

October 29, 1999

SECY-99-256

FOR: The Commissioners

FROM: William D. Travers /s/  
Executive Director for Operations

SUBJECT: RULEMAKING PLAN FOR RISK-INFORMING SPECIAL TREATMENT  
REQUIREMENTS

PURPOSE:

To obtain the Commission's approval of a rulemaking plan and issuance of an Advance Notice of Proposed Rulemaking for risk-informing special treatment requirements.

SUMMARY:

The staff has prepared a rulemaking plan (Attachment 1) that describes an alternative risk-informed approach to special treatment requirements.<sup>1</sup> These alternative requirements would vary the treatment applied to structures, systems, and components (SSCs) on the basis of their safety significance using a risk-informed categorization method. SSCs that are safety significant would be subject to greater regulatory control than SSCs of low safety significance. This

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<sup>1</sup>Special treatment requirements are current requirements imposed on structures, systems, and components that go beyond industry-established requirements for equipment classified as commercial grade that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.

approach differs from the current special treatment requirements, which are based on those SSCs that are determined to be safety-related or important to safety based on deterministic considerations. This alternative approach would maintain safety while reducing unnecessary regulatory burden to licensee's and improving the staff's regulatory effectiveness and efficiency. The rulemaking plan implements the approach described under Option 2 in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998.

Four issues that represent significant challenges to completing this rulemaking have been identified: (1) selective implementation (discussed in SECY-98-300), (2) potential impact of these rule changes on other rules (e.g., 10 CFR Part 19, 10 CFR 50.120, 10 CFR Part 54, 10 CFR Part 55), (3) the type and amount of staff review required before licensees can implement the alternative requirements, and (4) the level of regulatory treatment required for SSCs based on their safety-significance.

The rulemaking plan includes six major efforts: (1) review of the South Texas Project (STP) exemption request;<sup>2</sup> (2) issuance of an advanced notice of proposed rulemaking (ANPR, Attachment 2); (3) a categorization pilot program; (4) review of a Nuclear Energy Institute (NEI) guideline on SSC categorization; (5) issuance of a proposed rulemaking; and (6) issuance of a final rulemaking. Some of these efforts are ongoing.

If Commission approval of the rulemaking plan is granted within 6 weeks of the date of this Commission paper, the staff estimates that the final rule can be submitted to the Commission for approval in October 2001. Licensee implementation could then begin in March 2002. Execution of the rulemaking plan is estimated to require 47 full-time equivalent (FTE) staff, and \$3.0 million of technical assistance over FY 2000, 2001, and 2002.

#### BACKGROUND:

In SECY-98-300, the staff presented three options for risk-informed modifications of 10 CFR Part 50: (1) continue ongoing rulemaking activities and risk-informed approaches making no changes to the current Part 50; (2) change the special treatment rules in Part 50 to modify their scopes to be risk informed; and (3) make changes to specific requirements in the body of regulations, including general design criteria (GDC).

Under Option 2 of SECY-98-300, it was recommended that risk-informed approaches to the application of special treatment requirements be developed. This option of SECY-98-300 only addressed implementing changes to the regulatory scope for SSCs needing special treatment in terms of providing assurance that the SSCs will perform their functions. It did not address changing the design of the plant or the design basis accidents, which establish the physical complement of plant systems included in the design. SECY-98-300 indicated that safety related SSCs that are of low safety significance would move from special treatment to normal industrial (sometimes called commercial grade) treatment. They would, however, remain in the plant and

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<sup>2</sup>STP has requested an exemption to a subset of the special treatment requirements included in the rulemaking plan to allow use of a risk-informed approach similar to that proposed in this rulemaking plan. This exemption request was submitted to the NRC on July 13, 1999.

be expected to perform their design function, although without the additional margin, assurance, or documentation required for current safety-related SSCs. Conversely, SSCs that are currently not safety-related but that are determined to be safety significant would move from normal industrial to regulatory treatment. The staff recommended proceeding with Option 2.

The staff also addressed three policy issues related to Option 2 in SECY-98-300: (1) voluntary versus mandatory conformance with the modified Part 50, (2) use of industry pilot studies with selected exemptions to facilitate implementation of Options 2 and 3, and (3) modification of the scope of the maintenance rule.

With respect to Option 2, in the staff requirements memorandum (SRM) for SECY-98-300 dated June 8, 1999, the Commission approved (1) implementing Option 2, including incorporation of the maintenance rule into Option 2; (2) voluntary implementation of the risk-informed alternative requirements, but deferred judgment on the issue of selective implementation; and (3) use of industry pilot studies.

The staff's rulemaking plan for implementing Option 2 is summarized below. The staff's effort regarding Option 3 of SECY-98-300 will be provided in another Commission paper. The two regulatory efforts are being coordinated and it is expected that the Option 3 effort will be able to build upon the framework discussed below.

#### DISCUSSION:

In response to the June 8, 1999 SRM, this paper provides a rulemaking plan as one of the following three attachments:

Attachment 1 is the rulemaking plan.

Attachment 2 is the ANPR.

Attachment 3 is the methodology and criteria for selecting candidate rules.

In the course of preparing the rulemaking plan, the staff (1) developed guiding principles in the form of a mission statement; (2) developed a general scheme to categorize SSCs and vary their treatment by overlaying a risk-informed approach onto the current deterministic framework; (3) identified the preferred rulemaking approach; (4) identified the rules to be considered for inclusion in the rulemaking; (5) developed an ANPR; (6) established the framework for an acceptable categorization pilot program; and (7) identified policy and implementation issues that present significant challenges to completing the rulemaking. The results of these efforts are summarized below and discussed in more detail in the attachments.

#### Mission Statement

The mission statement is described in Section 1.2 of the rulemaking plan (Attachment 1). The mission statement provides the strategies and objectives for the effort. Its purpose is to provide overall guidance in determining what issues and approaches are appropriate and it contains measures for determining whether the rulemaking effort is successful.

## General Scheme for Categorization and Treatment

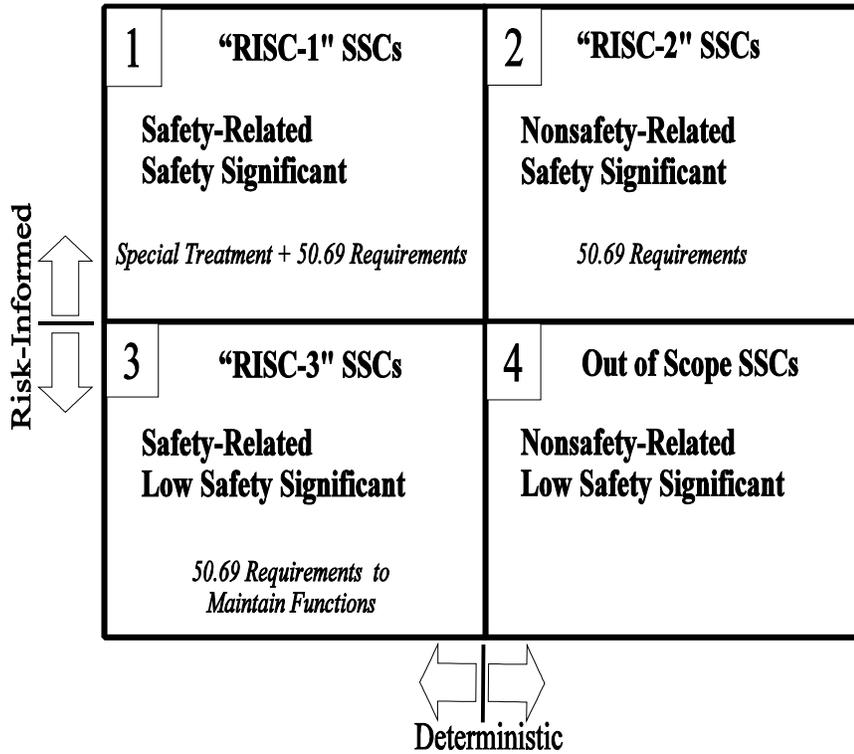
The purpose of this rulemaking is to develop an alternative regulatory framework that enables licensees, using a risk-informed process for categorizing SSCs according to their safety significance (i.e., a decision that considers both traditional deterministic insights and risk insights), to reduce unnecessary regulatory burden for SSCs of low safety significance by removing these SSCs from the scope of special treatment requirements. In the process, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance. This framework should improve regulatory effectiveness and efficiency, and contribute to enhanced plant safety. To accomplish this goal, it is necessary to amend the governing regulations. The current regulations use terms such as “safety-related,” “important to safety,” and “basic component” to identify the groups of SSCs and associated activities that require “special treatment.” This rulemaking will build into the regulations an alternative that offers licensees the flexibility of utilizing a risk-informed process to evaluate the need for special treatment. This risk-informed process will ensure that risk insights will be used in a manner that complements the NRC’s traditional deterministic approach. The risk-informed approach will be consistent with the defense-in-depth philosophy, will maintain sufficient safety margins, will ensure that any increase in core damage frequency or risk is small and consistent with the safety goal policy statement, and will include a performance measurement strategy. The risk-informed framework will also be aligned to the NRC Reactor Inspection Oversight process by incorporating the cornerstones from the reactor safety and radiation protection safety areas into the SSC categorization process.

A graphical depiction of the changes that are expected to result from a risk-informed re-categorization of SSCs is illustrated in Figure 1. The figure is only intended to provide a conceptual understanding of the new SSC categorization process. The staff’s thinking is continuing to evolve on this matter and as suggested in the Advisory Committee on Reactor Safeguards (ACRS) letter of October 12, 1999, the staff will explore whether more than two levels of safety significance is a better approach. The staff is requesting stakeholder feedback regarding safety significance categories in question C.3 of the ANPR. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new risk-informed categorization. The risk-informed categorization would group SSCs into one of the four boxes in Figure 1.

Box 1 of Figure 1 contains safety-related SSCs that a risk-informed categorization process concludes are significant contributors to plant safety. These SSCs are termed risk-informed safety class 1 (RISC-1) SSCs. SSCs in this box would continue to be subject to the current special treatment requirements. In addition, it is possible that some of these SSCs may have additional requirements concerning reliability and availability, if attributes which cause an SSC to be safety significant are not sufficiently controlled by current special treatment requirements. However, the staff is not currently aware of any examples of this situation.

Box 2 depicts the SSCs that are nonsafety-related, and that the risk-informed categorization concludes make a significant contribution to plant safety. These SSCs are termed RISC-2 SSCs. Examples of RISC-2 SSCs could include the station blackout emergency diesel, startup feedwater pumps, or SSCs that function for pressurized water reactor (PWR) “feed and bleed” capability. For RISC-2 SSCs, there will probably need to be requirements to maintain the reliability and availability of the SSCs consistent with the probabilistic risk assessment (PRA). As discussed below, it is currently envisioned that 10 CFR 50.69 (i.e., the new rule) would

Figure 1: Diagram of Categorization and Treatment



contain the regulatory treatment requirement for RISC-1 and RISC-2 SSCs regarding the reliability and availability of these SSCs.

Box 3 depicts the currently safety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-3 SSCs. The rulemaking would revise Part 50 to contain alternative requirements (per §50.69) such that RISC-3 SSCs would no longer be subject to the current special treatment requirements. For RISC-3 SSCs, it is not the intent of this rulemaking to allow such SSCs to be removed from the facility, or to have their functional capability lost. Instead, the RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance. The staff may determine that this level of assurance can be provided by licensee's commercial grade programs. As discussed below, it is currently envisioned that §50.69 would contain the regulatory treatment requirements for RISC-3 SSCs.

