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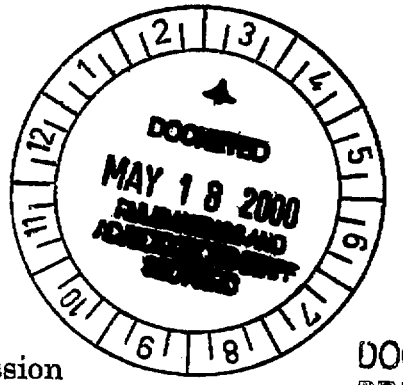

May 17, 2000

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

DOCKET NUMBER
PROPOSED RULE PR 21,50,52,54 +100
(65FR 11488)

ATTENTION: **Rulemakings and Adjudications**

SUBJECT: **Advance Notice of Proposed Rulemaking on Risk-Informing Special Treatment Requirements, (65 Fed. Reg. 11488, March 3, 2000)**

PROJECT NO: **689**

Dear Ms. Vietti-Cook:

These comments are submitted by the Nuclear Energy Institute (NEI)[1] on behalf of the nuclear energy industry in response to the Nuclear Regulatory Commission's *Federal Register* Notice on its Advance Notice of Proposed Rulemaking (ANPR), *Risk-Informing Special Treatment Requirements* (65 Fed. Reg. 11488, March 3, 2000). Enclosure 1 provides comments on specific issues raised in the ANPR that are not addressed by the ANPR questions. Enclosure 2 provides the industry's detailed response to the ANPR questions.

Overall Approach to Risk-Informing the NRC Regulatory Regime

We believe it is important to build on the existing regulatory improvement activities that are using a risk-informed, performance-based approach. The overall program for implementing risk-informed regulatory improvements should contain four elements:

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[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

TEMPLATE = SECY-067

SECY-02

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- Improving NRC Assessment and Oversight Process
- Improving the scope of structures, systems and components (SSCs) that are governed by NRC special treatment regulations (Option 2 to SECY 98-300)
- Improving NRC technical requirements (Option 3 to SECY 98-300)
- Improving NRC administrative requirements

Initially the industry supported an approach similar to that described in the ANPR for implementing Option 2. Now, with the benefit of nine months of regulatory interaction and the experience gained on developing a detailed implementation guide, we recommend that only a subset of the candidate regulations be addressed under Option 2, with the remaining regulations addressed in two other segments: 1) the administrative element for risk-informing NRC regulations, and 2) a separate parallel activity, risk-informing Technical Specifications.

Administrative Requirements

For a number of the administrative requirements, such as 10 CFR 50.72 and 10 CFR 50.59, regulatory improvement projects were started prior to the onset of risk-informed regulation, and are approaching completion. Rather than delay these interim improvements, we suggest that we allow sufficient time to assess the full impact of these changes before embarking on another layer of change.

Technical Specifications

We recommend that improvements to 10 CFR 50.36, *Technical Specifications,* be treated as a separate activity because of the regulatory and licensing complexities involved in improving §50.36 activities. This task would address the synergies between §50.36 and §50.65 requirements.

Need for a New Detailed Appendix to Part 50

We disagree with the need for a detailed regulatory appendix (Appendix T) to Part 50. Risk-informed activities and other regulatory improvements have included a risk-informed SSC categorization element and have been satisfactorily implemented without the need for a prescriptive regulatory appendix. Previous detailed and prescriptive regulatory appendices have resulted in a rigid and impractical regulatory regime, e.g., Appendix R to Part 50. Over time, such rigidity discourages and inhibits NRC and industry from taking advantage of new ideas, advances in technology, and insights from operating and regulatory experience. The result is numerous and significant regulatory exemptions which undermine public confidence in the NRC.

Selective Implementation

The process for adopting Option 2 should allow for selective implementation. Commercial nuclear power plants have varying licensing bases, detailed designs and operational practices. What is beneficial at one plant may not be beneficial at another. What is risk-significant at one plant might not be risk-significant at another. To require full implementation of all risk-informed NRC special treatment requirements under Option 2 could increase, not eliminate, unnecessary burden.

Concerns over selective system implementation are unfounded and do not take into consideration the regulatory controls and licensee practices that have been put in place in response to the maintenance rule. Most of the nonsafety-related SSCs that will be categorized as safety-significant will have been identified under the maintenance rule. For most licensees, additional controls and monitoring have been imposed to the extent necessary to provide reasonable assurance that the safety-significant (risk-significant) functions will be satisfied.

Need for Prior NRC Review and Approval

We disagree that there has to be a link between level of detail and prior NRC review and approval. A number of regulations have been issued and implemented without the need for prior NRC review and approval, and without detailed implementation requirements. To assist in implementation, and to avoid misunderstandings and misinterpretation, NRC-endorsed guidelines were developed prior to implementation.

In view of the voluntary nature of risk-informed regulation, we believe that the NRC should be notified by a licensee of its intent to adopt §50.69. The notification would include statements on PRA quality, the methodology used in the risk-evaluation process, the list of regulations being adopted, and a discussion of the extent to which the licensee's approach is consistent with an endorsed guideline. There are active regulatory interactions on the content of a guideline for implementing Option 2.

Impact on Other Regulations, 10 CFR Part 54 and 10 CFR Part 21

It is unclear from the ANPR whether 10 CFR Part 54 is included in the Option 2 scope. NEI believes that a risk-informed option for Part 54 should be developed to ensure regulatory consistency and coherency.

Part 21 is a complex regulation with hard links to the Atomic Energy Act. As such, any change to the scope of Part 21 would be a complex and prolonged activity that may involve a change to the Atomic Energy Act. As a result, the industry believes

that Part 21 should not be included in the Option 2 scope. Once we have gained more experience and a better understanding of implementing risk-informed regulations, we would be in a better position to assess the need to address Part 21 in a risk-informed environment.

Identification and Control of Attributes Requiring Special Treatment

The objective of §50.69 is to improve the efficiency and effectiveness of the regulatory process by focusing special treatment requirements on those SSCs that have high safety-significance. Option 2 also defines special treatment requirements for RISC-3 SSCs only because of direct links to regulatory technical requirements, not because of safety-significance. In a risk-informed regulatory regime, just as in the existing regime, a graded approach to implementing requirements is appropriate.

We generally agree with the proposed quadrant categorization concept. Specific details of treatment of the various categories are provided in the detailed responses to the Section E questions in Enclosure 2. One minor variation is that we believe there should be two subcategories for RISC-2 SSCs:

1. Nonsafety-related SSCs that are currently identified as "important-to-safety" and that are categorized as safety-significant, and
2. Other nonsafety-related SSCs that are categorized as safety-significant.

RISC-2(1) SSCs would continue to be subject to the existing special treatment requirements. RISC-2(2) SSCs would be subject to a monitoring program and commercial level (balance-of-plant) controls that provide reasonable assurance that the safety-significant functional requirements identified by the risk-informed evaluation process will be satisfied.

Changing Technical Requirements & Design Bases

We believe that changes to NRC technical requirements will be addressed in Option 3 to SECY 98-300, *Risk-Informing NRC Technical Requirements,* not in Option 2. Attempts to include changes to technical requirements in Option 2 appears to suggest that the transition to risk-informed regulation should be completed in one step. This would be a major undertaking and is not considered the optimum approach. It would be a significant departure from the approach approved by the Commission in the SRM on SECY 98-300.

PRA Completeness and Quality

In 1998, the industry took steps to address these elements through the Industry PRA Certification and Peer Review Program. The NRC staff has been involved in, and kept apprised of, these activities. Recently, NEI submitted NEI-00-02, *Probabilistic Risk Assessment Peer Review Process Guidance,* for NRC review to support Option 2 implementation.

The consensus standards organizations are developing formal standards that also could be used to assess PRA quality and completeness. These new draft standards reflect the elements in the industry's certification process and could be an alternative PRA "gauge" for existing licensees that have not been certified or for new licensees. To require full and sole compliance with a draft ASME standard, the final form of which is unknown, introduces significant uncertainty and would delay risk-informed regulatory improvements.

If there are questions relating to these comments, please contact Biff Bradley (202-739-8083, e-mail reb@nei.org), or Adrian Heymer (202-739-8094, e-mail aph@nei.org).

Sincerely,

Stephen D. Floyd

Enclosures

c. The Honorable Richard A. Meserve, Chairman, NRC
The Honorable Greta Joy Dicus, Commissioner, NRC
The Honorable Nils J. Diaz, Commissioner, NRC
The Honorable Edward McGaffigan Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
Dr. William D. Travers, Executive Director for Operations, NRC

Enclosure 1

Summary of Industry Comments on ANPR for Risk-Informing Special Treatment Requirements

This enclosure provides comments on the following issues that are discussed in the ANPR and are not directly addressed by the ANPR questions:

- Focus of risk-informed, performance-based regulation
- Individual licensing and technical evaluations of SSCs
- NRC Notification

Focus of risk-informed, performance-based regulation

Licensees are motivated to ensure functionality of all equipment to maintain the value of their asset, regardless of whether the equipment is governed by regulatory requirements.

In the proposed industry approach described in the responses to the ANPR questions, the focus is on both a risk-informed categorization for the application of special treatment requirements, and a performance-based assessment of such controls. Both these elements are essential and are of equal importance if we are to gain full benefit from the new risk-informed, performance-based regulatory regime. In such a regime, it is important to focus on SSC functionality, rather than rigid compliance with a non-technical, non-operational regulatory interpretation of the term "operable."

In a risk-informed, performance-based regime, the prime focus should be on whether the SSCs would satisfy their safety function(s). In the past there have been significant and unnecessary intra-industry discussions and regulatory interactions on whether an SSC is "operable," even though there is general agreement that the SSC would satisfy its safety function(s), should an unplanned plant transient occur.

