stakeholders were asked to provide feedback on staff options and whether a minimum risk threshold should be specified in the regulations.

# Stakeholder Comments -

There was no consensus concerning the consideration of integrated risk. One stakeholder argued that comparisons to the QHOs must include all site risks (existing plants and new plants). However, other stakeholders observed that plants are licensed individually and that the NRC has traditionally considered risk on a per-reactor basis. There was some support for comparing the integrated risk from all new plants at a site to the QHOs.

# Staff Perspectives -

The staff believes that insights gained through the evaluation of the various options being considered in the licensing strategy for the NGNP and the PBMR pre-application review will help reconcile the diverse stakeholder opinions for generically resolving this policy issue. There is no compelling reason to seek generic resolution of this policy issue at this time because all near-term combined license applications will be for LWRs and these can be licensed using the existing regulations and because the only non-LWRs that require near-term staff attention for potential licensing are the NGNP and the PBMR.

# E. ACRS Views

## Issue –

In a September 21, 2005 letter, the ACRS raised a number of questions related to new plant licensing. The ACRS discussed issues related to requiring enhanced safety and how to account for the risk from multiple reactors at a single site. The details of the ACRS discussion could be found in the September 21, 2005, letter that was attached to the ANPR. The Commission, in a September 14, 2005, SRM directed the staff to consider ACRS views in developing a subsequent notation vote paper addressing these policy issues. As part of the ANPR, the ACRS letter was included and stakeholders were asked to provide feedback on the ACRS views.

### Stakeholder Comments -

Stakeholders expressed a variety of opinions about the views of the ACRS on the appropriate level of safety and treatment of integrated risk for new plants. One stakeholder commented that the ACRS had raised important and relevant points about these issues that warrant further consideration by the staff. In contrast, another stakeholder concluded that the points raised by the ACRS had already been adequately addressed in the Framework.

### Staff Perspectives -

The staff believes that insights gained through the evaluation of the various options being considered in the licensing strategy for the NGNP and the PBMR pre-application review will help reconcile the diverse stakeholder opinions for generically resolving this policy issue. There is no compelling reason to seek generic resolution of these policy issues at this time because all near-term combined license applications will be for LWRs and these can be licensed using the existing regulations, and the only non-LWRs that require near-term staff attention for potential licensing are the NGNP and the PBMR.

# F. Containment Performance Standards

#### lssue –

The Commission has directed the staff to develop options for containment functional performance requirements and criteria that take into account such features as core, fuel, and cooling system design. As part of the ANPR questions, stakeholders were asked for feedback regarding how to define containment, its safety functions, and its functional performance standard including physical security considerations.

# Stakeholder Comments -

Stakeholders generally believed that containment performance standards should be developed, at a high level, on a technology-neutral basis and should be viewed as a plant-wide safety function rather than a predetermined barrier or set of barriers separate from other aspects of the design. Stakeholders believed that technology-specific guidance could then be provided to support implementation and that the resulting design features that perform the containment

function would be design specific and could range from pressure retaining to non-pressure retaining structures provided the release criteria are met. In addition, stakeholders believed that risk considerations should be used in developing the requirements and implementing guidance so as to facilitate design-specific implementation.

Stakeholders also stated that the physical security safety functions of containment should be design specific because the overall design (e.g., below ground siting) will play a major role and will need to be considered.

Stakeholders considered that the frequency categories and the process for selection of licensing basis events contained in the Framework were reasonable for assessing containment functional performance; however, the application of the Framework defense-in-depth principles should be applied on a design specific basis. With respect to how the Framework uses an F-C curve and the QHOs from the Commission's Safety Goal Policy to judge the acceptability of event sequences, including containment performance, stakeholders suggested that an additional criterion (a CCDF curve) should be added to the Framework to complement the F-C curve by addressing integrated risk. Stakeholders felt that situations would then be prevented where one event sequence would cause the entire design to be unacceptable or where a group of event sequences in one frequency range would concentrate risk in one area. Stakeholders also felt that this would still allow designers more flexibility.

# Staff Perspectives -

In general, stakeholders did not agree with the staff's proposed containment performance standards as documented in the Framework. However, the staff believes that the Framework already addresses many of the comments although it is recognized that additional explanation and clarification may be needed in the Framework to better convey what is intended. The proposed requirements addressed containment as part of defense-in-depth, requiring the plant to have a containment functional capability to prevent an unacceptable release of radioactive material to the public.

The staff believes that insights gained through the development of the licensing strategy for the NGNP and completion of the PBMR pre-application review will help it to better understand these policy issues and to reconcile stakeholder opinions.

# H. Defense-in-Depth

# Issue –

In SECY-03-0047, "Policy Issues Related to Licensing Non-Light-Water Reactor Designs," issued March 28, 2003 (ML030160002), the staff recommended that the Commission approve the development of a policy statement or description (e.g., a white paper) on defense-in-depth for nuclear power plants to describe the objectives of defense-in-depth (philosophy), the scope of defense-in-depth (design, operation, etc.), and the elements of defense-in-depth (high level principles and guidelines). The policy statement or description would be technology neutral and risk informed and would be useful in providing consistency in other regulatory programs (e.g., Regulatory Analysis Guidelines). In the SRM to SECY-03-0047, issued June 26, 2003, the Commission directed the staff to consider whether it can accomplish the same goals in a

more efficient and effective manner by updating the Commission policy statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," to include a more explicit discussion of defense-in-depth, risk-informed regulation, and performance-based regulation. As part of the ANPR questions, stakeholders were asked to comment on whether a better defense-in-depth definition for future plants should be included as a separate policy statement, a revision to the PRA policy statement, or as an update to Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis," and whether such a description should be completed on the same schedule as 10 CFR Part 53.

# Stakeholder Comments -

Most stakeholders felt that a new policy statement on defense-in-depth for future plants was needed. A holistic and technology-neutral defense-in-depth statement that recognizes the role of inherent safety and passive approaches, in addition to the traditional use of redundant and diverse active systems, would be helpful in advance of developing the requirements of a new 10 CFR Part 53. The Framework definition was regarded as a good start, but further iteration was advocated by a number of stakeholders. The policy statement should address the interdependency between defense-in-depth, protective strategies, and design criteria in relation to the safety margins incorporated in a new design. Because the scope of defense-in-depth is broader than just PRA, stakeholders felt a separate policy statement on defense-in-depth is needed. The stakeholders also noted that modifying Regulatory Guide 1.174 for new plants may be difficult because it is focused on existing deterministic requirements as well as LWR risk metrics like CDF and LERF.

# Staff Perspectives –

The staff believes that at least a draft policy statement on defense-in-depth for future plants should be developed on a timely basis. Before it is finalized, such a statement could be evaluated and tested via the insights gained through the development of the NGNP licensing strategy and completion of the PBMR pre-application review.