Box 4 depicts SSCs that are nonsafety-related and continue to be categorized as not being significant contributors to plant safety. These SSCs are out of scope of both current special treatment and any future regulatory controls of §50.69. The functional performance of these SSCs is controlled under the licensee's commercial grade program (no change from the current requirements).

## Rulemaking Approach

As described in Section 4.1 “Selection of the Rulemaking Approach” of the rulemaking plan, the staff is recommending a rulemaking approach that would include development of a new Part 50 rule. This rule would be supported with an appendix that utilizes new terminology as presented in Figure 1. The staff is recommending this approach in lieu of modifying the definition of “safety-related” and defining “important to safety” as was suggested in SECY-98-300 because if the current terminology is redefined to include a risk-informed part and voluntary and selective implementation is allowed, the meaning of “safety-related” and “important to safety” would be licensee and rule-specific. The staff believes that this outcome would result in confusion among both the staff and industry. With the use of new terminology, it would be immediately apparent whether a licensee was using the risk-informed alternative or the current requirement. The staff’s proposed terminology, as previously described, is risk-informed safety class (RISC)1, 2, and 3.

The rulemaking approach includes two parts. The first part is a new rule, 10 CFR 50.69, that will allow the use of the new risk-informed categorization for the regulations identified within that rule.<sup>3</sup> Section 50.69 will require that licensees use a method that complies with criteria in a new Appendix T “Categorization of SSCs Into Risk-Informed Safety Classes,” or is otherwise found acceptable by the staff, to identify the appropriate SSCs for each risk-informed safety class. Section 50.69 will also provide requirements for regulatory treatment depending on the risk-informed safety class. Licensees would be allowed to use the risk-informed approach for any of the rules, or sets of rules as appropriate, that are identified in §50.69. The second part is a new 10 CFR Part 50 Appendix T that provides the criteria and categorization processes to properly identify safety significant SSCs that require special treatment. An objective of this rulemaking is to attempt to establish criteria in Appendix T such that licensee’s who satisfy those requirements will be able to implement the risk-informed alternative with little or no prior staff review of the categorization process. The staff will not be able to determine the feasibility of this approach until after both the South Texas Project (STP) exemption effort and the categorization pilot program are complete.

## Candidate Rules

The staff’s methodology for determining the set of rules that should be considered for modification includes (1) a review of the regulations to identify those that use a scope based on terminology such as “safety-related,” “important to safety,” or a similar construct; (2) development of criteria for establishing which rules belong in this effort; and (3) evaluation of the rules identified in the first step against the criteria. A fourth step, which would be accomplished as part of the proposed rulemaking, would be to review other regulations that do not have a safety-related or important-to-safety type scope to identify any requirement that may be affected by the modifications to the special treatment requirements. This method is described in detail in Attachment 3.

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<sup>3</sup>This approach assumes that identifying in §50.69 the set of regulations to which the risk-informed categorization can be applied will be a sufficient regulatory modification. It is possible that some rule-specific issues may also need to be addressed in this new rule. If these rule-specific issues become excessive, the staff may alternatively modify some individual rules.

The staff's preliminary assessment using this method identified the following rules for consideration in this rulemaking (**bold** means the rule was discussed as an example of a special treatment rule in SECY-98-300):

50.34, Contents of applications; technical information (FSAR)

**50.36, Technical specifications**

50.44, Combustible gas control

50.48, Fire protection

**50.49, Environmental qualification**

50.54(a)(3), Conditions of licenses (in reference to Quality Assurance Programs only)

50.55, Conditions of construction permits

**50.55a, Codes and standards**

**50.59, Changes, tests and experiments<sup>4</sup>**

**50.65, Monitoring effectiveness of maintenance**

50.71(e), Maintenance of records, making of reports

**50.72/50.73, Reporting**

Appendix A, General Design Criteria

GDC 1, Quality standards and records

GDC 2, Design bases for protection against natural phenomena

GDC 3, Fire protection

GDC 4, Environmental and dynamic effects design bases

GDC 37, Testing of emergency core cooling system

GDC 40, Testing of containment heat removal system

GDC 42, Inspection of containment atmosphere cleanup systems

GDC 43, Testing of containment atmosphere cleanup systems

GDC 45, Inspection of cooling water system

GDC 46, Testing of cooling water system

**Appendix B, Quality Assurance**

Appendix J, Containment leakage

Appendix R, Fire Protection

Appendix S, Seismic

Part 21, Reporting of defects and noncompliance

Part 52, Advanced Reactors

Part 54, License Renewal

Part 100, Appendix A, Seismic

Advanced Notice of Proposed Rulemaking

The ANPR (Attachment 2) provides a description of, and requests that the public comment on: (1) the alternative new terminology and proposed criteria (the proposed Appendix T); (2) the staff's proposed approach for modifying the special treatment requirements; (3) the staff's expectations with respect to conduct of the pilot program; (4) the staff's proposed activities and

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<sup>4</sup>Although §50.59 is considered a special treatment requirement, the change to §50.59 is proposed to be limited to obviating the need for an evaluation of the change in special treatment for a safety-related SSC that is of low safety significance (see rulemaking plan Section 4.3).

schedules for completion; and (5) certain policy and implementation issues. The staff believes that the ANPR provides the following benefits:

1. It is consistent with the strategy in the mission statement to use processes that maximize the opportunity for public participation. The ANPR does not preclude the use of meetings and workshops, both of which are planned. The effectiveness of the meetings and workshops may be improved by providing preliminary staff positions in the ANPR.
2. As a formal request for comments, the ANPR will receive high visibility within the industry and from other external stakeholders and establishes a timetable by which comments must be received. The schedule assumes that this exchange of information will reduce the time required to address comments on the proposed rulemaking because many issues may be resolved on the basis of public comments received on the ANPR.
3. By describing the contemplated new terminology and acceptance criteria for the proposed Appendix T, the ANPR would facilitate early implementation of the categorization pilot program and may encourage additional licensees to participate in this program.
4. It provides an early basis for evaluating the draft NEI categorization guideline, which is expected to be submitted for staff review in December 1999.
5. The ANPR does not commit the NRC to implement the contemplated rulemaking; it is only a mechanism for receiving stakeholder input. In the event the staff determined that this rulemaking was not feasible, the staff could discontinue its efforts.

#### Pilot Program

The proposed approach includes two distinct pilot activities as part of the pilot program. They are (1) review of the STP exemptions as a proof-of-concept prototype pilot and (2) a categorization pilot program to demonstrate the acceptability of the contemplated new Appendix T and the NEI guideline.

The staff's review of the STP exemption request will address many of the same issues as this rulemaking. It may establish the type of staff review necessary to allow implementation of risk-informed alternatives and will address the regulatory treatment associated with maintaining the functionality of RISC-3 SSCs. It is not expected, however, that the STP exemption will demonstrate whether the contemplated Appendix T or the NEI guideline is adequate.

The categorization pilot program will be conducted to demonstrate the adequacy of the contemplated new terminology and categorization acceptance criteria in the proposed Appendix T. The staff further recommends that final rulemaking be deferred until the staff has confirmed the acceptability of the proposed rule language and the NEI guideline. Under the proposed schedule, the staff would complete this evaluation in July 2001. The staff could then issue exemptions to the pilot program participants at that time.

## Policy and Implementation Issues

The staff is evaluating a number of issues to determine their effect on the scope and character of this rulemaking. These issues are summarized below, and additional details are provided in the ANPR.

### 1. Selective Implementation

Selective implementation is defined as either implementing a subset of alternative regulatory treatment requirements or implementing those requirements for a subset of SSCs at a facility, or both. In SECY-98-300, the staff stated that if selective implementation is allowed, some licensees could focus their efforts in areas where unnecessary regulatory burden could be reduced, and may not focus in areas where it would be appropriate to place additional regulatory controls on SSCs given their safety significance. Therefore, selective implementation was judged incompatible with the intent of risk-informed regulation. However, the Commission determined that a decision on this topic was premature. The staff now believes that selective implementation for a subset of alternative special treatment requirements should be accommodated. The staff has not reached a conclusion regarding selective implementation for a subset of SSCs, but acknowledges that implementation of this framework would likely be through a phased approach by licensees. Selective implementation of alternative regulatory treatment requirements would introduce additional complexity into the regulatory process and the staff will need to assess the practicality of the approach. In addressing this issue, the staff will need to establish an implementation approach which recognizes all of the NRC's outcome oriented goals, not just reducing unnecessary regulatory burden. The staff is continuing to evaluate this issue and thus is seeking stakeholder feedback through the ANPR.

### 2. Effect on Other Regulations

The staff has determined that implementation of risk-informed alternatives in Part 50 may affect implementation of other regulations (e.g., Part 21, Part 55, and Part 54). In some cases, such as operator licensing (Part 55), rule changes may not be necessary; however, licensees may need to make changes to programs implementing these regulations in order to ensure compliance. In other cases such as Part 21 and Part 54, it appears that changes may be needed (Refer to Section 4.3 of the rulemaking plan).

### 3. Staff Review Requirement

As described in SECY-98-300 and in the mission statement objectives, the preferred approach is to avoid the need for prior staff review and approval of either the licensee's PRA and SSC categorization process (other than confirmation that it meets the criteria in the proposed Appendix T) or the results of that process (i.e., the list of SSCs of safety significance). This approach may not be feasible. In that event, the staff will need to determine what level of review would be necessary.

By providing detailed categorization requirements in the proposed Appendix T, it is the staff's intent to provide a regulatory framework supporting implementation of risk-informed alternative requirements without prior NRC review and approval. Appendix T

will be developed, in part, from existing guidance such as RG 1.174, and from experience gained by review of the South Texas Project (STP) Graded Quality Assurance methodology. Several significant aspects of the proposed categorization technique rely upon subjective and qualitative judgement. For example, it is expected that an expert panel will consider defense-in-depth as part of the assessment of SSC risk significance. Terms such as defense-in-depth and margin of safety are often defined only in qualitative, not quantitative, terms. Such terms are difficult to translate into inspectable and enforceable regulations yielding consistent, objective results. Therefore, application of these concepts within Appendix T creates a significant challenge for the staff. It should be noted that work to risk-inform the technical requirements of 10 CFR 50 (Option 3) must also address the defense-in-depth and safety margin issue and the work in this area will be closely coordinated between Options 2 and 3. To support a “no prior approval” approach, Appendix T will need to be constructed such that expert panels will reach sound and consistent judgements. It is important to note that SSCs categorized as RISC-3 are not being removed from regulatory treatment (i.e., there will be some requirements in 50.69 to address functionality). If the staff cannot develop criteria that result in consistent, objective results, then some level of prior NRC review and approval will be necessary.

The “no prior staff approval” approach puts increased emphasis on the quality of the underlying PRA. It is currently the staff’s intention that the issue of PRA quality will be addressed through the staff’s endorsement of national consensus standards on PRA quality.

#### 4. Identification and Control of Attributes Requiring Special Treatment

The staff anticipates development of regulatory controls for RISC-1 and RISC-2 SSCs to ensure the attributes of these SSCs that make them safety significant are adequately preserved. For RISC-1 SSCs, it is possible that existing special treatment requirements do not adequately address these attributes. For RISC-2 SSCs, the safety significant attributes are probably not subject to regulatory control in the existing deterministic framework. Therefore, for these components, the staff is considering what are the appropriate regulatory controls that should be applied.