Individual licensing and technical evaluations of SSCs

The ANPR suggests that for each change of SSC categorization or change in special treatment requirements, a licensing commitment evaluation should be performed and documented. This is not practical or necessary. There is no need for an individual licensing evaluation of each SSC that is not categorized as safety-significant. If the SSC is of minimal or no safety-significance, it should not be subject to NRC commitments. The main objective of a risk-informed approach to regulations is to focus management activities on those matters that have safety-significance. To require detailed and documented licensing evaluations of every

commitment made on SSCs that are now categorized as RISC-3 is unnecessary. It would result in the unnecessary expenditure of large NRC and industry resources on a task that has minimal or no safety-significance.

There is a well-established process for managing NRC commitments, which in a totally risk-informed regime should be associated with safety-significant SSCs. However, we acknowledge that for RISC-3 SSCs, a licensee needs to understand and document the required functions that are required by regulation or directly credited in the safety analyses (Chapter 15 analyses) required by regulation.

The only difference between RISC-3 and RISC-4 SSCs is that the RISC-3 SSCs are directly and specifically referenced in an existing regulation or the safety analyses required by an existing regulation. Thus, RISC-3 SSCs need to satisfy the functional technical requirements of these regulations until the technical requirements are risk-informed under Option 3. As a result, under Option 2, RISC-3 SSCs are the subject of a single licensing commitment that imposes commercial level (balance-of-plant) special treatment requirements (monitoring or controls) to provide reasonable assurance that the functions required by regulation or credited in the safety analyses required by regulation will be satisfied. This single commitment supercedes all other licensing commitments for RISC-3 SSCs because of the low safety-significance of the RISC-3 SSCs.

The failure of RISC-3 SSC to satisfy a requirement or the assumptions or conclusions in the safety analyses required by regulation would be reviewed and resolved through the new NRC oversight process and would involve a Significance Determination Process evaluation and appropriate licensee corrective action.

The basis of the safety-significant categorization process is the risk-evaluation process that combines PRA insights, operating experience, engineering concepts and a plant-level, expert panel solicitation (the Integrated Decision-Making Panel (IDP)). The risk-informed categorization process includes a technical evaluation of the change in categorization for each SSC, and assesses the overall impact of the changes in SSC categorization. The basis for the categorization will be documented. Licensee monitoring and, where applicable and appropriate, licensee corrective action programs assess and provide reasonable assurance that the SSCs will continue to satisfy their required functions.

NRC Notification

In view of the voluntary nature of risk-informed regulation, a licensee should notify the NRC prior to implementing §50.69. The notification would include:

- the list of regulations being adopted;

- reference to an NRC-endorsed guideline including any exceptions, or a detailed description of an alternative SSC categorization methodology;
- a summary of, or reference to, a process for resolving PRA quality issues;
- treatment provisions, if different from those described in an endorsed guideline;
- a general schedule for implementation; and
- a technical specification change submittal, if needed.

Enclosure 2

Industry Response to Specific Questions in the ANPR for a Risk-Informed Approach for Implementing NRC Special Treatment Requirements

The industry response to the questions listed in the ANPR is provided below.

A.1. If the NRC elects to pursue a phased rulemaking approach, how should the rules identified be prioritized/phased?

The industry initially agreed with the overall approach to implementing risk-informed regulation approved by the Commission in its SRM on SECY 98-300, Options for Risk-informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities." Now with the benefit of further industry and regulatory interactions and evaluations, we recommend that the overall program for improving NRC regulations through a risk-informed approach should have four main elements:

- Improving the NRC assessment and oversight process
- Safety-significant categorization of SSCs, and the application of NRC special treatment requirements based on that categorization (Option 2)
- Risk-informing NRC technical requirements (Option 3)
- Risk-informing NRC administrative requirements (additional element)

The industry's initial list of candidate regulations for consideration under Option 2 was almost identical to the NRC's list of regulations. Now, with the benefit of recent regulatory interactions and experience on drafting a detailed guideline we recommend that Option 2, as proposed in the ANPR, should be split into three segments.

- Option 2 regulations as listed in the ANPR except for the following two segments:
  - Administrative requirements
  - Technical Specifications

Option 2 Scope of Regulations

Under the three-segment approach, the following regulations would be included in the Option 2 segment:

- 10 CFR 50.44, *Standards for combustible gas control system in light-water-cooled power reactors,*
- 10 CFR 50.49, *Environmental qualification of electric equipment important to safety for nuclear power plants*

- 10 CFR 50.54(a), *Conditions of licenses (Changes to Appendix B programs)*
- 10 CFR 50.55, *Conditions of construction permits*
- 10 CFR 50.55a, *Codes and standards*
- 10 CFR 50.65, *Requirements for monitoring the effectiveness of maintenance at nuclear power plants*
- 10 CFR 50, Appendix A, *General Design Criteria for Nuclear Power Plants*
- 10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*
- 10 CFR 50, Appendix J, *Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors*
- 10 CFR 50 Appendix S, *Earthquake Engineering Criteria for Nuclear Power Plants*
- 10 CFR Part 54, *Requirements for renewal of operating licenses for nuclear power plants*
- Appendix A to Part 100, *Seismic and Geologic Siting Criteria for Nuclear Power Plants*

In addition, there would be conforming changes to regulations such as 10 CFR 50.2, *Definitions,* and 10 CFR 50.34, *Contents of applications; technical information.*

These regulations would be incorporated into §50.69 to allow the SSC scope to be amended to one that is based on risk-informed insights.

Administrative Requirements

Rulemakings on some administrative regulations were initiated before the onset of the risk-informed improvement program described in SECY 98-300. We believe it would be more beneficial to complete those rulemakings as they stand. Also, Option 2 and Option 3 will provide valuable and additional insights on these administrative requirements. Thus, the improvements to the administrative requirements should be scheduled to occur at a later date. The administrative requirements to be included in the fourth element for risk-informing NRC regulations are:

- 10 CFR 50.34, *Contents of applications; technical information;*
- 10 CFR 50.54, *Conditions of licenses;*
- 10 CFR 50.59, *Changes, tests and experiments;*
- 10 CFR 50.71, *Maintenance of records, making of reports;*
- 10 CFR 50.72, *Immediate notification requirements for operating nuclear power reactors*;
- 10 CFR 50.73, *Licensee event report system*;
- 10 CFR Part 52, *Early site permits; standard design certifications; and combined licenses for nuclear power plants*;
- 10 CFR Part 21, *Reporting of Defects and Noncompliance;* and

- Appropriate conforming changes to other regulations.

In addition, we believe that this element should include a complete review of NRC reporting requirements and activities covering all areas to reduce duplicative reports, data, and reporting functions.

Technical Specifications

On 10 CFR 50.36, *Technical specifications,* we recommend that a separate activity should be initiated because of the regulatory and licensing complexities associated with this regulation. This task would be conducted in parallel to Option 2 implementation. It would increase the focus on the safety limits and encompass:

- risk-informing the SSC scope of Technical Specifications;
- addressing the current duplicative requirements in §50.36 and §50.65(a)(4), specifically between Allowed Outage Times (AOTs)/Surveillances and the §50.65 plant risk-configuration control requirement; and
- assessing, and as necessary, addressing, the inclusion of administrative requirements.

A.2. Proceeding with changes to special treatment requirements before establishing a risk-informed design basis (establishment of a risk-informed design basis is being addressed by a separate task) may create inconsistencies between the treatment of SSCs and the functions they serve for the deterministic design basis. Are there any detrimental effects (licensing or otherwise) associated with changing the special treatment requirements before changing the design basis? Please provide a discussion of the detrimental effects that you believe would result.

The industry does not believe there would be a detrimental effect in changing the scope of SSCs governed by regulations before evaluating risk-informed improvements to the technical requirements (the existing design basis). However, if the Option 2 pilot projects indicate there is minimal industrywide benefit in implementing Option 2, attention and priority should be focused on risk-informing the technical and administrative requirements. It should be noted that individual licensees still might wish to proceed with Option 2. In this case, a group of licensees might continue the regulatory interactions to assist in the §50.69 rulemaking activity.

Changes to technical requirements are not included under Option 2. This option only focuses on the scope of SSCs that are subject to special treatment requirements, and adjusts the scope of those special treatment requirements consistent with safety. Option 3 will assess the need to adjust the technical requirements of NRC regulations, including the technical requirements embedded in special treatment regulations.

As stated in the response to question A1, we believe that a segmented rulemaking approach would be more beneficial and practical than a single comprehensive rulemaking that attempted to address scope, technical and administrative requirements in one mega-rulemaking proceeding.

In the industry's proposed approach, we anticipate that Option 2 and the implementation of risk-informed improvements to Technical Specifications would be parallel activities. Option 3, which will initially focus on §50.44 and 10 CFR 50.46 before assessing other technical requirements, is considered a longer project than Option 2. As such, risk-informing NRC administrative requirements would be started at a later date, once the industry and the NRC has had a chance to collate insights from the other risk-informed activities described in these comments. Such an approach is the optimum way of expediting the framework for enhancing management focus on safety-significant equipment and procedures while reducing unnecessary burden.

A.3. (a) What should the proposed rule state in order to clearly identify the scope of SSCs in each special treatment requirement for which the rule provides a regulatory alternative? (b) If the Commission should decide to impose alternative requirements to the special treatment requirements and/or if the Commission should decide to impose risk requirements on RISC-1, RISC-2, and/or RISC-3 SSCs, how should the proposed rule be constructed in order to clearly identify the scope of SSCs for which the alternative requirements apply?

We propose the following draft rule language for Option 2:

10 CFR 50.69, Risk-Informing Scope of Special Treatment Requirements

(a)(i) A licensee shall notify the Commission in writing of its intent to adopt this Section. The notification and, where applicable, the methodology shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(ii) The notification letter shall:
(A) List the regulations being adopted under this section;
(B) Provide a reference to, or describe the risk-informed methodology that is consistent with, the requirements of this Section and Appendix T to this Part;
(C) Provide a summary of, or reference to, a process for resolving PRA quality issues;
(D) Describe the SSC special treatment provisions for each category if different than those listed in this Section;
(E) Provide a general schedule for implementation; and
(F) Include, where applicable and appropriate, a Technical Specification change submittal.