For RISC-3 SSCs, appropriate controls must be established to preserve functional performance. For example, safety-related hydrogen recombiners installed in large dry containments may be determined to be of low safety significance. Nonetheless, the hydrogen recombiner’s function must be preserved until such time that 10 CFR 50.44 criteria are revised under Option 3. It is expected that criteria for preservation of functional capability (at a reduced level of assurance ) will be developed and incorporated into 10 CFR 50.69. Defining the controls that are appropriate for maintaining functionality of RISC-3 SSCs will be a significant challenge.

Regarding the appropriate level of regulatory controls to be placed on RISC-1, RISC-2, and RISC-3 SSCs, the staff expects that it will receive significant stakeholder feedback through the ANPR. Refer to questions E.1 through E.4 of the ANPR.

#### LEGAL ANALYSIS AND BACKFIT ANALYSIS:

The Office of the General Counsel (OGC) has not identified any bases for legal objection to the contemplated rulemaking approach. The rulemaking provides an alternative method for ensuring that the requirements of the Atomic Energy Act (AEA) of 1954 as amended are complied with, that there can be reasonable assurance of adequate protection to public health and safety, that the operation of a nuclear power plant will not impose an undue risk to public health and safety, and that appropriate levels of protection are provided to minimize danger to life and property. Accordingly, OGC believes that the AEA provides the Commission with sufficient authority to promulgate the contemplated rule. OGC has concluded that the contemplated rulemaking appears to comply with rulemaking requirements.

OGC has also determined that the contemplated rulemaking would not constitute a backfit as defined in Section 50.109(a)(1). This determination is made on the basis that each of the rules being modified in this rulemaking would provide a voluntary alternative to licensees that wish to utilize risk-informed methods for selecting the SSCs that are subject to special treatment requirements. Licensees that choose not to use such an approach can continue to rely upon their existing designations of safety-related and important to safety.

#### SCHEDULE:

The proposed schedule, described in Section 17 of the rulemaking plan, includes six major efforts: (1) the STP exemption; (2) the ANPR; (3) the categorization pilot program; (4) the NEI guideline review; (5) the proposed rulemaking; and (6) the final rulemaking. Assuming that the staff requirements memorandum (SRM) for this rulemaking plan paper is issued within 6 weeks of the date of this Commission paper, the staff's proposed schedule would result in the following projected milestone dates:

1. A proposed rulemaking package submitted to the Commission for approval in September 2000.
2. A final rulemaking package submitted to the Commission for approval in October 2001.
3. Licensee implementation could begin in March 2002.

The proposed schedule, while achievable, does assume that all issues can be resolved promptly. As described in the rulemaking plan, even short delays in many of the tasks could delay the project as a whole. In addition, since this rulemaking represents a developmental activity, it is possible that extensive public comments or unforeseen issues could arise that may be difficult to resolve and thus delay the schedule.

#### RESOURCES:

As described in Section 17 of the rulemaking plan, the total resources estimated for this effort are 47 FTE and \$3.0 million in technical assistance, as illustrated in the following table. The resource estimates are consistent with each office's budget, except for the FY 2000 technical assistance estimate for NRR.

	FY 2000		FY 2001		FY 2002	
	FTE	\$ (000s)	FTE	\$ (000s)	FTE	\$ (000s)
<b>NRR</b>	22*	1,350	12	150	3	0
<b>RES</b>	2	500	3	500	3	500

\*This includes 3 FTE to review the STP exemption.

In addition to the program office resources, OGC will require approximately 1 FTE total over the three fiscal years, and other offices (Administration, OCIO, OCFO) should require less than 1 FTE combined in support of this effort. None of these offices will require technical assistance funds.

During the staff's interactions with industry, the public, ACRS and other stakeholders in September and October 1999, the difficulty of the task of identifying the appropriate level of assurance for each safety class became apparent. Thus, additional effort may be necessary to establish the impact of removing equipment from the scope of the current special treatment requirements, and to assess the appropriate level of assurance in the proposed §50.69. For NRR, the preliminary technical assistance estimate for this effort is that it could be as much as \$1.1 million more than budgeted for FY 2000. At this time the staff plans to move ahead using internal resources. At mid-year the staff will reassess using the PBPM process to identify whether additional resources are needed. The staff will then provide the results of the PBPM assessment for the agency mid-year review to identify whether resources should be reallocated.

These estimates are tentative and may change as better information is developed as a result of public comments on the ANPR, and as the staff addresses the technical and policy issues associated with the rulemaking. In the event schedule delays occur, substantial revisions to the estimated resources would be necessary, in particular for FY 2002. In the event reprogramming is necessary as a result of issues that are raised or schedule delays, the staff will use the PBPM process to reallocate resources as necessary at that time.

These estimates only encompass the effort associated with the rulemaking, including development of appropriate regulatory and inspection guidance. It does not include resources necessary to implement the final rules, such as staff training or review and inspection of licensee programs (except for the effort to review the STP exemption and pilot plant program and exemptions). The implementation resources can be better estimated once a final decision on the regulatory approach has been made (e.g., whether prior staff review and approval is required).

COORDINATION:

The staff conducted three information briefings with the ACRS, and provided an information briefing for the Committee to Review Generic Requirements (CRGR). By letter dated October 12, 1999, the ACRS indicated its general agreement with staff's proposal to develop a new rule and supporting appendix to risk-inform special treatment requirements. OGC has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the Chief

Information Officer has reviewed the rulemaking plan for information technology and information management implications and concurs in it. However, the plan suggests changes in information collection requirements that must be submitted to the Office of Management and Budget at the same time the rule is forwarded to the Federal Register for publication.

The staff is also developing an internal and external communications plan regarding the rulemaking. The objective will be to engage internal (e.g., NRC staff, ACRS, CRGR) and external (e.g., NEI, licensees, members of the public) during the rulemaking process.

RECOMMENDATIONS:

The staff recommends that:

1. The staff issue the ANPR in Attachment 2. The staff requests action within 10 days. Action will not be taken until the SRM is received. We consider this action to be within the delegated authority of the EDO.
2. The Commission approve the rulemaking plan as described in Attachment 1.

Original signed by

William D. Travers  
Executive Director  
for Operations

- Attachments:
1. Rulemaking plan for Risk-Informing Special Treatment Requirements
  2. Proposed ANPR
  3. Rule selection methodology

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 3. Rule selection methodology

\*SEE PREVIOUS CONCURRENCE

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# RISK-INFORMING SPECIAL TREATMENT REQUIREMENTS

## RULEMAKING PLAN

10 CFR PART 21, 10 CFR PART 50, 10 CFR PART 54, 10 CFR PART 100

### 1.0 Regulatory Issue

#### 1.1 Problem Statement

In Option 2 of SECY-98-300 “Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities,” the staff proposed making changes to the scope of structures, systems, and components (SSCs) requiring special treatment. The staff did not define the phrase “special treatment,” but rather chose to provide some insight into the meaning of this terminology by using specific examples of regulations that impose special treatment requirements. The current scope of SSCs covered by the special treatment requirements governing commercial nuclear reactors<sup>5</sup> is deterministically based and stems primarily from the evaluation of selected design basis events, as described in updated final safety analysis reports (UFSARs). This regulatory framework provides reasonable assurance of no undue risk to the health and safety of the public. However, recent advances in technology, coupled with operating reactor experience, have suggested that an alternative approach, one that maintains safety with a reduction in unnecessary burden, is possible. The new approach would use a risk-informed process for evaluating SSC safety significance, that would, in turn, result in a more focused determination of which SSCs should receive special treatment requirements. This revised regulatory framework should allow both NRC staff and industry to focus resources on regulatory issues of greater safety significance.

#### 1.2 Background

As directed by a staff requirements memorandum (SRM) of June 8, 1999, the staff is implementing Option 2 of SECY-98-300. Specifically, the Commission directed the staff to evaluate strategies to make the scope of the commercial nuclear reactor regulations that impose unique requirements identified in this discussion as “special treatment requirements,” risk-informed. For the purposes of this rulemaking effort, the staff has defined special treatment requirements broadly as current requirements imposed on SSCs that go beyond industry-established requirements for equipment classified as “commercial grade” that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements. Typically, the regulations establish the scope of SSCs that receive special treatment using one of three different terms: “safety-related,” “important to safety,” or “basic component.” The terms “safety-related” and “basic component” are defined in the regulations, while “important to

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<sup>5</sup>These regulations reside in 10 CFR Part 21, 10 CFR Part 50, 10 CFR Part 54, and 10 CFR Part 100.

safety” (used principally in the general design criteria of Appendix A to 10 CFR Part 50) is not explicitly defined.

The risk-informed approach discussed in this plan for establishing an alternative scope of SSCs subject to special treatment requirements is intended to complement the NRC’s traditional deterministic approach. The risk-informed approach will be consistent with the defense-in-depth philosophy, will maintain sufficient safety margins, will provide reasonable assurance that necessary safety functions will be performed, will ensure that increases in core damage frequency or risk are small and consistent with the safety goal policy statement, and will ensure that a performance measurement strategy is employed.

It is important to note that, consistent with SECY-98-300, this rulemaking effort, while intended to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed, is not intended to allow for the elimination of SSC functional requirements, or to allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, by restructuring the regulations to allow an alternative risk-informed approach to special treatment, this rulemaking should enable licensees and the staff to focus their resources on SSCs that make a significant contribution to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach should allow a reduced level of assurance that these SSCs will meet functional requirements.

The following describes the staff’s vision, strategies, and objectives for this rulemaking effort. The staff believes that they have been developed in a manner that is consistent with the agency’s performance goals:

**Vision**            Develop alternative regulations in Part 50 (and other applicable parts) that would modify the requirements for special treatment to focus on those SSCs that have been identified as important to protect public health and safety using a risk-informed approach.

**Strategies**        Increase the use of risk-informed approaches to modify the special treatment requirements imposed on SSCs under existing Part 50 requirements (and those of other applicable parts).

Maintain overall safety provided by the existing Part 50 while reducing unnecessary burden associated with these requirements for licensee operational and licensing activities and for NRC oversight and licensing activities.

Risk-inform the special treatment requirements imposed on SSCs under Part 50 (and other applicable parts) in a manner that encourages public participation and results in public confidence in the product and process.

**Objectives** Establish the criteria for acceptable methods for determining the SSCs that require special treatment in the regulations of Part 50. These criteria should be sufficiently clear and robust such that if a licensee's program meets the criteria there is not a need for staff review and approval of the plant-specific program.

Assign priorities to the rules to be modified, taking into consideration the reduction of unnecessary burden for industry, the effect on staff efficiency and effectiveness, and public confidence, and the complexity of modifying each rule.

Ensure that the categorization process has been evaluated under a pilot program to verify that the requirements and their associated guidance can be implemented by industry, and that the results of licensee implementation provide reasonable assurance that public health and safety is maintained.

Issue a proposed rule for the initial set of rules to be modified within 1 year of the Commission's approval of the rulemaking plan, and a final rule within 1 year of the completion of the associated pilot program.

The proposed risk-informed regulatory alternatives should reduce unnecessary burden so that licensees with more than 10 years remaining on their license would find it beneficial to voluntarily implement the risk-informed alternative requirements.