(iii) At periodic intervals not to exceed 36 months, a licensee shall update the PRA to reflect the current plant configuration and operating data. At this time the licensee shall determine whether changes to the risk-informed SSC categorization are necessary. The bases for changes in SSC categorization shall be documented and available for NRC review.

(b)(i) A licensee, using a risk-informed evaluation methodology that satisfies the requirements of Appendix T to this Part, may adjust the scope of structures, systems and components that are governed by any combination of the following regulations:

10 CFR Part 50--Sections 50.44, 50.49, 50.54(a), 50.55, 50.55a, 50.65;
10 CFR Part 50--Appendix A, Appendix B, Appendix J, and Appendix S;
10 CFR Part 54;
10 CFR Part 100; and
10 CFR Part 100--Appendix A

(ii) A licensee that selects Appendix B to Part 50 to be included in the scope of regulations adopted under this Section may make changes to its quality program description that is described or referenced in its Safety Analyses Report without prior NRC review and approval providing there is reasonable assurance that the safety-significant functions will be satisfied, as demonstrated by the satisfaction of the performance criteria required by this section.

(c)(i) For licensees that are implementing this Section, there shall be at least four SSC categories:
(A) ***Risk-Informed Safety Class 1 structures, systems and components*** *are safety-related structures, systems and components that have been identified as being safety-significant by the licensee's risk-informed evaluation methodology.*
(B) ***Risk-Informed Safety Class 2 structures, systems and components*** *are:*
(1) Important-to-safety (nonsafety-related) structures, systems and components that are identified as safety-significant by the licensee's risk-informed evaluation methodology, and
(2) Nonsafety-related structures, systems and components that are categorized as safety-significant by the licensee's risk-informed evaluation methodology.
(C) ***Risk-Informed Safety Class 3 structures, systems and components*** *are safety-related structures, systems and components that are directly and specifically referenced in the regulations or directly credited in the safety analyses required by regulation, yet are identified as not being safety-significant by the licensee's risk-informed evaluation methodology.*
(D) ***Risk-Informed Safety Class 4 structures, systems and components***

are structures, systems and components that are identified as not being safety-significant and are nonsafety-related.

(ii) For a licensee that has a different SSC categorization scheme than that prescribed in paragraph c(i), the NRC notification letter shall provide a description of how the licensee's categories correlate to those described in this Section.

(d) The regulatory controls and required special treatment requirements associated with the regulations adopted under this Section for the recategorized SSCs are:
(A) ***Risk-Informed Safety Class 1 structures, systems and components*** *shall satisfy the special treatment requirements in the regulations that a licensee has chosen to adopt from those listed in paragraph b(i) of this Section, consistent with the significance to safety. The licensee's change control process for RISC-1 SSCs shall include a provision that provides reasonable assurance that RISC-1 safety-significant function(s) will be satisfied following a facility change that involves a RISC-1 SSC.*
(B)(1) ***Risk-Informed Safety Class 2(1) structures, systems and components*** *shall be subject to the applicable "important-to-safety" requirements defined in §50.48, §50.49, §50.55a, §50.62, §50.63, and the following Appendices to Part 50: A, B, J, R and S.*
(B)(2) ***Risk-Informed Safety Class 2(2) structures, systems and components*** *shall:*
(i) Satisfy a performance monitoring program that provides reasonable assurance that the safety functions identified by the risk-informed evaluation process will be satisfied;
(ii) Be subject to commercial level controls and specifications imposed by the licensee that provide reasonable assurance that the safety-significant functions identified by the risk-evaluation methodology are satisfied. Such programs shall include a change control provision that provides reasonable assurance that RISC-2 safety-significant function(s) will be satisfied following a facility change that involved RISC-2 SSCs;
(iii) Be subject to a reporting program for deficiencies that result in a failure to satisfy a safety-significant function.
(C) ***Risk-Informed Safety Class 3 structures, systems and components*** *shall be subject to the following requirements and associated licensing commitments:*
(1) A licensee-established monitoring program, or where a monitoring program is inappropriate or impractical, commercial level controls and specifications defined by the licensee. Such licensee-administered programs, controls and specifications shall provide reasonable commercial-level assurance that the functional requirements of the applicable regulation, or the assumptions and conclusions of the applicable section of the licensee's safety

analyses will be satisfied.
(2) A change control process that satisfies the requirements of §50.59
*(D) **Risk-Informed Safety Class 4 structures, systems and components** are not subject to regulatory requirements.*

Appendix T to Part 50, Methodology for the risk-informed categorization of Structures, Systems and Components

(a) The determination of SSC safety significance is an integrated decision-making process that uses risk, operational experience, and traditional engineering insights. The process for categorizing SSCs shall include the following:

(i) An assessment of the licensee's specific probabilistic risk assessment (PRA) to support the categorization process against an industry consensus standard or the industry's PRA Certification and Peer Review process, or other NRC-endorsed process;
(ii) The use of the PRA to determine the relative importance of modeled SSCs to accident prevention and mitigation that includes:
(A) A determination of relative importance of SSCs using the PRA importance measures.
(B) The use of risk metrics and importance measures based on both CDF and LERF, and that provide information on the relative contribution of an SSC to total risk.
(C) Screening criteria for categorizing SSCs into the safety significant and the low safety significant categories based on an assessment of the overall impact of SSC re-categorization and a comparison of this impact to the acceptance criteria for changes in CDF and LERF.
(D) A truncation value for PRA model quantification set to a value that captures the significant contributors to risk.
(E) Sensitivity analyses of SSC importances.
(iii) The use of an integrated decision-making panel (IDP) of knowledgeable personnel familiar with the plant to determine the safety significance of SSCs. The panel shall consider the results of the PRA, deterministic and other traditional engineering analyses, and operating experience.

IDP membership, experience, and knowledge shall encompass the main plant processes and the main engineering disciplines.

(iv) Defense-in-depth activities and criteria that are adjusted for, and take into account, risk-insights.

(v) Take into account appropriate safety margins that are associated with key functional goals and requirements.

(vi) Evaluations of the change in risk resulting from reclassifying SSCs to assess the overall change in risk following the recategorization process associated with a system or group of systems, and of the complete plant.

The IDP shall document its basis for determining acceptable changes in risk if a PRA model is not available to evaluate the change in risk from an external initiating event or plant operating modes.

(vii) Documentation covering PRA, PRA quality, PRA results and risk profile changes, IDP decision-making criteria, IDP membership, IDP conclusions, and the revised SSC functional criteria and controls shall be available for review.

Additional changes and additions to Part 50 to clarify risk-informed regulation and safety-significant SSCs

10 CFR 50.2, Definitions

Construction or constructing, *when used in relation to a risk-informed, performance-based approach to the requirements of this Chapter, means the analysis, design, manufacture, fabrication, quality assurance, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety-significant.*

Safety-significant structures, systems and components (SSCs) *are the set of SSCs that a risk-informed evaluation process has identified as important to maintain an acceptable and consistent level of safety.*

A risk-informed evaluation methodology is *an evaluation that combines probabilistic risk insights, operating experience and engineering analyses.*

Commercial level controls *are those work controls, processes and equipment specifications that have been developed by the licensee and its contractors to assure satisfactory operation of the facility, as determined by the licensee.*

10 CFR 50.54(a)(3)

Each licensee described in paragraph (a)(1) of this section may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC, ***or for licensees that have selected Appendix B to this Part in the adoption of §50.69, providing the criteria in §50.69 (d) are satisfied.*** Changes to the quality assurance program description must be submitted to the NRC in accordance with the requirements of Sec. 50.71(e). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment ***for those licensees that have not adopted §50.69:***

(i).....

A.4. If the Commission should decide to impose alternative requirements to the special treatment requirements and/or if the Commission should decide to impose risk requirements on RISC-1, RISC-2, and/or RISC-3 SSCs, how should the alternative requirements be expressed to ensure clarity (please provide examples of how the requirements should be phrased)? Should the alternative requirements be expressed prescriptively or in a performance-based approach? Should the alternative requirements be placed in each specific special treatment regulation for which an alternative is being provided, or should the alternative requirements be included in the proposed new rule?

See response to A.3.

The industry believes that the new and improved regulatory requirements should be included in §50.69, to the extent proposed in the response to question A.3. Such an approach is necessary because some licensees may choose not to adopt risk-informed improvements to the regulations.

In our response to question A.3, we have provided draft language for consideration which we believe provides sufficient clarity with an appropriate level of licensee flexibility. We believe the draft language should be based on performance-based and risk-informed requirements that are linked to each regulation. The proposed language is based on that used in previous risk-informed, performance-based applications.

Additional clarifications would be provided in the guidance documents for implementing Section 50.69.

In general, specific technical attributes within the special treatment requirements are not being changed under Option 2, which focuses on the scope of SSCs to be governed by special treatment requirements.

A.5. Please provide an estimate of the expected costs and benefits of implementing risk-informed special treatment requirements.

Commercial nuclear power plants have varying licensing bases, detailed designs and operational practices. What is beneficial at one plant may not beneficial at another. Costs of implementation and potential benefits vary according to the design, licensing bases, management practices, and whether licensees are able to pool resources.

Good estimates on implementation costs and potential benefit cannot be made until there is more certainty with regard to the implementation process. Once a better understanding on the draft guidance is established, the industry should be in a position to provide a reasonable estimate of the costs and benefits. One of the objectives of the pilot programs is to attain a better estimate of implementation costs and benefits from §50.69.

After 30+ years of operating and regulating nuclear power plants, and with advances in technology and analytical techniques, the industry and the NRC are in a better position to determine what equipment has safety-significance compared to the initial regulatory determinations. Plant-specific analyses have identified some nonsafety-related SSCs and practices that have safety-significance, and also identified some safety-related equipment and practices that have minimal or no safety-significance. By focusing regulations and management (NRC and industry) attention on the set of SSCs that have safety-significance, safety will be enhanced, while reducing the regulatory resource loading.

A.6. Please comment on the benefits of risk-informing 10 CFR 50.36?

There are several on-going activities related to improving Technical Specifications through risk-informed approaches. In view of these activities and the additional and complex task of risk-informing the Technical Specifications, the industry has formed a working group to address and better coordinate the industry's input on improving Technical Specifications.

We recommend that a separate activity be initiated to address risk-informing Technical Specifications. Such an activity should be implemented in parallel with Option 2. It should provide the vehicle for the efficient elimination of duplicative regulatory requirements. It would improve regulatory coherency, and regulatory efficiency and effectiveness through the elimination of ambiguous terms and duplicative requirements. Such a task would focus on the safety limits and the following tasks:

- risk-informing the SSC scope of Technical Specifications;
- addressing the current duplicative requirements in §50.36 and §50.65(a)(4), specifically between Allowed Outage Times (AOTs)/Surveillances and the §50.65 plant risk-configuration control requirement; and
- assessing, and as necessary, addressing the inclusion of administrative requirements.

B.1. Are the screening criteria reasonable and have the rules that have been evaluated (see the attached Table) been screened correctly against the screening criteria? Please provide rule-specific comments on reduction of unnecessary burden and the need to modify a rule in order to maintain safety (Criterion III).

The screening criteria that were used to identify the candidate regulations for Option 2 are reasonable. The process provided results similar to the list of regulations developed by the industry.

Having identified candidate regulations, the industry has further refined the approach based on the experiences gained in regulatory interactions and in developing a detailed guidance document. Our conclusions are that Option 2 should be split into three segments as discussed in the response to question A.1.

B.2. Are there any other rules, in addition to those that have been evaluated, that should be considered as part of this effort? Please provide specific comments identifying any rules that you belief should be considered and the reasons for recommending their inclusion.

As stated in the response to B.1., we believe the optimum approach is to split Option 2 into three segments: Option 2, administrative requirements, and Technical Specifications. The list of regulations to be included in these sections is provided in the response to question A.1.

B.3. Are there any rules that have been identified for inclusion that should not be included? Please provide specific comments identifying those rules and the reasons for recommending their exclusion.

Technical Specifications, 10 CFR 50.36

Our response to question A.6 provided our rationale for not including §50.36 in the Option 2 activities, and for making risk-informed improvements to Technical Specifications a separate project.

Part 21

10 CFR Part 21 was initially included in the industry's initial scope of candidate regulations. However, Part 21 is a complex regulation with hard links to the

Atomic Energy Act. This regulation was introduced as a result of the enactment of Section 206 of the Energy Reorganization Act of 1974, which amended the Atomic Energy Act. The Act required any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity to make reports relating to defects in basic components that could cause a substantial safety hazard.

The scope of Part 21 is not based on risk-informed insights. It is governed by the term "basic component" which is defined in the Atomic Energy Act, Section 223:

> "...the term 'basic component' means a facility structure, system or part thereof necessary to assure—
>
> (1) the integrity of the reactor coolant pressure boundary;
> (2) the capability to shut down the reactor and maintain it in a safe shutdown condition; or
> (3) the capability to prevent or mitigate the consequences of accidents which could result in an unplanned release of quantities of fission products in excess of the limits established by the Commission."
> (generally, 42 USC sec.2273)

Part 21 provides additional details and clarifications in its definition of a basic component. Section 21.3 defines substantial safety hazard as:

> "....a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter."

Changing the Part 21 SSC scope would be a complex and prolonged activity that might involve a change to the Atomic Energy Act. As a result, the industry believes that improvements to Part 21 should be separated from Option 2 activities. A complete evaluation of the need to amend Part 21 to comport with a risk-informed regime should be performed as part of the element to risk-inform NRC administrative requirements. Such an evaluation should take into account the experiences gained in implementing Option 2, and from regulating licensees that have adopted §50.69. Such an evaluation should include an assessment of the need for legislative action.

For licensees adopting §50.69, Part 21 would continue to apply to RISC-1 SSCs.

Part 21 would not apply to RISC-3 SSCs because a failure could not cause a substantial safety hazard, since these SSCs have minimal or no safety significance.

Part 21 would not apply to RISC 2 or RISC 4 SSCs because these are not basic components as defined in the Act or in Part 21.

10 CFR 50.59

Initially we believed that §50.59 should be included in the Option 2 matrix. Now, nine months later, and following substantial progress on the existing §50.59 rulemaking, we recognize that it would be premature to attempt further changes to this regulation at this time. To introduce an additional change to §50.59 would further complicate the understanding and implementation of the existing §50.59 improvement activities. Once the industry has gained experience at initiating the new §50.59 process, an evaluation of the benefits of risk-informing this regulation should be performed under the element for risk-informing NRC administrative requirements. The ultimate goal is for §50.59 to apply only to safety-significant SSCs.

RISC-1 SSCs would be subject to §50.59. In addition, for SSCs that are categorized as safety-significant because of a beyond design bases function, a licensee's change control program should include a provision that provides reasonable assurance that RISC-1 safety-significant function(s) will be satisfied following a facility change that involves a RISC-1 SSC.

The new rule, §50.69, should impose change control provisions on RISC-2 SSCs that would not be included in the existing §50.59 evaluation scope. The new provision would require an evaluation of all changes to RISC-2 SSCs to provide reasonable assurance that the safety-significant function(s) will be satisfied following a facility change that involved RISC-2 SSCs. This provision, which should be incorporated into the §50.69 rule, would be reassessed when §50.59 is risk-informed in the element for risk-informing NRC administrative requirements.

Until Option 3 is completed, RISC-3 SSCs should continue to be subject to §50.59. These SSCs are directly referenced in the regulations or credited in the safety analyses required by regulation and should be the subject of a regulatory change control process.

The categorization process may identify other safety-related SSCs that are not categorized as safety-significant, and that are not directly and specifically referenced in a regulation or directly referenced in the safety analyses required by regulation. These SSCs may be categorized as RISC-4 on completion of a satisfactory §50.59 evaluation.

10 CFR 50.72 & 10 CFR 50.73

At this stage, we do not believe it would be beneficial to delay the existing §50.72 and §50.73 rulemakings to introduce a risk-informed reporting option. Risk-informing §50.72 and §50.73 should be included in the element for implementing risk-informed improvements to NRC administrative requirements.

While we have proposed that §50.72 and §50.73 should not be included under Option 2, we recognize the need for a reporting mechanism for RISC-2 SSCs. We propose that an addenda to §50.73 should be incorporated into the §50.69 rulemaking process to introduce a performance-based reporting mechanism for RISC-2 SSCs as the interim solution until §50.72 and §50.73 are risk-informed. Our initial thought is that reporting requirements for RISC-2 SSCs should be linked to a failure to satisfy a performance criterion established as part of the monitoring program for RISC-2 SSCs. We have yet to fully develop the details of such an approach and are willing to work with the NRC staff to develop the appropriate language and implementation guidance for this interim solution.

In regard to RISC-3 SSCs, §50.72 and §50.73 requirements would not be applicable because such SSCs have minimal or no safety significance.

In view of the other risk-informed, performance-based regulatory improvements that have been introduced in the last four years, there has been an increased regulatory focus on plant performance. As a result, more information on equipment performance is being provided to the NRC. We believe that there would be benefit in performing a complete review of NRC reporting requirements and activities that would include licensee reporting updates, equipment performance, and plant status reports under the element to risk-inform NRC administrative requirements. The objective of such a review would be to eliminate unnecessary and duplicative reporting requirements and focus reporting requirements on those matters that have safety significance.

Other Administrative Requirements

In our response to question A.1, we provided our rationale for recommending that the administrative requirements be treated as a separate activity, and proposed a list of regulations to be included in the administrative element for risk-informing NRC regulations.

C.1. Are the elements identified for the appendix appropriate and adequate for establishing a risk-informed process to categorize SSCs with respect to their significance to safety?

We disagree with the need for a detailed regulatory appendix in view of satisfactory implementation of previous risk-informed improvements that have involved SSC categorization; e.g., §50.65, ISI, IST, and Option B to Part 50, Appendix J.

Experience has shown significant long-term problems with detailed regulatory appendices. Over time, detailed regulatory appendices have become impractical and unmanageable. They result in excessive and unnecessary expenditure of NRC and industry resources on numerous exemption requests to incorporate advances in technology or operating experience. An example is Appendix R to Part 50 which is now the subject of numerous and significant exemptions that undermine public confidence in the NRC regulatory process.

An example of the industry's concerns and questioning on the need for prescriptive detail is reflected in the detailed and prescriptive language in the ANPR relating to the Integrated Decision-Making Panel (IDP), an expert panel.

In the trial implementation of §50.65, the NRC staff commented favorably on the expertise and conduct of licensees' expert panels (see NUREG 1526). In the baseline inspections, the majority of licensees implemented the expert panel process in the same exemplary manner as the pilot plants. There was minimal guidance or requirements on who should be on these expert panels, their level of experience, membership qualifications, or the procedures to be used. We acknowledge that during the baseline inspections some shortcomings were noted in a few licensee programs. Those licensees took appropriate corrective actions to address these issues. In addition, consensus standards' organizations have provided additional guidance (ASME Code Case OMN-3) on expert panel deliberations. We are not aware of any concerns or problems that now warrant such prescriptive detail on the IDP in an appendix to the regulations.

While we acknowledge that a more detailed regulation adds certainty and predictability to the process, it imposes significant regulatory rigidity and inflexibility. Such inflexibility would impose a substantial long-term burden on those licensees adopting §50.69 in a competitive generating market. It would discourage and inhibit licensees from implementing further improvements gained from experience or advances in technology. We need to strike a balance between predictability and flexibility in implementation of the regulations.