## **2.0 Existing Regulatory Framework**

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing reasonable assurance of adequate protection to public health and safety. The current body of NRC regulations and their implementation are largely based on a "deterministic" approach. Requirements were devised on the basis of a defined set of events that are analyzed as "design basis events." This approach has employed the use of safety margins, operating experience, accident analysis, and qualitative assessments of risk, relying on the application of a defense-in-depth philosophy. One element of this defense-in-depth approach is the imposition of "special treatment" requirements on SSCs important to safety to provide reasonable assurance that such SSCs will meet functional requirements during postulated design basis conditions. Special treatment requirements are imposed on nuclear reactor applicants and licensees through numerous regulations that have been promulgated since the 1960's. These requirements specify different scopes of equipment for different special treatment requirements depending on the specific regulatory concern.

Against this deterministic regulatory backdrop, the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA) in 1995. To implement this Commission policy, the staff developed guidance on the use of risk information for reactor license

amendments issuing Regulatory Guide (RG) 1.174 and its supporting regulatory guides: RG 1.175 (Risk-informed Inservice Testing), RG 1.176 (Graded Quality Assurance), RG 1.177 (Risk-informed Technical Specifications [TSs]), and RG 1.178 (Risk-informed Inservice Inspection). Currently, the staff is processing applications that use risk information as part of their technical justification utilizing the referenced regulatory guidance. In this respect, the Commission has been successful in developing and implementing a regulatory means for factoring risk insights into the current regulatory framework. One such risk-informed submittal, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company requested that the NRC staff approve a revised Operations Quality Assurance Program (OQAP), incorporating the methodology for graded quality assurance (QA), that was based on PRA insights. The STP graded QA proposal was essentially an extension of the existing regulatory framework. Specifically, the STP approach continued to use the traditional safety-related categorization, but allowed for gradation of safety significance within the "safety-related" categorization (consistent with Appendix B) through use of a risk-informed process. Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP on November 6, 1997. In its letter and the accompanying safety evaluation, the staff concluded that for the proposed graded QA approach the licensee's methodology for determining the relative safety significance of plant SSCs was acceptable, that appropriate QA controls had been defined for the established categories of SSCs, that adequate feedback mechanisms had been established to adjust the graded QA program if operational performance indicated such a need, and that all pertinent regulatory requirements continued to be satisfied.

Subsequent to NRC's approval, the licensee identified implementation difficulties associated with the graded QA program. For a large number of SSCs that the licensee judged to be of low risk significance, and for which the licensee reduced the QA requirement, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, or seismic requirements continue to impose substantial requirements. Therefore, if the licensee needs to replace such a component, there is still a need to meet all such special requirements when procuring the replacement even though the SSC in question may have been determined to be of low safety significance and QA controls have been reduced. These "special treatment" requirements have prevented the licensee from realizing the full potential reduction in unnecessary regulatory burden for SSCs judged to have little or no safety importance. In an effort to achieve the full benefit of the graded QA program (and in fact go beyond the staff's previous approval of a graded QA approach), the licensee submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including Appendix B) for SSCs categorized as of "low safety significance" or as "nonrisk significant." This proposal is currently being reviewed by the staff.

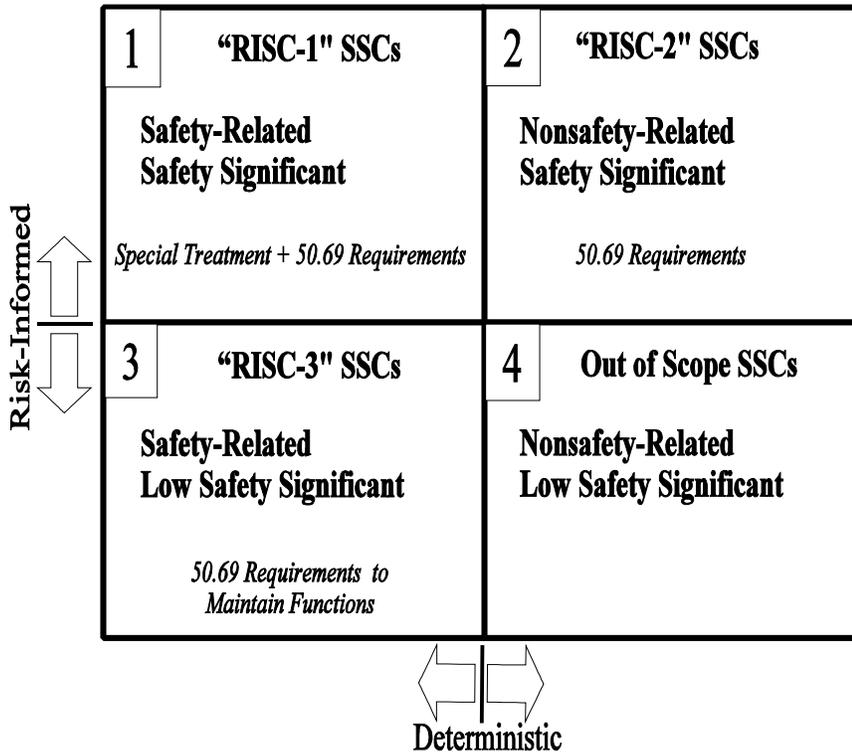
As already mentioned, SECY-98-300 was sent to the Commission on December 23, 1998, to obtain the Commission's agreement on a list of three options for ensuring the governing commercial reactor regulations are risk-informed. As described in SECY-98-300, "Option 2" which pertains to this rulemaking effort was to risk-inform the scope of regulations which impose special treatment requirements. By SRM dated June 8, 1999, the Commission directed

the staff to implement Option 2 of SECY-98-300. Thus, the staff has initiated the rulemaking effort described in this plan.

### 3.0 How the Regulatory Issue Will Be Addressed By Rulemaking

The purpose of this rulemaking is to develop an alternative regulatory framework that enables licensees, using a risk-informed process for categorizing SSCs according to their safety significance (i.e., a decision that considers both traditional deterministic insights and risk

**FIGURE 1: Diagram of Categorization and Treatment**



insights), to reduce unnecessary regulatory burden for SSCs of low safety significance by removing these SSCs from the scope of special treatment requirements. In the process, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance. This framework should improve regulatory effectiveness and efficiency, and contribute to enhanced plant safety. To accomplish this goal, it is necessary to amend the governing regulations. The current regulations use terms such as "safety-related," "important to safety," and "basic component" to identify the groups of SSCs and associated activities that require "special treatment." This rulemaking will build into the regulations an alternative that offers licensees the flexibility of utilizing a risk-informed process to evaluate the need for special treatment. This risk-informed process will ensure that risk insights will be used in a manner that complements the NRC's traditional deterministic approach. The risk-informed approach will be consistent with the defense-in-depth philosophy, will maintain sufficient safety margins, will ensure that any increase in core damage frequency or risk is small and consistent with the safety goal policy statement, and will include a performance measurement strategy. The risk-informed framework will also be aligned to the NRC Reactor Inspection Oversight process by incorporating the cornerstones from the reactor safety and radiation protection safety areas into the SSC categorization process.

A graphical depiction of the changes that are expected to result from a risk-informed re-categorization of SSCs is illustrated in Figure 1. The figure is only intended to provide a conceptual understanding of the new SSC categorization process. The staff's thinking is continuing to evolve on this matter and as suggested in the Advisory Committee on Reactor Safeguards (ACRS) letter of October 12, 1999, the staff will explore whether more than two levels of safety significance is a better approach. The staff is requesting stakeholder feedback regarding safety significance categories in question C.3 of the Advance Notice of Proposed Rulemaking (ANPR). Refer to Attachment 2 of the SECY paper that forwards this rulemaking plan to the Commission. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new risk-informed categorization. The risk-informed categorization would group SSCs into one of the four boxes in Figure 1.

Box 1 of Figure 1 contains safety-related SSCs that a risk-informed categorization process concludes are significant contributors to plant safety. These SSCs are termed risk-informed safety class 1 (RISC-1) SSCs. SSCs in this box would continue to be subject to the current special treatment requirements. In addition, it is possible that some of these SSCs may have additional requirements concerning reliability and availability, if attributes which cause an SSC to be safety significant are not sufficiently controlled by current special treatment requirements. However, the staff is not currently aware of any examples of this situation.

Box 2 depicts the SSCs that are nonsafety-related, and that the risk-informed categorization concludes make a significant contribution to plant safety. These SSCs are termed RISC-2 SSCs. Examples of RISC-2 SSCs could include the station blackout emergency diesel, startup feedwater pumps, or SSCs that function for pressurized water reactor (PWR) "feed and bleed" capability. For RISC-2 SSCs, there will probably need to be requirements to maintain the reliability and availability of the SSCs consistent with the probabilistic risk assessment (PRA). As discussed below, it is currently envisioned that 10 CFR 50.69 (i.e., the new rule) would contain the regulatory treatment requirement for RISC-1 and RISC-2 SSCs regarding the reliability and availability of these SSCs.

Box 3 depicts the currently safety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-3 SSCs. The rulemaking would revise Part 50 to contain alternative requirements (per §50.69) such that RISC-3 SSCs would no longer be subject to the current special treatment requirements. For RISC-3 SSCs, it is not the intent of this rulemaking to allow such SSCs to be removed from the facility, or to have their functional capability lost. Instead, the RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance. The staff may determine that this level of assurance can be provided by licensee's commercial grade programs. As discussed below, it is currently envisioned that §50.69 would contain the regulatory treatment requirements for RISC-3 SSCs.

Box 4 depicts SSCs that are nonsafety-related and continue to be categorized as not being significant contributors to plant safety. These SSCs are out of scope of both current special treatment and any future regulatory controls of §50.69. The functional performance of these SSCs is controlled under the licensee's commercial grade program (no change from the current requirements).

## 4.0 Rulemaking Alternatives

This section:

- (1) Evaluates various alternative rulemaking strategies (Section 4.1);
- (2) Describes the selection of rules (that contain special treatment requirements) rules which are being considered for inclusion into the rulemaking effort (Section 4.2);
- (3) Discusses unique considerations for specific rules that contain special treatment requirements (Section 4.3); and
- (4) Evaluates the best approach for implementation of the rulemaking (Section 4.4).

### 4.1 Selection of the Rulemaking Approach

Section 4.1 evaluates various alternative rulemaking strategies. The agency's performance goals (i.e., maintain safety, reduce unnecessary regulatory burden, increase efficiency and effectiveness, enhance public confidence) are used as criteria to judge each regulatory approach.

Numerous rulemaking strategies were considered for implementing this risk-informed initiative. The strategies judged to be most viable are:

1. New Term: This approach entails the definition in 10 CFR 50.2 of a new term (i.e., "safety-significant SSCs") that describes for the purposes of special treatment requirements which SSCs are safety-significant and therefore need to be within the scope of the rules containing special treatment requirements. This new term would then be incorporated into the scope of each rule that contains special treatment requirements to allow licensees to voluntarily revise the scope of SSCs that are subject to special treatment requirements (i.e., only SSCs that are safety-significant would need to receive special treatment). To determine which SSCs are safety significant, the staff would issue a new Part 50 appendix that contains the requirements governing the categorization of SSCs consistent with the new term defined in §50.2, or alternatively the staff could issue a regulatory guide that contains the SSC categorization guidance.
2. Redefine Current Terminology: This approach would expand the definition of the term "safety-related" in 10 CFR 50.2, or as an alternative define the term "important to safety" such that the redefined term would contain a portion that allows special treatment requirements to be risk-informed. Licensees could then elect to risk-inform the scope of SSCs that are subject to special treatment in all the applicable rules. This approach expands the meaning of the current terms (which reside in the existing rules) so there is no need to add new terms to the governing regulations. However, there would need to be a significant effort to go through all the regulations to make sure that the staff did not unintentionally revise any non-special treatment rules and make appropriate changes to preclude such occurrences. In a similar fashion to the "new term" approach described above, this approach would also need to be supplemented with either a new Part 50 appendix that contains the requirements governing the risk-informed categorization of SSCs, or alternatively the staff could issue a regulatory guide that contains the SSC categorization guidance.

3. New Rule: This approach entails the development of a new rule in Part 50 (currently the rule would be 10 CFR 50.69) that would “list” the rules that contain special treatment requirements that may have their scope risk-informed in accordance with the methodology requirements contained in either an appendix to Part 50, or guidance contained in a regulatory guide (similar to above two approaches in this respect). It is not clear at this point whether this approach of “listing” the rules is practical and efficient, or whether it is better to revise the scope of each special treatment rule to reference §50.69 for additional requirements concerning the alternative approach. In addition to identifying which rules can be risk-informed for special treatment, the new rule would contain some new requirements concerning the type of regulatory treatment that SSCs would receive. RISC-1, RISC-2, and RISC-3 SSCs (i.e., boxes 1, 2, and 3 of figure 1) would receive some type of regulatory treatment. For example, it is expected that the new rule will include a requirement that RISC-3 SSCs (safety-related SSCs that are determined to be of low safety significance) would have their functionality maintained through the use of commercial practices and standards. The new rule could also specify that RISC-1 and RISC-2 SSCs (either safety-related or nonsafety-related) that are determined to be significant contributors to plant safety for events that are beyond the design basis of the facility shall have their reliability and availability maintained such that the assumptions of the PRA continue to be valid. For the purposes of this discussion, this regulatory treatment is referred to as a Reliability Assurance Program.

After comparing these alternatives, the staff eliminated alternative 2. The staff decided not to define or redefine the existing terms (i.e., “safety-related” or “important to safety”) primarily because this approach was judged to be relatively inefficient and ineffective from a regulatory standpoint. The staff concluded that the use of the same terms having two different meanings would unnecessarily complicate and confuse the existing regulations governing power reactors. The potential level of confusion could be significant considering the potential for licensees to elect to implement the risk-informed alternative for only for a subset of revised rules, resulting in the use of similar language with different meanings in the licensee’s licensing basis documents and in the associated plant implementation documents. In fact, this type of confusion would be unavoidable during the time period when licensees are phasing in the new approach at their facilities as they re-categorize the SSCs in various plant systems. Both the terms “safety-related” and “important to safety” have a long regulatory history that has established their meaning and interpretation in both a technical and regulatory sense. The staff concludes that it is better to avoid the potential for reopening previous debates concerning these terms (and the associated resource drain for both the NRC staff and industry).

Regarding the remaining two alternatives, the staff judges alternative 3 to be the most clear and expedient approach requiring fewer staff resources to implement since it appears to avoid the need to develop and incorporate a new definition into the regulations (i.e., the staff has not determined whether it will define RISC-1, RISC-2, and RISC-3 in the regulations). This approach avoids the consequential need to revise the scope of each regulation containing special treatment requirements to insert the newly defined term. However, as already mentioned the staff may still need to revise the scope of each rule to refer to §50.69, if the staff concludes that this course of action is the most efficient and effective approach. Alternative 3 has the benefit of grouping or integrating all the risk-informed requirements into one rule. This contributes to regulatory clarity and makes it easier for both licensees and the staff to implement the regulation (as opposed to having risk-informed requirements incorporated into each regulation). Additionally, the new rule approach enables the staff to “cleanly” identify in

one place what the regulatory treatment requirements will be for each risk-informed safety class (see figure 1). Specifying these types of regulatory treatment requirements for the alternative 1 approach would be more difficult and confusing because it would require changing the specific regulations that were intended only for “design basis” events to address RISC-2 and RISC-3 SSCs. In the case of RISC-2 SSCs, this would mean revising the current Part 50 regulations which have a design basis focus to address SSCs that are important for beyond design basis events. In the case of RISC-3 SSCs, this would mean revising the current Part 50 regulations to maintain design basis function but with less assurance. From a regulatory perspective, to revise the Part 50 regulations to address RISC-2 and RISC-3 SSCs is a difficult task. More importantly, it appears that it would confuse the Part 50 regulations with respect to what it means to be within the design basis and what it means to be functional. On the other hand, the new rule alternative enables the staff to address these two difficult issues in a separate, stand-alone regulation which has the least impact on existing regulations. From this perspective, the new rule approach appears to be a more effective and efficient regulatory approach.

Since alternative 3 would incorporate new requirements into 10 CFR 50.69 concerning the regulatory treatment for SSCs categorized as RISC-2 and RISC-3, it is not simply a “scope” approach to special treatment. It could therefore be viewed as going beyond the Commission’s June 1999 SRM to implement option 2 of SECY-98-300. However, the staff concludes that the new rule alternative is consistent with the Commission’s directive and SECY-98-300 because the alternative only expands the “scope” approach as necessary to facilitate a sound technical and regulatory approach for risk-informing special treatment requirements. For example, without some additional requirements placed into the §50.69, RISC-2 SSCs that are “scoped” into the new rule would have no requirements placed on them since the current regulations do not generally have applicability for beyond design basis events. It is in those events that RISC-2 SSCs make a significant contribution to plant safety.

Regarding whether alternative 3 should be supported with an appendix to Part 50 or with a regulatory guide, the staff concludes that an appendix is the preferable approach. A regulatory approach that is supported with a Part 50 appendix has the potential to be constructed such that it supports implementation of risk-informed alternative without the need for prior NRC review and approval of either the licensees’ risk-informed categorization methodologies or the resultant equipment lists (i.e., use of a regulatory guide would require NRC staff review and approval). Incorporation of categorization methodology requirements into an appendix in the regulations minimizes the interaction required with licensees to implement the new regulatory approach, provides greater regulatory stability and predictability, and is judged to result in the least burden on staff and industry resources. This conclusion assumes that the staff can construct an appendix that contains regulatory criteria that maintain safety and are sufficiently clear to both the staff and industry so that there is consistent implementation of the criteria (i.e., that expert panels reach sound and consistent technical decisions regarding SSC categorization) and the staff can conclude that safety is maintained without the need for prior review and approval of the licensee’s SSC categorization methodology. An appendix constructed to such standards would also contribute to greater regulatory stability and predictability regarding the staff’s inspection efforts. The staff recognizes that this will be a difficult task from both a technical and legal perspective. It involves a new type of regulatory approach that requires an explicit, detailed appendix. It is not clear at this point in time whether such an approach can be developed. Therefore, it is possible that the ultimate regulatory approach may involve staff review that relies on a less detailed and explicit appendix.

Assuming that a “no prior staff approval” appendix approach can be developed, the staff will need to make its safety determination principally based on the conclusion that the appendix ensures sufficient fidelity of the categorization process to support the more general conclusion that plant safety is maintained. Performance monitoring of re-categorized equipment (RISC-3 SSCs) appears to have significant limitations. For RISC-3 SSCs, there is likely to be limited capability for meaningful monitoring of these SSCs because, in many cases, the original special treatment requirements were the principal means for providing assurance that such SSCs would function under design basis conditions. For instance, the SSC can not be tested under design basis conditions and so additional requirements like §50.49 and 10 CFR 50 Appendix B were imposed on the SSC to provide assurance that such SSCs would satisfy functional requirements under design basis conditions. The staff expects that the experience gained from the pilot plants will help it resolve whether a regulatory approach that does not involve prior NRC review and approval is feasible.

It is also important to note that a “no prior staff approval” approach puts increased emphasis on the necessary quality of the supporting PRA. It is currently the staff’s intentions that the issue of PRA quality will be addressed through the staff’s endorsement of national consensus standards on PRA quality.

If the staff concludes that it must review to some extent the licensee’s categorization of SSCs, then the staff will reconsider which regulatory approach to pursue. The conclusion above is based primarily on the judgement that the burden is less for both the staff and industry for the “no prior approval” appendix approach. The basis for this conclusion is that the net impact on staff resources is less when this activity is regulated through the performance of risk-informed inspections (performed consistent with the regulatory oversight process) that inspect the licensees’ implementation of the new SSC categorization process rather than regulating this activity as both a licensing action (i.e., prior review and approval) and as an inspection task. As already mentioned, a well constructed appendix (and supporting inspection guidance) that contains clear, unambiguous criteria as to what is required to comply with the new approach, should provide greater regulatory stability to the inspection process which should in turn contribute to fewer resources (for both the staff and industry) being required for the inspection activity. However, this inspection activity has potential to be resource intensive (under the assumption that the staff will not be reviewing and approving the licensee’s re-categorization methodology) for both the staff and industry unless such inspections are well defined, focused, and both staff inspectors and licensees clearly understand what it means to comply with the new regulatory approach for classifying SSCs. The staff currently believes that it is possible to establish such an inspection framework. It is also important to note that any regulatory approach which either requires prior NRC review and approval of the re-categorization methodology or which contains an inspection component that is ambiguous regarding what the requirements are for the new categorization process, may be viewed by industry as having too much uncertainty regarding what will be acceptable, and being too unpredictable regarding the potential costs to implement the regulatory alternative. Consequently, the staff believes that under a “prior NRC review and approval” approach, licensees would be less likely to pursue this risk-informed regulatory alternative.

Conclusion: The “new rule” alternative, for the reasons stated above, is judged to be the best regulatory approach assuming that it can be implemented without the need for extensive prior NRC review and approval of licensees’ risk-informed categorization approaches and assuming that the new rule does not become too unwieldy (i.e., in which case the staff may need to revise

the scope of each rule to refer to §50.69). The staff will rely, in part, on the pilot plant experience to determine whether such a regulatory framework can be constructed, or whether there will be a need to structure the regulatory framework to require some level of prior staff review and approval of licensee's SSC risk-informed categorization effort. The key elements that would be contained in a new rule and supporting appendix to implement this preferred regulatory alternative are provided in Attachment 2 to the SECY paper (the ANPR) that transmits this rulemaking plan to the Commission.

#### 4.2 Rulemaking Implementation/Selection of Special Treatment Rules

A detailed discussion of the screening of the regulations containing special treatment requirements is provided as Attachment 3 to the SECY paper that forwards this rulemaking plan to the Commission. Section 4.2 provides an overview of this rule screening effort. The regulations governing commercial reactors were screened using the five criteria and associated measures identified below, to identify the list of special treatment regulations that should be considered in this rulemaking effort:

- |             |  |
|-------------|--|
| Criterion 1 | The rule includes special treatment requirements.  |
| Measure 1   | For the purposes of identifying special treatment regulations for possible inclusion in this rulemaking, the staff defines "special treatment" as follows:<br><br>Special treatment requirements are requirements imposed on SSCs that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. Any rule that specifies such broadly defined requirements is considered a special treatment rule. |
| Criterion 2 | The rule needs to be included in the rulemaking effort because risk-informing the special treatment requirements will improve internal efficiency and effectiveness.   |
| Measure 2   | The staff judged that the internal review and inspection effort could be reduced for the subject rule if its special treatment requirements were risk informed (while maintaining safety)  |
| Criterion 3 | The rule needs to be included in the rulemaking effort because risk-informing the special treatment requirements will reduce unnecessary burden on licensees or applicants or it needs to be included to maintain safety.  |
| Measure 3   | The staff made a preliminary analysis to assess whether risk-informing the special treatment requirements of the subject rule would reduce unnecessary burden. Industry input on benefits/costs associated with rules should weigh heavily in the final decision. Identification of pilot plants interested in modifying a specific requirement should be considered as sufficient evidence that a rule reduces burden.  |
| Criterion 4 | The rule needs to be included in the rulemaking effort to minimize the need for exemptions, or the rule needs to be included to facilitate rulemaking for another rule.  |
| Measure 4   | The staff assessed whether the subject rule needed to be addressed or revised in the rulemaking effort to avoid the need for exemptions once the special   |

treatment rulemaking is implemented (i.e., to avoid the problem that STP encountered with graded QA).