If a new appendix is deemed necessary, it should define only the main elements and attributes of a risk-informed evaluation process that combines PRA, operational experience, new analytical techniques, and new technologies. It should not attempt to define in prescriptive detail how to implement a risk-evaluation process. It is

more appropriate for detailed implementation procedures and processes to be defined in a guidance document, not a regulation.

An NRC-endorsed implementation guide provides the appropriate degree of regulatory flexibility and finality, providing the guide satisfies the other elements in the regulations. Such an approach enables lessons learned and improvements to be incorporated in a more efficient manner. The industry is developing a draft implementation guideline that will be reviewed by the NRC as part of the pilot project activities.

In the response to question A.3, we provided a list of main elements of a risk-informed categorization process that would be placed in Appendix T. The elements are listed again for convenience.

> *(a) The determination of SSC safety significance is an integrated decision-making process that uses both risk insights and traditional engineering insights. The process for categorizing SSCs shall include the following:*
>
> *(i) An assessment of the licensee's specific probabilistic risk assessment (PRA) to support the categorization process against an industry consensus standard or the industry's PRA Certification and Peer Review process, or other NRC-endorsed process;*
> *(ii) The use of the PRA to determine the relative importance of modeled SSCs to accident prevention and mitigation that includes:*
> *(A) A determination of relative importance of SSCs using the PRA importance measures.*
> *(B) The use of risk metrics and importance measures based on both CDF and LERF, and that provide information on the relative contribution of an SSC to total risk.*
> *(C) Screening criteria for categorizing SSCs into the safety significant and the low safety significant categories based on an assessment of the overall impact of SSC re-categorization and a comparison of this impact to the acceptance criteria for changes in CDF and LERF.*
> *(D) A truncation value for PRA model quantification set to a value captures the significant contributors to risk.*
> *(E) Sensitivity analyses of SSC importances.*
> *(iii) The use of an integrated decision-making panel (IDP) of knowledgeable personnel familiar with the plant to determine the safety significance of SSCs. The panel shall consider the results of the PRA, deterministic and other traditional engineering analyses, and operating experience.*
>
> *IDP membership, experience, and knowledge shall encompass the main plant processes and the main engineering disciplines.*

(iv) Defense-in-depth activities and criteria that are adjusted for, and take into account, risk-insights.

(v) Take into account appropriate safety margins that are associated with key functional goals and requirements.

(vi) Evaluations of the change in risk resulting from reclassifying SSCs to assess the overall change in risk following the recategorization process associated with a system or group of systems, and of the complete plant.

The IDP shall document its basis for determining acceptable changes in risk if a PRA model is not available to evaluate the change in risk from an external initiating event or plant operating modes.

(vii) Documentation covering PRA, PRA quality, PRA results and risk profile changes, IDP decision-making criteria, IDP membership, IDP conclusions, and the revised SSC functional criteria and controls shall be available for review.

C.2. Is the appendix written at a level sufficient to support a no prior NRC review approach? Are there specific areas that warrant additional requirements?

We disagree that there should be a link between level of detail and no prior NRC review and approval. A number of recent regulations have been issued without the need for prior NRC review and approval. Subsequent NRC inspections determine whether the licensee has satisfied the regulations. Regulatory guides (sometimes NRC-endorsed industry guidelines) are published to provide licensees with specific implementation guidance and ideas. Such guidance documents assist licensee and NRC staff in understanding the specific requirements and assist in avoiding misinterpretations and misunderstandings.

Option B to Part 50, Appendix J and 10 CFR 50.65 were issued following significant industry-regulatory interaction. There was no prior NRC review and approval for each licensee. The industry produced implementation guides which were endorsed in NRC regulatory guides. Licensee compliance with the new rules was assessed through NRC inspections following the enactment of the final rule. Similarly, a licensee that chooses to adopt §50.69 would be expected to implement §50.69 without NRC prior review and approval in a manner that satisfies the requirements.

The industry is developing an implementation guide for §50.69. In an effort to resolve implementation issues prior to issuance of the final rule, the industry and the NRC will evaluate the implementation guideline using the pilot plants. The industry guideline will be but one method of implementing the rule. Other methods would be appropriate providing they satisfy the requirements of §50.69.

NRC Notification

In view of the voluntary nature of risk-informed regulation, a licensee should notify the NRC prior to implementing §50.69. The notification would include:

- the list of regulations being adopted;
- a reference to an NRC-endorsed guideline including any exceptions, or a detailed description of an alternative SSC categorization methodology;
- a summary of, or reference to a process for resolving PRA quality issues;
- a description of the special treatment provisions, if different from those described in an endorsed guideline;
- a general schedule for implementation; and
- a technical specification change submittal, if needed.

C.3. The approach described in this ANPR would define two levels of safety significance. Would it be better to define more than two levels? For example, South Texas uses a four level approach where they categorize equipment as having high safety significance, medium safety significance, low safety significance, and no safety significance. (Note however, that South Texas is not proposing to apply four different types of treatment for the four levels of significance.) What are the benefits of using an approach where more than two levels of safety significance are defined? Would it be better to define more than two levels in this rulemaking?

The proposed four-quadrant SSC categorization approach is acceptable as an interim step to a full risk-informed regulatory regime. The industry agrees that an ultimate goal is for two categories, safety-significant and commercial. Regulatory requirements would apply to safety-significant SSCs consistent with safety importance.

We believe that the STP Nuclear Operating Company's approach is compatible with the approach described in the ANPR. The South Texas Project has been working with the NRC staff on risk-informed applications for over four years. Many licensees see the South Texas Project as a litmus test not only for Option 2, but also for risk-informed regulation in general. Few licensees will commit resources necessary to implement risk-informed regulatory improvements if the South Texas Project falters. We agree that the efforts expended to date positions the South Texas Project as a unique proof-in-concept plant for Option 2. Additional industry pilot plants are needed to specifically pilot the generic guidance development for Option 2.

One of the objectives of a risk-informed regulatory regime is to improve efficiency and effectiveness. At present there are three main categories of SSC: safety-related, important-to-safety, and nonsafety-related. Having more categories may ease the interim categorization and treatment determinations but could result in

long-term management issues. We believe the quadrant approach is but a transition stage.

It is important to allow licensees the flexibility to have additional categories, if there is a benefit, providing those additional categories comport with the overall principles described in the guideline.

As stated in our response to question A.3, a licensee may have a different set of categories, but needs to provide a correlation between the licensee specific categorization scheme and that described in §50.69.

Questions C4 – C.7.

The responses to the other ANPR questions address the issues described in questions C.4 through C.7. The industry's PRA certification and peer review process, and the consensus standards activities relating to PRA quality and completeness, address the detailed PRA implementation and completeness issues.

The industry's comments on the need for a detailed appendix to the regulations and on the need for detailed and prescriptive requirements on expert panels (IDPs) is provided in the response to questions C.1 and C.2.

On PRA documentation, the previous risk-informed regulation categorization activities have addressed this issue. The conclusions of the expert panel should be documented and available for review. The implementation guideline, which is in the course of development, has a section on documentation. The guideline will be reviewed by the NRC as part of the pilot project implementation and will be amended, as necessary, to incorporate lessons learned from the pilot projects.

D.1. How should the pilot plant program be constructed and implemented in order to adequately pilot the elements in the appendix?

The industry supports the concept of pilot plant implementation for Option 2 to provide practical feedback and insights into the rulemaking process before the rule and any associated guidance are finalized. For a licensee to volunteer to become a pilot plant, there needs to be significant incentive and certainty. Until there is a reasonable regulatory understanding on the draft guidance, few licensees are going to commit resources to implement a pilot project.

The industry is drafting a guidance document to act as the basis for pilot implementation. Pilot plant licensees would implement the guidance on SSC categorization, or submit an exemption request to allow special treatment requirements to be modified. As the pilot projects progress, the guidance will be amended to incorporate lessons learned and appropriate NRC observations. On

completion of the pilot project, the guideline will be reviewed for endorsement by the NRC in a regulatory guide.

The industry, through the NSSS owners groups, is considering pilot projects that would cover at least two systems from a broad range of plants for a sample set of regulations. We agree that this approach would help fully develop and validate the implementation methodology for generic application to other systems and regulations for all plants wishing to adopt §50.69.

Pilot plants will seek exemptions to NRC regulations to apply and pilot the special treatment requirements defined in Option 2. Some pilot plants may wish to deviate from the generic guidance because of differing designs and establish licensee practices. This is both necessary and beneficial from a pilot project perspective. The varying approaches, approved by the NRC in the exemption process, will be assessed and evaluated by the NRC staff. As necessary and appropriate, a licensee might adjust its approach based on implementation insights and NRC input during the pilot project. The final guideline would take into consideration the lessons learned from all the pilot activities, yet may not exactly reflect each pilot plant's Option 2 implementation. As such, a pilot licensee should not be required to adjust its approach just based on changes in the final guideline content unless there is a safety-significant basis for such a change.

D.2. Please comment on the need or lack of need to pilot each of the rules affected by this effort.

There is no need to specifically pilot each rule. The aim of the pilot project is to test the efficacy of the risk-informed categorization process, the application of special treatment requirements based on safety significance, and the guideline applicability to a sample set of special treatment regulations. Under Option 2, only the scope of SSCs that are governed by NRC requirements are changed. The special treatment requirements described in the proposed rule will be applied to SSCs based on the results of the risk-informed categorization process.

Testing the guideline against a sample set of regulations and systems is sufficient for resolving implementation issues and providing the bases and confidence for industrywide implementation on the complete spectrum of Option 2 regulations.

E.1. How should the special treatment requirements for SSCs that are currently safety-related for one reason but found to be safety significant for a different reason be modified? Should special treatment of safety-related SSCs be modified to address risk-significant attributes that are identified as a result of a risk-informed categorization process? If so, how should treatment be identified and controlled?

The industry acknowledges that the risk-evaluation process could identify new safety-significant functions for SSCs that are presently categorized as safety-related. In such cases, a licensee would make an engineering determination on whether the equipment could satisfy the newly identified function. If there was not reasonable assurance that the newly identified function could be satisfied, a licensee has two choices: determine the impact of not crediting the newly identified function, or take action to provide reasonable assurance that the newly identified safety-function will be satisfied. Such action would be assessed and taken on a case-by-case basis depending upon circumstances and could involve a broad range of changes, ranging from changes in operational procedures to changes in design.

Option 2 does not change the technical requirements of existing regulations. Risk-informed improvements to NRC technical requirements will be addressed under Option 3.

We believe that Option 2 activities should not impose or amend NRC technical requirements resulting from severe accident (beyond design bases) considerations. Such an activity would attempt to implement and complete the transition to risk-informed regulation in one step. This would be a major departure from the approach approved by the Commission in the SRM on SECY 98-300. Changes to technical requirements would be addressed under Option 3, "Risk-Informing NRC Technical Requirements." The objectives of Option 2 are the categorization of SSCs based on safety-significance, and the application of special treatment requirements based on safety-significance. However, we agree that under Option 2 licensee controls and programs should provide reasonable assurance that safety-significant (including beyond design bases) functions that are identified in the risk-informed evaluation process will be satisfied.

Both RISC-2(2) SSCs and RISC-3 SSCs are subject to a monitoring program that provides reasonable assurance that the safety-significant or regulatory functions will be satisfied. Regulatory control and awareness is assured through the satisfaction of the performance criteria and the licensee's corrective action program. For RISC-2(2) SSCs, additional requirements are applied consistent with safety-significance because of the variance in the safety-significant impact of these SSCs. It should be noted that the vast majority of RISC-2 SSCs would have already been identified as having increased safety-significance in the implementation of the maintenance rule. As a result, monitoring would have already been applied to these SSCs, and where necessary and appropriate, the licensee would have imposed additional commercial level controls.

RISC-2(2) and RISC-3 SSCs are subject to commercial level controls as determined by the licensee. RISC-2(1) SSCs remain subject to existing regulatory controls, applied in a manner consistent with safety significance.

Experience in implementing §50.65 has shown that commercial level controls are sufficient for ensuring that the safety functions are satisfied, as demonstrated by the satisfaction of the maintenance rule performance criteria.

E.2. What regulatory treatment should be applied to safety-significant SSCs which are not currently safety-related?

In the quadrant approach there should be two subcategories for RISC-2 SSCs (nonsafety-related, safety-significant SSCs):

1. nonsafety-related SSCs that are currently identified as "important-to-safety" and are categorized as safety-significant, and
2. nonsafety-related SSCs that are categorized safety-significant.

RISC-2(1) SSCs would continue to be subject to the existing requirements.

RISC-2(2) SSCs would be subject to the following requirements:

- A performance monitoring program that provides reasonable assurance that the safety functions identified in the risk-informed evaluation process will be satisfied;
- Commercial level controls and specifications imposed by the licensee that provide reasonable assurance that the safety-significant functions identified by the risk-evaluation process are satisfied. Such programs shall include a change control provision that provides reasonable assurance that the safety-significant function(s) will be satisfied following a facility change that involved RISC-2(2) SSCs;
- A performance-based reporting program for deficiencies that result in a failure to satisfy a safety-significant function identified in the risk-informed evaluation process.

As proposed in previous questions, 10 CFR 50.59, *Changes, tests and experiments,* (see section on §50.59) is not included in the Option 2 scope of regulations. We recognize that some RISC-2(2) SSCs might not be encompassed by the current §50.59 evaluation process. Since RISC-2(2) SSCs are safety significant, they should be the subject of a regulatory control process. The proposed §50.69 rule language provided in response to A.3 includes the provision for a control process for RISC-2(2) SSCs.

For seismic and other environmental attributes, a licensee would evaluate the ability of the SSC to satisfy the identified safety-function using a commercial standard of assurance, i.e., standard balance-of-plant criteria: an engineering specification and review to determine that the SSC satisfies the specification.

For most licensees, the elements of the monitoring program for implementing the maintenance rule would be sufficient, provided the maintenance rule program is not just based on maintenance preventable functional failures, and that the §50.69 performance criteria satisfy the assumptions and conclusions of the plant-specific PRA.

For these (RISC-2) SSCs that are subject to the maintenance rule, deficiencies are resolved and, as necessary, improvements are made under the licensee's commercial programs to assure that the functions will be satisfied. These commercial programs include similar elements to the Appendix B to Part 50 program, covering design, control, procurement, corrective action, testing, and special processes. The change control program will need to be supplemented as described above. Also, as part of the process of adopting §50.69, PRA data and configuration will be updated at periodic intervals.

E.3. Explain whether the design control and procurement requirements in Appendices A and B of 10 CFR part 50 should apply to safety-significant SSCs which are not currently safety-related (i.e., RISC-2 SSCs).

RISC-2(1) SSCs

Where appropriate and applicable, RISC-2(1) SSCs would be subject to the requirements of "important-to-safety" SSCs. Specific criteria in Appendix A to Part 50 would continue to be applied to these SSCs. Appendix B to Part 50 already allows for a graded implementation based on safety significance. The regulatory guides define specific quality criteria, a subset of Appendix B for these "important-to-safety" SSCs. There is no need for additional controls.

RISC-2(2) SSCs

It is not necessary for RISC-2(2) SSCs to be subject to 10 CFR Part 50, Appendix A, or Appendix B.

We do agree that the change control process for RISC-2 SSCs should include an evaluation to determine that there is reasonable assurance that the safety-significant function(s) will be satisfied following a change to the facility that involves a RISC-2(2) SSC. In addition, the general plant PRA update that is required to be completed at least every 36 months will address the potential for overall risk increases from a series of changes.

The maintenance rule, §50.65, requires the following:

> "Each holder of a license to operate a nuclear power plant under §§50.21(b) or 50.22 shall monitor the performance or condition of structures, systems, or components, against licensee-established goals, in a manner sufficient to

provide reasonable assurance that such structures, systems, and components, as defined in paragraph (b), are capable of fulfilling their intended functions."

The process for determining the scope of SSCs that are governed by the maintenance rule is generally the same as the process used for identifying those SSCs that are safety significant under §50.69. In general, RISC-2 SSCs have satisfied the requirements of §50.65. The controls and design specifications are to commercial level standards. Through the monitoring and corrective action requirements of §50.65 the (safety) functions have been and will continue to be satisfied. Licensees' current processes and controls for RISC-2 SSCs that are included in the scope of the maintenance rule have been sufficient to assure that the intended (safety) functions will be satisfied.

Appendix B to Part 50 already allows for a graded implementation, consistent with safety significance. The commercial controls applied by licensees to non-regulated equipment and activities are similar, but not as extensive or documented, as the 18 criteria of Appendix B, a graded form of Appendix B. There is no need for additional controls beyond those proposed in the response to question A.3 and this section of questions.

E.4. (a) Should 10 CFR part 21 requirements be imposed upon vendors who supplied safety-related components to licensees who subsequently select the new regulatory approach? If not, what regulatory basis would there be for not imposing such requirements on those vendors? Would the failure to impose Part 21 requirements on such vendors be inconsistent with the underlying statutory basis for Part 21, viz., Section 206 of the Energy Reorganization Act of 1974, as amended? What regulatory provisions are necessary to assure that the underlying purpose of Section 206 and 10 CFR part 21 are fulfilled under the alternative regulatory approach?

(b) If such requirements are imposed, what difficulties would such vendors experience in fulfilling their Part 21 responsibilities and how could these difficulties be addressed in this rulemaking? What specific rule provisions are necessary in order to fairly impose Part 21 vendors who supply basic components to licensees who at some point decide to adopt the alternative approach?

(c) Discuss whether the alternative regulatory approach, with respect to the new categories, is inconsistent with the definition of basic component in Section 223.b of the Atomic Energy Act (which imposes criminal liabilities for knowing and willful violations of NRC rules, regulations orders and license conditions that result, or if undetected could have resulted in significant impairment of a "basic component"). If there is an inconsistency, does it have any adverse effects on licensees? What rulemaking provisions could eliminate or minimize such adverse effects?

E.4.(a) Response

10 CFR Part 21 was initially included in the industry's initial scope of candidate regulations. However, Part 21 is a complex regulation with hard links to the

Atomic Energy Act. This regulation was introduced as a result of the enactment of Section 206 of the Energy Reorganization Act of 1974, which amended the Atomic Energy Act. The Act required any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity to make reports relating to defects in basic components that could cause a substantial safety hazard.

The scope of Part 21 is not based on risk-informed insights. It is governed by the term "basic component" which is defined in the Atomic Energy Act, Section 223:

> "...the term 'basic component' means a facility structure, system or part thereof necessary to assure—
>
> (1) the integrity of the reactor coolant pressure boundary;
> (2) the capability to shut down the reactor and maintain it in a safe shutdown condition; or
> (3) the capability to prevent or mitigate the consequences of accidents which could result in an unplanned release of quantities of fission products in excess of the limits established by the Commission."
> (generally, 42 USC sec.2273)

Part 21 provides additional details and clarifications in its definition of a basic component. Section 21.3 defines substantial safety hazard as:

> "...a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter."

Changing the Part 21 SSC scope would be a complex and prolonged activity that might involve a change to the Atomic Energy Act. As a result, the industry believes that improvements to Part 21 should be separated from Option 2 activities. A complete evaluation of the need to amend Part 21 to comport with a risk-informed regime should be performed as part of the element to risk-inform NRC administrative requirements. Such an evaluation should take into account the experiences gained in implementing Option 2 and from regulating licensees that have adopted §50.69. Such an evaluation should include an assessment of the need for legislative action.

For licensees adopting §50.69, Part 21 would continue to apply to RISC-1 SSCs.