Criterion 5 The rule needs to be included in the rulemaking effort to ensure that the licensing basis is appropriately documented and controlled (e.g., FSAR updates, documentation of methodology used for implementing risk informed changes, staff or licensee reviews related to implementation of risk informed changes).

Measure 5 The staff assessed whether the rule contained requirements that relate to the documentation and control of the licensing basis.

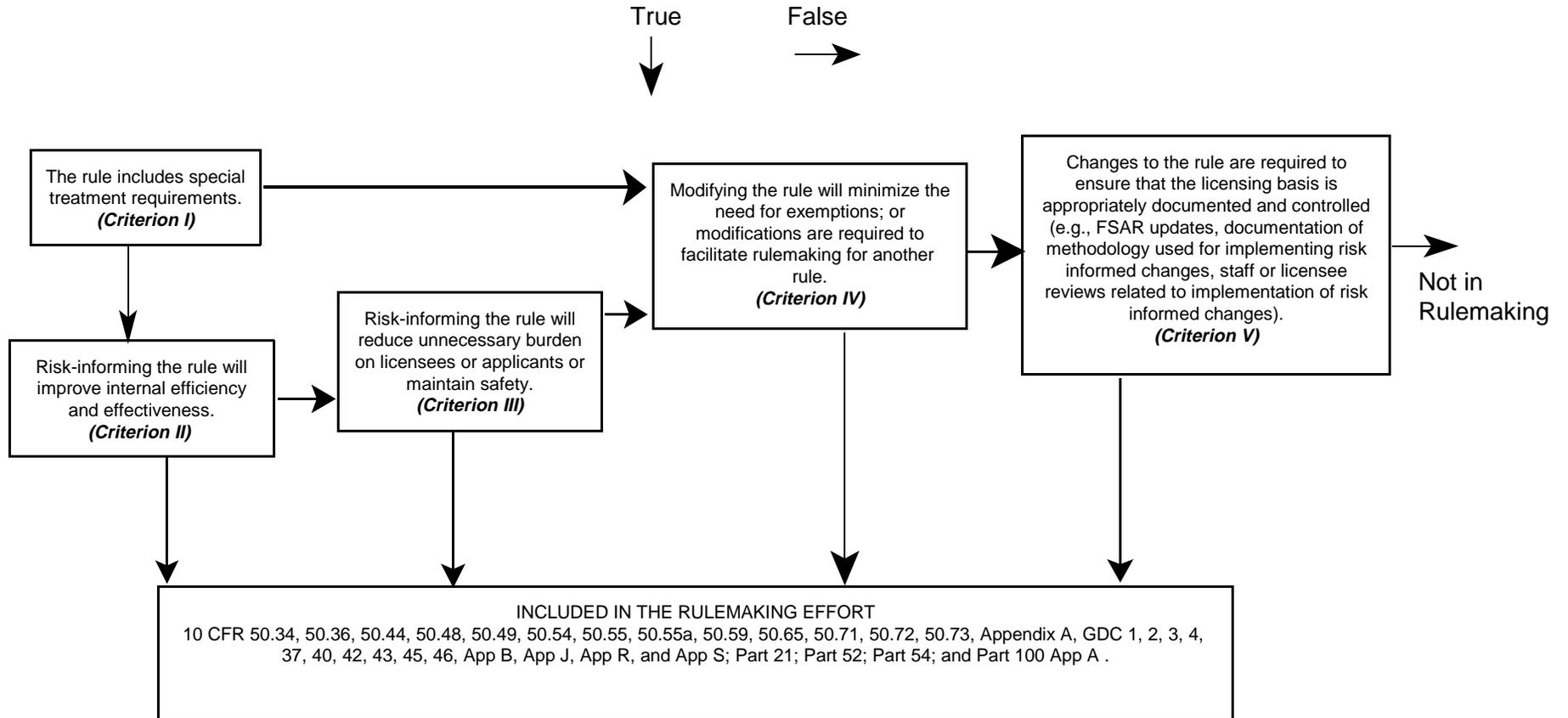
Figure 2 depicts how the screening criteria were utilized to screen the regulations. Refer to Attachment 2 (i.e., the ANPR) of the SECY paper that forwards this rulemaking plan to the Commission for a detailed summary of the results of the screening process.

As a result of the staff's rule screening effort, the staff concluded that the following rules containing special treatment requirements should be considered as part of the rulemaking effort:

1. 10 CFR 50.34
2. 10 CFR 50.36
3. 10 CFR 50.44
4. 10 CFR 50.48
5. 10 CFR 50.49
6. 10 CFR 50.54(a)(3)
7. 10 CFR 50.55
8. 10 CFR 50.55a
9. 10 CFR 50.59
10. 10 CFR 50.65
11. 10 CFR 50.71(e)
12. 10 CFR 50.72
13. 10 CFR 50.73
14. 10 CFR Part 50 Appendix A General Design Criteria 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46
15. 10 CFR Part 50 Appendix B
16. 10 CFR Part 50 Appendix J
17. 10 CFR Part 50 Appendix R
18. 10 CFR Part 50 Appendix S
19. 10 CFR Part 21
20. 10 CFR Part 52
20. 10 CFR Part 54
21. 10 CFR Part 100, Appendix A

At present, the above list of rules does not contain 10 CFR Part 55 or 10 CFR 50.120. It is possible that the staff's efforts to risk-inform the special treatment requirements could result in the need to make conforming changes to these regulations.

Figure 2: Screening Process and Results



4.3 Rulemaking Implementation/Rule-specific Approaches and Considerations:

Section 4.3 discusses unique considerations for specific rules that were screened for inclusion in this rulemaking effort.

10 CFR 50.34

10 CFR 50.34 identifies the required information that applicants must provide in preliminary and final safety analysis reports. It, therefore, is a rule that contains special treatment requirements in the form of documentation requirements for certain SSCs.

This regulation may need to be revised to ensure that future applicants properly document the categorization of SSCs with regard to special treatment. Given that this requirement applies to future applicants, the priority for revising this rule is low.

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10 CFR 50.36

The staff determined that 10 CFR 50.36 is a rule that imposes special treatment requirements. It establishes operability, surveillance, limiting conditions of operation, and monitoring requirements on SSCs. Regarding 50.36, the staff makes the following observations:

1. The potential unnecessary burden reduction from risk-informing the scope of SSCs subject to TS requirements is judged to be minimal due in large part to the new standard TS effort, which resulted in a large percentage of TS requirements being relocated from the TS. A large percentage of the remaining SSCs would probably be judged to be safety significant (i.e., either RISC-1 or RISC-2 SSCs) and would retain their special treatment.
2. To comply with a modified §50.36, licensees would be required to submit TS amendments in accordance with 10 CFR 50.90. The §50.90 process also introduces an element of uncertainty due to the possibility that a hearing on the proposed TS change may be requested with the subsequent impact on costs. This possibility represents an additional burden on both licensees and the staff associated with changing this rule. As a result, it is possible that risk-informing the scope of special treatment for §50.36 could be a net burden increase.
3. There are ongoing activities that are successfully making different aspects of the current TS risk-informed within the current regulatory structure of 10 CFR 50.36 (i.e., consistent with Option 1 of SECY-98-300). As a result, the benefits of the risk-informed evaluation process (maintain safety while reducing unnecessary burden thereby leading to a better focus of staff and industry resources on safety) are being achieved without a rulemaking effort and therefore with less commitment in staff resources.
4. To make 10 CFR 50.36 risk informed is a very complex task that appears to require a fundamental change to the §50.36 regulatory criteria. This has ramifications for the underlying accident analyses and associated key assumptions. This type of effort appears to extend beyond the current rulemaking effort and perhaps is better considered as a potential Option 3 (per SECY-98-300) effort.

The staff ANPR contains a request for input from stakeholders concerning the potential for reducing unnecessary burden associated with the special treatment requirements imposed by this regulation. Depending on this feedback, the staff will determine whether 10 CFR 50.36 should remain part of this rulemaking effort.

#### 10 CFR 50.44

Though not the focus of this rule, §50.44 includes special treatment requirements in the form of equipment qualification requirements. Specifically, for equipment located within containment, §50.44 requires that equipment to be capable of withstanding the consequences of a hydrogen-oxygen recombination without loss of safety function.

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#### 10 CFR 50.48 (Appendix R and GDC 3)

10 CFR 50.48 (including Appendix R to 10 CFR Part 50 and GDC 3) contains special treatment requirements. There is currently an ongoing rulemaking effort to risk-inform fire protection requirements. The staff will coordinate its special treatment rulemaking activities with the appropriate technical group to ensure that these regulations are revised if it is practical to do so consistent with ongoing effort (i.e., such that it does not unduly delay the ongoing rulemaking). If it is not possible to take advantage of ongoing efforts, then the rule will be addressed in a manner similar to the other special treatment rules.

#### 10 CFR 50.49

The current 10 CFR 50.49 provides a defined scope for electrical equipment items to receive special treatment. For 10 CFR 50.49, special treatment refers to required established measures and activities performed on electrical equipment items to ensure that these items perform their safety functions during and if necessary following exposure to harsh environmental service conditions resulting from design basis events. Electrical equipment important to safety and within the scope of 10 CFR 50.49 consist of three groups of equipment items. These three groups of equipment items important to safety and associated attributes are:

- Safety-related electric equipment (referred to as “Class 1E” equipment in Institute of Electrical and Electronics Engineers [IEEE] 323-1974) that is relied upon to remain functional during and following design basis events
- Nonsafety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions (or provide misleading information to the operators)
- Certain post-accident monitoring equipment as indicated in Revision 2 of RG 1.97, “Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident.”

Consistent with the approach on other special treatment regulations, the objective of amending 10 CFR 50.49 would be to incorporate an alternative that allows for a risk-informed scope for SSCs that require qualification in accordance with §50.49. For SSCs re-categorized as having low safety significance, the functional requirements of the equipment would be maintained with less assurance.

10 CFR 50.54(a)(3)

This regulation is incorporated into this rulemaking effort because changes to this rule may be needed to facilitate the rulemaking. Specifically, 10 CFR 50.54(a)(3) requires that changes to the QA program that reduce commitments receive prior NRC approval. Changes to equipment categorization are controlled through 10 CFR 50.59. 10 CFR 50.54(a)(3) may need revision to allow reductions in commitments (graded quality treatment) for RISC-3 SSCs to which the full scope of QA program description is currently applied. This may be true whether the changes are authorized under Appendix T without prior staff approval or whether the staff review and approves the changes pursuant to Appendix T and 10 CFR 50.69. In the latter case, a change to 50.54(a)(3) may not be necessary because the reduced controls could be reviewed simultaneously with other submitted information.

10 CFR 50.55a

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In order to change the scope of components to which the ASME Code requirements would apply (in accordance with 10 CFR 50.55a), either the "scope" as specified in the ASME Code would have to be changed or the NRC would have to specifically approve an alternative scope (i.e., in 10 CFR 50.55a or as a plant-specific alternative pursuant to 10 CFR 50.55a(a)(3)(i)). Changes would also need to be made to Regulatory Guide 1.26, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," other regulatory guidance documents, and to the licensee's USAR and procedures. There are ongoing industry initiatives aimed at risk-informing inservice testing and inspection activities without directly affecting the scope of components covered by the Code (e.g. changes to test frequencies and methods, changes to inspection selection techniques and criteria). The staff will continue to work with industry on these ongoing risk-informed activities. To preclude the need for granting exemptions to 10 CFR 50.55a, the staff recommends that 10 CFR 50.55a be revised to allow the replacement of ASME Code class 2 and 3 components that are categorized as RISC-3 with non-Code components. However, because ASME Code Class 1 components are part of the reactor coolant pressure boundary and a principal fission product barrier, the staff does not recommend repair and replacement of these SSCs with non-Code components consistent with the defense-in-depth philosophy. Additionally, the staff does not recommend risk-informed repair/replacement activities for containment components (another principal fission product barrier) covered under section IWE and IWL.

10 CFR 50.59

In a similar fashion to §50.54(a)(3), 10 CFR 50.59 is included in this rulemaking effort since changes to the regulation may be needed to facilitate the rulemaking. The change to §50.59 is proposed to be limited to obviating the need for an evaluation of the change in special treatment for a safety-related SSC that is now categorized as RISC-3. Changes in functional capability for SSCs of low safety significance that are described in the FSAR will still require evaluation in accordance with §50.59. Currently, the staff concludes that RISC-3 SSCs that are re-categorized to enable special treatment requirements to be reduced or eliminated do not need to be subject to 10 CFR 50.59 because it is anticipated that categorization in accordance with the new appendix requirements will be essentially redundant to the evaluation required by 10 CFR 50.59. This conclusion is clearly dependent on the ultimate structure and content of the new appendix. If this conclusion proves to be valid, then the staff will need to assess

whether §50.59 needs revision to support this approach or whether the current rule can be interpreted to allow this approach.

For RISC-2 SSCs, the staff will need to assess whether such SSCs need to be described in the updated final safety analysis report (UFSAR) in accordance with §50.71(e). If so, then future changes to RISC-2 SSCs would then be subject to 10 CFR 50.59. The staff recognizes that the §50.59 criteria may not apply to these SSCs since these SSCs typically are safety-significant only due to their functioning in events which are beyond the traditional design basis events. A possible solution is to evaluate future proposed changes to these RISC-2 SSCs such that a decrease in plant safety would require prior NRC review and approval consistent with the spirit of the §50.59 regulation. This possibility appears to require rulemaking. Another possible solution is to construct Appendix T to contain a requirement to maintain the reliability and availability of these RISC-2 SSCs consistent with the PRA assumptions. The staff needs to assess whether such a requirement would effectively supersede §50.59 and could constitute an acceptable change control mechanism.

#### 10 CFR 50.65

The existing maintenance rule (MR) contains three areas that impose special regulatory treatment to sets of defined SSCs. These three scopes apply to maintenance at decommissioning status plants (§50.65(a)(1)), assessing the risk of maintenance at operating plants (§50.65(a)(4)), and monitoring the effectiveness of maintenance at operating plants (§50.65(b)(1)).

The staff recently revised §50.65 to add paragraph (a)(4) which has a risk-informed scope. Under the current rulemaking effort, the objective for §50.65 would be to make its special treatment requirements risk-informed while preserving the recent §50.65(a)(4) change. Additionally, changes to §50.65 must be considered for the potential impact on license renewal. As stated in the Statements of Consideration (SOC) for the license renewal rule, the Commission determined that the license renewal rule should credit the existing programs, in particular the MR, for narrowing the scope of Part 54. Refer to the discussion of Part 54 below for more specific considerations on revising the scope of the MR and its impact on license renewal.

#### 10 CFR 50.71(e)

This regulation was screened into the rulemaking effort because it contains special treatment requirements that impose documentation and licensing basis control requirements on SSCs. Although the review to date indicates that the current rule is sufficient to support the current rulemaking effort, it has been included in the rulemaking effort because further evaluation is needed. It may be necessary to revise the rule to ensure that the appropriate aspects of the licensee's risk-informed categorization of SSCs is described in the UFSAR.

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#### 10 CFR 50.72, 10 CFR 50.73—Ongoing Rulemakings

10 CFR 50.72, and 10 CFR 50.73 are rules containing special treatment requirements. There are ongoing rulemaking activities dealing with these rules, although the ongoing rulemakings do not involve risk-informing the scope of special treatment. The staff will coordinate its special treatment rulemaking activities with the appropriate technical groups to ensure that these regulations are revised if it is practical to do so consistent

with ongoing efforts (i.e., such that it does not unduly delay the ongoing rulemaking). If it is not possible to take advantage of ongoing efforts, then the rule will be addressed in a manner similar to the other special treatment rules.

#### 10 CFR 50 Part 50 Appendix A GDC

In general, the staff has concluded that the GDC do not need to be revised to implement the risk-informed special treatment rulemaking. Most GDC simply require certain equipment to be provided in the facility design, or they require specific functional requirements to be part of the facility design.

However, some of the GDC of 10 CFR Part 50 Appendix A impose special treatment requirements on SSCs that are termed “important to safety.” The first five GDC are broadly applicable GDC that impose “special treatment” requirements. For GDC 1 through 4, unless some additional flexibility is incorporated into Appendix A (i.e., a change to the specific GDC, a change to the introduction section of Appendix A, or both), the staff currently concludes that these GDC would prohibit a licensee from removing the associated special treatment requirements from SSCs categorized as RISC-3 SSCs. For example, GDC 1 would continue to require QA treatment for SSCs that are “important to safety” even if the Appendix B special treatment requirements were risk-informed. In order to fully implement risk-informed alternative QA treatment, a licensee would need an exemption to GDC 1, unless that rule is modified.

Several GDC contain requirements that have been interpreted by the staff as requiring continued testing throughout the life of the facility. These GDC as currently interpreted may need revision. GDC 37, 40, 42, 43, 45, and 46 contain language that states “testing to assure,” which has been interpreted to mean that the subject GDC requires testing throughout the life of the facility for the specific SSCs of concern. An issue may arise where an SSC that was formerly “important to safety” may now be categorized as low safety significant (i.e., RISC-3 SSC). Even if the implementing regulation in Part 50 is revised to allow for the special treatment alternative approach, the GDC as currently written would still require testing unless the staff approves an exemption to that requirement, hence the need for revision.

#### 10 CFR Part 50 Appendix B

QA regulations contain special treatment requirements. These requirements are found in the following regulations:

- Requirements for a QA program: 10 CFR Part 50 Appendix A, GDC 1, and 10 CFR Part 50, Appendix B
- Requirements for administrative controls in Technical Specification: 10 CFR 50.36(c)(5) and 10 CFR 50.36(c)(6)
- Requirement to describe the QA: 10 CFR 50.34(b)(6)(ii)
- Requirements to control changes to the QA program description: 10 CFR 50.4(b)(7), 10 CFR 50.54(a), and 10 CFR 50.71(e)

This rulemaking will revise Appendix B (and associated QA requirements) to offer licensees an optional risk-informed approach to determine the scope of SSCs requiring QA controls, and the nature of those controls. Changes to Appendix B must also be considered for the potential impact on 10 CFR Part 71 and 10 CFR Part 72 which reference Appendix B.

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#### 10 CFR Part 50 Appendix J

Appendix J was screened into this rulemaking as a special treatment rule because it imposes testing requirements on certain SSCs that are not imposed on commercial-grade SSCs. The staff judges that risk informing this appendix may lead to less testing and therefore would reduce unnecessary regulatory burden on the licensees. Although the 1995 revision to Appendix J was characterized as risk-informed, the changes were not as extensive as those expected in the risk-informed Part 50 effort. The revision primarily decreased testing frequencies, whereas risk-informing the scope of SSCs that are subject to Appendix J testing would remove some components from testing (i.e., to the extent that defense-in-depth is maintained in accordance with the risk-informed evaluation process).

#### 10 CFR Part 21

Part 21 applies procurement and reporting requirements for SSCs delineated by the term “basic component,” which is also used in the Atomic Energy Act of 1954, as amended (AEA). The current definition of “basic component” includes design, analysis, and consulting services associated with SSCs. This structure needs to be preserved under the new risk-informed approach. Revising the scope of 10 CFR Part 21 would serve as a vehicle for risk-informing this rule. A potential discrepancy between Part 21 and the AEA could arise if the Part 21 definition of “basic component” is revised. This refers to the situation where the staff establishes through this rulemaking a set of SSCs that are safety-significant (i.e., RISC-1 and RISC-2 SSCs) which are different than the set of SSCs that are “basic components” (i.e., safety-related SSCs) and for which the AEA provides criminal penalties. Under such a scenario, it appears inappropriate to have a criminal penalty associated with an SSC that is determined to be of low safety significance. This complication extends to Part 19 which requires licensees to post NRC prepared notices addressing the requirements of the AEA and Part 21.

The staff will also evaluate whether the current Part 21 dedication process can be used to address RISC-2 SSCs that are brought into the scope of special treatment because of their safety significance. The current regulations, in general, do not recognize accidents that are beyond design basis. Therefore, bringing an SSC into the “scope” of a rule containing special treatment requirements is not meaningful because the rule typically will not apply, since the significance of these SSCs is derived from their function in events that are beyond the current design basis of the plant. The staff will assess whether the dedication process is a useful regulatory vehicle for addressing this situation.

#### 10 CFR Part 52

Although this regulation was screened into the rulemaking effort as a candidate rule that may require revision as part of risk-informed special treatment rulemaking effort, the

review performed to date indicates that this regulation does not require revision since it simply references other regulations (mostly Part 50) and does not impose any unique special treatment requirements.

#### 10 CFR Part 54

The staff has determined that changes to Part 54 are required, if license renewal is sought for a facility that has revised its licensing basis to incorporate the alternative risk-informed approach to special treatment. These changes to Part 54 are required because 10 CFR 54.4 explicitly defines the scope of the license renewal rule using the traditional deterministic approach. Therefore, conforming changes should be made to the scope of Part 54 to ensure consistency with Part 50.

The use of risk in establishing the scoping criteria within Part 54 was addressed by the Commission in 1995 when amending Part 54. The Commission determined that the scope of the license renewal rule be deterministic in nature, consistent with the licensing basis of currently operating plants, and that risk should not be used to establish license renewal scoping criteria. A change in the definition of safety-related in Part 54 would, therefore, involve a policy change by the Commission.

The goal of the license renewal program is to establish a stable, predictable, and efficient license renewal process. The staff believes that a revision of Part 54 at this time could have a significant effect on the stability and consistency of the processes being established for of preparation of license renewal applications, and for NRC staff review. Allowing a voluntary alternate scoping criteria will necessitate the development of an alternate renewal process, and create inconsistencies between license renewal applications and the staff's review at a time when the license renewal process is just being established. Guidance would need to be developed regarding format and content of a renewal application, staff review criteria, and inspection guidance for conducting onsite scoping inspections.

Because of the as-yet undefined effects of risk-informing Part 50, it is questionable whether any licensee which is considering license renewal would seek to implement a risk-informed Part 50 first because of the uncertainty created in the license renewal regulatory framework. Therefore, it seems unlikely that there will be any interaction between these efforts within the next few years. The difference between deterministic and risk-informed scopes could be large, given the large numbers of components classified as low safety-significant and non-risk significant at STP (i.e., which would be comparable to the staff's designation of RISC-3 and out of scope SSCs).