Part 21 would not apply to RISC-3 SSCs because a failure could not cause a substantial safety hazard, since these SSCs have minimal or no safety significance.

Part 21 would not apply to RISC 2 or RISC 4 SSCs because these are not basic components as defined in the Act or in Part 21.

E.4.(b) Response

A supplier or a dedicating entity is required to immediately report to the NRC incidents where a basic component supplied to such facility or activity contains a defect, which could create a substantial safety hazard. The vendor is informed through the purchase order or contract that Part 21 is applicable. Until Part 21 is amended, that requirement still applies to licensees even in a risk-informed regulatory regime.

Vendors often choose not to comply with the requirements of a licensee's purchase order that invokes Part 21 and Appendix B. When this occurs, a licensee procures the equipment using its commercial grade item dedication process to satisfy the requirements of Part 21. Under Option 2, the same practices would be applied until the regulation is changed.

Option 2 is voluntary. Some licensees will adopt Option 2, others will not. A vendor will still be required to inform the NRC of defects in components supplied under Part 21 to a licensee that could cause a substantial safety hazard.

E.4.(c) Response

The intent of the Atomic Energy Act and Part 21 is to ensure that the NRC and licensees are informed of deficiencies in equipment that could have substantial safety implications. A supplier is made aware of such equipment through a licensee's purchase order or contract requirements. Under Option 2, RISC-1 SSCs whose failure could result in a substantial safety hazard would be subject to Part 21. RISC-3 SSCs would not be subject to Part 21 because a failure could not cause a substantial safety hazard.

There are no significant inconsistencies in a risk-informed approach to Part 21 that would result in a safety concern. The proposed approach for implementing Option 2 remains consistent with the requirements of the Act and Part 21.

E.5. What regulatory treatment requirements are necessary to ensure the functional capabilities of SSCs that are safety-related because of the plant's deterministic licensing basis but found to be of low safety significance are maintained?

Safety-related, low safety significant SSCs (RISC-3 SSCs) will be required to demonstrate functionality to the extent that satisfies the regulatory requirement directly and specifically referenced in a regulation, or directly referenced in the assumptions or conclusion in a licensee's safety analyses that are required by regulation.

Functionality would be assessed through the implementation of a monitoring program. For the majority of licensees, the elements used in the monitoring program for the maintenance rule would be sufficient, providing the program is not just based on maintenance preventable functional failures, and the performance criteria satisfy the requirements of the regulation or the safety analyses required by regulation. The other requirements of Section 50.65 would not apply. RISC-3 SSCs would be subject to commercial controls and practices, as per the licensee's balance-of-plant activities.

Where monitoring is impractical or inappropriate, commercial level controls are applied consistent with safety significance to provide reasonable assurance that the required functions are satisfied. The degree of assurance is one of a commercial standard. Such programs have many elements that are similar to an Appendix B to Part 50 program, implemented consistent with safety-significance, and with less emphasis on process and documentation. These are the same type of controls and programs as those being applied against RISC-2 SSCs. However, based on operating experience, and the need for greater assurance, a licensee may decide to impose additional or more refined controls on RISC-2 SSCs to provide an additional degree of assurance.

NRC reporting requirements would not be applied to RISC-3 SSCs.

E.6 To what degree should severe accidents be incorporated into licensing basis under the effort to risk-inform special treatment requirements?

Beyond design basis scenarios are included in the evaluation process for categorizing SSCs. The objective of Option 2 is to adjust the scope of SSCs based on safety significance, and then apply the special treatment requirements consistent with safety significance. It is not the intent under Option 2 to address specific technical special treatment requirements that are linked to severe accident scenarios. The industry has already implemented programs for the management of severe accidents that have been reviewed and approved by the NRC. The need and extent for imposing new or additional technical requirements for severe accidents will be assessed under Option 3.

We believe that Option 3 to SECY 98-300, *Risk-Informing NRC Technical Requirements*, should address the need to amend NRC technical requirements resulting from severe accident (beyond design bases) considerations. At that time, and as necessary and appropriate, the licensing basis would be amended.

We do not believe it is practical to change the technical requirements and special treatment requirements in one single rulemaking. Such a step would be a major departure from the approach approved by the Commission in the SRM on SECY 98-300. Changes to technical requirements should be addressed as a separate activity

under Option 3. However, we agree that under Option 2 licensee controls and programs should provide reasonable assurance that safety-significant (including beyond design bases) functions that are identified in the risk-informed evaluation process will be satisfied. As such, the performance criteria may reflect insights from the risk-informed evaluation process that are associated with beyond design bases activities.

Also, see response to question E.1.

F.1. What are the potential advantages and disadvantages of selective implementation with regard to the selection of rules and selection of systems?

The process for adopting Option 2 should allow for selective implementation of the listed regulations.

Few commercial nuclear power plants have the same design, or operations and maintenance practices. Plants have varying licensing bases, detailed designs and operational practices. What is beneficial at one plant may not beneficial at another. What is risk-significant at one plant might not be risk-significant at another. To require full implementation of all risk-informed NRC special treatment requirements under Option 2 could increase, not eliminate, unnecessary burden. Risk-informed regulatory improvement activities would stagnate and few plants would choose to adopt the improvements. For a licensee, the optimum and most practical approach to implementing 10 CFR 50.69 is to implement the regulation in a phased manner, regulation by regulation, as determined by each licensee within the framework of the §50.69 rule.

Licensees should be given significant flexibility in the development of a schedule to implement Option 2. A licensee may not need to evaluate all systems based on engineering knowledge and operating experience or because of the results from previous risk-informed activities. There may be some systems that can be readily categorized as RISC-1, RISC-2, or RISC-4 based on previous work. In such cases the licensee should document the reference for such conclusions. Such a decision is based on compatibility between the §50.69 risk-informed evaluation process and the previous licensee categorization process. As such, for some plants there may be sufficient basis to categorize the SSC without exercising the risk-informed evaluation process described in the guideline. In such cases, the licensee's expert panel would review and document its conclusions, based on previous documented analyses and reports.

The process of categorizing SSCs is long. To require full and complete implementation of all systems within a short timeframe is impractical. A licensee must be permitted to develop a schedule for evaluating the safety significance of its systems in a phased and selective manner. It is expected because of system

interdependencies and the need to improve efficiencies that a licensee would eventually categorize all systems.

Concerns over selective system implementation are unfounded and do not take into consideration the regulatory controls and licensee practices that have been put in place in response to the maintenance rule. Most of the nonsafety-related SSCs that will be categorized as safety-significant will have been identified as safety-significant (risk-significant) under the maintenance rule. For most licensees, additional controls and monitoring have been imposed to the extent necessary to provide reasonable assurance that the safety-significant (risk-significant) functions will be satisfied. In effect, for many licensees, the maintenance rule identified and put in place appropriate controls for RISC-2(2) SSCs that provide reasonable assurance that the safety function, identified in the risk-informed evaluation process, will be satisfied.

F.2. What bounds should be set on the scope of SSCs evaluated under a risk-informed regulatory framework? Should all systems be evaluated, or can some subset be considered?

A licensee must be allowed the flexibility to perform the categorization evaluations in a phased manner. In view of the SSC categorization experiences gained in implementing previous risk-informed regulations and activities, a licensee would be expected to evaluate:

1. those SSCs that were once safety-related or "important-to-safety" and have not been categorized as safety-significant; and
2. those nonsafety-related SSCs that other risk-informed regulatory activities have categorized as high risk-significant.

It is not necessary to evaluate all systems. A licensee may be able to directly categorize a set of systems based on previous risk-informed work and directly categorize an SSC as RISC-1, RISC-2, or RISC-4. In addition, a conclusion may be reached based on existing traditional engineering with a high degree of certainty that the SSC is RISC-1 or RISC-4, e.g., primary coolant boundary systems, and potable water systems.

Also, see response to question F.1.

F.3. What limits should be paced on the set of rules for implementation? Should licensees be required to implement all risk-informed rules? If not what limitations are appropriate?

There is no need for limits in regard to the adoption of special treatment requirements under Option 2.

The Commission has already stated that the adoption of a risk-informed regulatory regime is an optional, voluntary program. We are not aware of any basis for changing that decision which was based on the recognition that: 1) plants are operating safely and public health and safety is assured, and 2) the imposition of risk-informed regulation may impose burden on plants that are scheduled to reach the end of their operating license in the near future.

The process for adopting Option 2 should allow for selective implementation of the listed regulations. This should not overly complicate the regulatory process because the risk-informed process will result in improved regulatory efficiencies in implementation and oversight. Safety will be enhanced even though the approach is selective.

Few commercial nuclear power plants have the same design, or operations and maintenance practices. Plants have varying licensing bases, detailed designs and operational practices. What is beneficial at one plant may not be beneficial at another. What is risk-significant at one plant might not be risk-significant at another. To require full implementation of all risk-informed NRC special treatment requirements under Option 2 would increase, not eliminate, unnecessary burden. Risk-informed regulatory improvement activities would stagnate and few plants would choose to adopt the improvements. For a licensee, the optimum and most practical approach to implementing 10 CFR 50.69 is to allow an optional and selective adoption of the applicable regulations, as determined by each licensee.

The optimum and most practical approach to implementing 10 CFR 50.69 is to implement the regulation in a phased and selective manner (regulation by regulation) for the regulations that a licensee has chosen to adopt. There is no basis for the imposition of a minimum set of regulations.

For any selected regulation, we expect a phased, system-by-system implementation because of the resource loading associated with the evaluation process. For that reason we believe that the NRC notification letter from the licensee should include a proposed schedule of implementation.

See responses to F.1 and F.2.

F.4. How can the NRC ensure that additional attention is given to risk-significant components if selective implementation is allowed?

For RISC-1 and RISC-2(1) SSCs, there is no change in regulatory requirements.

For RISC-2(2) SSCs, monitoring under the maintenance rule and the application of existing commercial controls provide reasonable assurance that the safety functions will be satisfied. Through the maintenance rule and the §50.69 reporting provisions for RISC-2(2) SSCs, the NRC will be aware of deficiencies that impact the safety

function. In general, most RISC-2(2) SSCs will have been included in the maintenance rule scope and will have satisfied the associated performance criteria. As such appropriate licensee attention and focus has been given to these SSCs. The same will be true for the implementation of §50.69. In such a manner the NRC will be assured that appropriate attention is being given to safety-significant SSCs and will be informed of deficiencies that impact safety.

(Also see responses to questions F.1. and F.2.)

G.1. What regulations may be affected by risk-informed changes to special treatment requirements in Part 50 and how are these regulations affected?

See response to question A.1.

The listed regulations impose additional controls and activities on safety-related and "important-to-safety" SSCs compared with the controls for balance-of-plant equipment. A number of these additional controls are not imposed consistent with safety. Now, with the benefit of advances in technology and 30+ years of operating experience, we have realized that some of the safety-related and "important-to-safety" SSCs are not safety-significant. Also, there are some commercial, balance-of-plant SSCs that have safety significance.

In regard to Section 50.54, there are a few subsections that impose limitations on changing controls, namely §50.54(a), §50.54(p), and §50.54(q). This regulation is included because it controls a licensee's ability to initiate changes to specific regulations, namely Appendix B, the emergency program and security requirements. As such, a licensee is prevented from making improvements to its programs because of the manner in which the regulations are crafted, "reduction in commitment" or the rigid and implacable interpretation in regard to the term "reduction in effectiveness."

10 CFR Part 54

It is unclear from the ANPR whether Part 54 is included in the scope. In the general section, Part 54 is included, yet in the section on specific issues a case is made for excluding Part 54.

NEI believes that a risk-informed option for 10 CFR Part 54 should be developed to ensure regulatory consistency and coherency for those licensees wishing to adopt Option 2 and also wishing to apply for license renewal. To exclude Part 54 from Option 2 activities would unnecessarily inhibit licensees that have a long range goal of license renewal or preclude those licensees that have been granted a renewed license from adopting a risk-informed approach.

10 CFR Part 21

See response to question E.4.

G.2. For those licensees implementing the new approach: (a) What, if any, GDC will require exemptions? (b) If exemptions would otherwise be necessary, is there a way and a regulatory basis for rulemaking to exempt, in whole or part, compliance with those GDCs for those licensees choosing the alternative regulatory approach?

An exemption is not necessary to Appendix A to Part 50 requirements (GDCs) as they are included in the scope of applicability for the §50.69 rulemaking.

Option 2 does not change technical requirements. It adjusts the scope of SSCs that are subject to special treatment regulations based on safety-significance. The SSC scope of applicability of Appendix A special treatment requirements is determined through a risk-informed evaluation process that incorporates insights from plant specific PRAs, operating experience, and insights from new technologies and analyses.

The basis for making the change to the SSC scope is the safety-significance categorization process. GDCs apply to "important-to-safety" SSCs. The GDC special treatment requirements would continue to apply to RISC-1 SSCs, and RISC-2(1) SSCs.

RISC-2(2) SSCs are required to satisfy the performance criteria that provide reasonable assurance that the safety functions will be satisfied. A failure to satisfy the performance criteria will result in corrective action. The extent and scope of the corrective action is assessed on a case-by-case basis and could include adjustment to controls or performance criteria. There is no need for the application of the GDCs to the RISC-2(2) SSCs. Many commercial program control criteria are similar to regulatory criteria, but with less emphasis on documentation and process.

The GDC special treatment requirements would not apply to RISC-3 because of their low safety-significance, and as such these SSCs are no longer important to safety. The regulatory criterion is that there be reasonable assurance that through monitoring or the use of commercial programs and controls, the functions which are directly and specifically referenced in a regulation or in the safety analyses required by regulation, will be satisfied. Controls and processes may be changed from special NRC mandated requirements to commercial practices, yet the (technical) design limits would remain unchanged.

G.3. Part 19 currently requires all licensees to post NRC Form 3. Would it be more or less confusing if all licensees posted a single, NRC-developed Form 3 that covered both licensees who remain with the existing regulatory regime as well as licensees that choose the alternative regulatory approach; or should an alternative Form 3 be developed, with the licensee required to post the applicable Form depending upon whether it chose to implement the alternative regulatory approach.

We do not believe that maintaining a single NRC Form 3 posting would confuse licensee staff and contractors. Under either a risk-informed or deterministic regulatory regime, the NRC Form 3 intent remains the same.

G.4. If a licensee were to adopt the alternative regulatory approach, would there be any inconsistency or discrepancy created between the term "operability" as currently used in technical specifications" limiting conditions for operations (LCOs) and the concept of "functionality" as proposed for SSCs in RISC-3? Please describe any adverse effects in detail, and discuss the manner in which these adverse effects can be avoided or minimized.

See response to question A.6.

The industry has proposed a new and separate regulatory task on Technical Specifications. In addition to addressing the synergies and duplicative requirements associated with plant configuration control it should also address and resolve the long-standing debates over operability vs. functionality that occur in discussions over allowed outage times. The task of risk-informing the Technical Specifications will also adjust the scope of SSCs that are subject to Technical Specifications. Such action will improve regulatory coherency and regulatory efficiency and effectiveness through the elimination of ambiguous terms and duplicative requirements.

Licensees have the option of submitting a license amendment to change Technical Specifications for matters that are not safety significant whether or not a licensee has adopted a risk-informed approach (Option 2) to the regulations.

G.5. What changes should be considered to provide consistency between affected regulations and risk-informed scope of special treatment?

One of the major objectives of risk-informed regulation is to improve the focus on safety and provide consistency in the regulatory process. The regulations should be applied to those SSCs and associated activities that have safety significance.

The regulatory improvements proposed under Option 2 are designed to ensure that one segment of the regulations, special treatment requirements, is applied to safety-significant SSCs in a manner consistent with safety. The NRC's preliminary proposals described in the ANPR, and modified through these comments, will

improve the consistency between the regulations and the safety-significance of plant SSCs. Other regulations will be adjusted under other risk-informed tasks, such as risk-informing NRC technical and administrative requirements. These activities are sufficient to ensure consistency between safety and the SSC scope of NRC regulations.

G.6. Please comment on the need and appropriateness of applying a risk-informed scope to license renewal (i.e., Part 54)?

NEI believes that a risk-informed option for 10 CFR Part 54 should be developed to ensure regulatory consistency and coherency for those licensees wishing to adopt Option 2 and also wishing to apply for license renewal. To exclude Part 54 from Option 2 activities would unnecessarily inhibit licensees that have a long range goal of license renewal or preclude those licensees that have been granted a renewed license from adopting a risk-informed approach.

License renewal activities and requirements should focus on matters that have safety significance. There are strong links between Part 54 and §50.65. Option 2 will provide the option to licensees for adjusting the SSC scope of §50.65. To ensure regulatory consistency, it is important that the SSC scope of Part 54 also should be amended to reflect risk-informed insights.

H.1. Given that the means for public participation for this effort is through comment in response to this advanced notice for proposed rulemaking and in response to a proposed rulemaking, is there a need to have an NRC review process such that there will be additional public participation as part of the licensing amendment process?

The industry fully supports and encourages the open dialogue that has been established by the NRC to provide public, licensee, and NRC staff participation. The existing rulemaking process already provides an avenue for public comment. Also, the existing regulatory process provides a method for the public to raise contentions and issues that have a link to safety. It is only through such open dialogue that a complete understanding of risk-informed regulatory improvements can be established.

The vast majority of licensee submittals are made public through the NRC's public document room filing system and the NRC web site. In our comments, we have recognized the need for a licensee to inform the NRC prior to adopting §50.69. As such, the public will be aware of the intent of a licensee to adopt a risk-informed regulatory regime, and will be informed of:

- the regulations being adopted;
- the risk-informed methodology that is consistent with the requirements of §50.69;

- the summary of, or reference to, a process for resolving PRA quality issues;
- the SSC treatment provisions for each category if different that those listed in the rule;
- a general schedule for implementation; and
- any changes to the Technical Specifications.

Also, the updates of the Final Safety Analyses Reports will include changes to those sections reflecting the new categorization nomenclature, RISC-1, RISC-2, RISC-3, and RISC-4. There have been, and will continue to be, public meetings and workshops that include public participation.

The existing process provides significant material for public review and provides sufficient opportunity for public input and participation on matters that have safety-significance. It is difficult to envision a higher degree of opportunity for public participation or access to information.

H.2. What level of NRC review is appropriate for a facility making the transition to a risk-informed regulatory regime?

A licensee will be required to inform the NRC of its intent to adopt §50.69. The response to questions H.1 and C.2 describes the material that would be included in a licensee's notification letter to the NRC.

The rule will provide the main categorization and treatment requirements. The guidance document(s) will describe the categorization process and SSC treatment implementation. The guidance will have been reviewed and endorsed by NRC and will have been subject to public comment prior to issuance of the final rule. Through the notification letter, the NRC will be aware of any variations from the endorsed guidance document(s), and will have the opportunity to request additional information or require NRC review of specific elements based on the content of the licensee's NRC notification letter. NRC staff will conduct inspections to assure compliance with the appropriate elements of §50.69. As such, there is no need for NRC review and approval prior to licensee implementation.

H.3. What regulatory controls need to be placed on licensees to implement risk-informed changes to special treatment without prior NRC approval?

There is no need for any additional regulatory controls beyond those prescribed in the new rule, and as described in the responses to these questions, namely, A.3., A.4., C.1., E.1 through E.6, and F.4., E.2 and E.3. See responses to previous questions.

H.4. Please comment on the need for revising 10 CFR 50.59 to facilitate the risk-informed approach.

At this time, the industry does not believe it would be beneficial to amend §50.59 as part of Option 2 activities.

See response to question B.3.