As discussed in the section addressing §50.65, changes to the maintenance rule scope need to be considered for their potential impact on the underlying basis for the Part 54 rule. Specifically, the license renewal rule, as revised in 1995, narrowed the scope of SSCs subject to aging review in large measure due to the implementation of 10 CFR 50.65. If the staff further reduces the scope of SSCs subject to §50.65 (as a result of this rulemaking), then the staff needs to assess whether this impacts the license renewal basis for eliminating certain components from the scope of Part 54. This assessment needs to be incorporated into the statement of considerations accompanying the rulemaking or make the appropriate modifications to Part 54. The staff would need to minimize any confusion and uncertainty that could be introduced into

the renewal process due to the effort to risk-inform Part 50 special treatment requirements.

10 CFR Part 100, Appendix A and 10 CFR Part 50, Appendix S

The seismic design requirements are special treatment requirements. These requirements, for current operating reactors, are incorporated into Appendix A to Part 100, which includes both seismological and geological siting and engineering design criteria. For new plant applications, the seismic design requirements (as a result of the recent rulemaking published on January 10, 1997) are set forth in Appendix S to Part 50. Appendix A to 10 CFR Part 100, Section VI, identifies which SSCs must meet the seismic design criteria utilizing the “safety-related” definition. Appendix S to Part 50 implements GDC 2 to require that SSCs “important to safety” be capable of withstanding the effects of natural phenomena such as earthquakes. The scope of both regulations can be made risk-informed through the current rulemaking.

4.4 Rulemaking Implementation/Phased Implementation of the Rulemaking

Two basic approaches for implementing this rulemaking have been identified: (1) a comprehensive “all regulations at once” approach or (2) a phased approach. It appears that a phased approach to implementation of the rulemaking is more feasible. Risk-informing the scope of the entire body of “special treatment” regulations is a large and complex task. The scope and structure of the current special treatment regulations are not consistent. Revision of these regulations to incorporate an alternative risk-informed scope (or to make reference to an alternate rule such as 10 CFR 50.69) appears to require the staff to examine each regulation and could involve somewhat unique approaches for different rules. The staff needs to gain some understanding of the impact of the risk-informed scope change on each special treatment regulation (i.e., re-categorization of SSCs made under the new appendix and the resultant change in scope of special treatment) to support the staff’s finding that reasonable assurance of no undue risk to the health and safety of the public is maintained following the rulemaking. Given the complexity of some of the regulations, from both a regulatory structure perspective in which it may be necessary for the staff to incorporate unique considerations into its new rule, and from a technical perspective where it may be difficult to assess the impact of less assurance of functional requirements for SSCs, it may make sense from a resource standpoint to implement this rulemaking in a phased manner. This approach would enable the staff to go forward with portions of the rulemaking in which there is the greatest potential for benefits in terms of the agency’s performance goals.

The alternative is to make the entire scope of the special treatment regulations risk-informed at one time, requiring the staff to assess the impact of the rulemaking on all of the special treatment rules of Parts 21, 50, 54, and 100. If feasible, this approach is preferred because it enables completion of the entire rulemaking on a more expedited schedule. However, it is recognized that this approach has a greater potential for delay in issuance of the final rulemaking (if complications surface on specific rules), and to have a greater potential for errors to occur that then require a subsequent rulemaking to fix.

Notwithstanding the issues discussed above, it remains the staff’s objective to complete this rulemaking for all the identified rules within the schedule discussed in Section 17.

## 5.0 Alternatives to Rulemaking

Alternative approaches that are intended to accomplish the objective of risk-informing special treatment requirements and that do not involve rulemaking are limited two ways:

1. At best, such alternatives can enable licensees to “grade” the special treatment. However, this requires that the governing regulation incorporates the flexibility to allow for grading. One such regulation is 10 CFR Part 50, Appendix B. More importantly, without regulatory changes, licensees may not be able to remove SSCs from special treatment requirements even when a risk-informed evaluation concludes that the SSCs are not important contributors to plant safety.
2. To remove SSCs from special treatment without a change to the governing regulations requires licensees to submit 10 CFR 50.12 exemption requests for staff review and approval. The review and approval of exemption requests can be resource intensive for both the staff and the industry. If the staff can approve such exemptions, and there is significant industry interest in risk-informing special treatment requirements, the more appropriate approach and the least resource-intensive approach in the long term is rulemaking.

On the basis of this information, the staff does not believe that there are alternative approaches as effective as rulemaking provided there is a reasonable level of industry interest in pursuing this risk-informed alternative. Otherwise, review and approval of a limited number of exemptions appears to be the more efficient approach.

## 6.0 Advance Notice of Proposed Rulemaking (ANPR)

The ANPR (Attachment 2 to the SECY paper that forwards this rulemaking plan to the Commission) will announce to the public the staff’s intentions to revise the governing regulations that impose special treatment requirements on SSCs in nuclear power plants. The ANPR requests public comment on: (1) the alternative new terminology and proposed criteria (the proposed Appendix T); (2) the staff’s proposed approach for modifying the special treatment requirements; (3) the staff’s expectations with respect to conduct of the pilot program; (4) the staff’s proposed activities and schedules for completion; and (5) certain policy and implementation issues. The staff believes that the ANPR provides the following benefits:

- It is consistent with the strategy in the mission statement to use processes that maximize the opportunity for public participation. The ANPR does not preclude the use of meetings and workshops, both of which are planned. The effectiveness of the meetings and workshops may be improved by providing preliminary staff positions in the ANPR.
- As a formal request for comments, the ANPR will receive high visibility within the industry and from other external stakeholders and establishes a timetable by which comments must be received. The schedule assumes that this exchange of information will reduce the time required to address comments on the

proposed rulemaking because many issues may be resolved on the basis of public comments received on the ANPR.

- By describing the contemplated new terminology and acceptance criteria for the proposed Appendix T, the ANPR would facilitate early implementation of the categorization pilot program and may encourage additional licensees to participate in this program.
- It provides an early basis for evaluating the draft Nuclear Energy Institute (NEI) categorization guideline, which is expected to be submitted for staff review in December 1999.
- The ANPR does not commit the NRC to implement the contemplated rulemaking; it is only a mechanism for receiving stakeholder input. In the event the staff determined that this rulemaking was not feasible, the staff could discontinue its efforts and publish a document in the *Federal Register* withdrawing the ANPR.

## 7.0 Impacts on Licensees

Licensees that wish to implement a risk-informed approach to special treatment will, at a minimum, incur the following impacts:

- The licensee will need to address PRA completeness and quality issues. At a minimum licensees will need to have a PRA that reflects the current plant configuration, is sufficiently complete for the intended application, meets some quality standard (this is not yet defined and could range from an “industry peer review” to requiring the PRA to be reviewed by the staff), and is kept current. Depending on the state of the licensee’s PRA, this activity could involve a significant commitment in resources.
- The licensee will need to develop the infrastructure to support the risk-informed evaluation of SSCs to determine safety significance. At a minimum, this task will probably involve the development of procedures governing the risk-informed SSC categorization process and will involve the establishment of a risk-informed expert evaluation team that systematically evaluates and documents the re-categorization of SSCs. It is also likely that licensees will need to revise the training program, as well as other affected plant procedures .
- The licensee will need to expend significant resources in evaluating the SSCs to determine safety significance, and thus determine the need for special treatment. When the licensee completes this evaluation of SSCs, there should not be a significant additional impact on resources to complete the implementation for different rules. The special treatment rules would continue to apply to RISC-1 SSCs (i.e., not all RISC-1 SSCs have §50.49 requirements, only those that are in harsh environments). RISC-2 SSCs that are scoped into regulatory treatment would have to meet the requirements of §50.69.

- The licensee will need to have a performance monitoring program as part of the risk-informed regulatory alternative. This will be a continuing effort and represents an additional resource impact.

This description of impacts assumes that the rulemaking approach described in Section 4.1 is implemented, and that as a result there is not a need for the staff to review a licensee submittal prior to implementation (i.e., the staff would regulate the risk-informed alternatives principally through a risk-informed inspection consistent with the new regulatory oversight process). If this assumption is not valid and the staff needs to review a submittal, there is a substantial additional impact, including significant cost uncertainty, for licensees that wish to pursue this risk-informed approach, given the potential for such staff reviews to be lengthy. As previously mentioned, if such a regulatory framework is developed, this additional impact could be sufficient to discourage many licensees from pursuing this regulatory alternative.

## 8.0 Benefits

The staff currently concludes that this proposed regulatory approach can be accomplished while achieving the staff's most important objective: maintaining safety. This rulemaking will allow licensees to relax the special treatment requirements only for those SSCs that do not make more than a minimal contribution to plant safety (i.e., RISC-3 SSCs). It is not intended that this rulemaking allow RISC-3 SSCs to be removed from the facility, or for the functional requirements for these SSCs to be defeated (i.e., functional requirements are to be maintained, albeit at a reduced level of assurance). The staff expects that some SSCs will be "scoped" into regulatory treatment (i.e., RISC-2 SSCs), and receive enhanced attention thereby increasing the level of assurance that such previous "nonsafety-related" SSCs will be perform as expected. This element of the rulemaking contributes to enhancing safety. Importantly, the regulatory approach will include a "performance monitoring" element, such that if the reliability of equipment degrades substantially (to the extent that it is not reasonable to expect the SSCs can meet functional requirements, or that the PRA assumptions that supported the SSC categorization are no longer valid), or if operational experience indicates that an SSC may be more important to plant safety than previously thought, consideration can be given to revising the SSCs categorization and associated treatment (recognizing that there are limitations associated with some aspects of performance monitoring as discussed in Section 4.1). Finally, this rulemaking effort should enable both the NRC and licensee to focus resources on issues having more importance to plant safety which contributes to enhancing plant safety.

While maintaining safety, the staff believes the following benefits would be realized as a result of this rulemaking.

### 8.1 Reduction Unnecessary Regulatory Burden

The reduction in unnecessary regulatory burden associated with implementing a risk-informed approach to special treatment will vary considerably with each licensee and are dependent on (1) the licensee's current plant programs (the more extensive "special treatment" programs are, the more potential benefit), (2) the age of the plant (newer plants tend to be larger, more complex, have more SSCs with imposed special treatment requirements, and have a longer remaining lifetime for pay back from burden relief, all of which add to a greater potential

benefit), (3) the number of rules that the licensee implements (the more rules implemented, the more potential burden relief) and (4) the amount of unnecessary regulatory burden reduction that licensees could realize is a direct function of the staff's requirements governing the risk-informed evaluation process. The more "restrictive" these requirements are in terms of classifying SSCs as "safety significant" (i.e., the more the process forces SSCs into the RISC-1 and RISC-2 boxes), and in being costly to implement, the less potential benefit that licensees can ultimately realize in terms of unnecessary regulatory burden reduction.

The staff will request industry input on the issue of unnecessary regulatory burden reduction as part of the ANPR. One indication of the potential savings that could be achieved through a risk-informed special treatment approach was provided by the licensee for STP during a presentation to the Advisory Committee on Reactor Safeguards in July 1999. The STP licensee estimated that full implementation of its exemption request (which involves relief from §50.49; §50.34 and 10 CFR Part 100; §50.65; 10 CFR Part 50 Appendix B; 10 CFR Part 50 Appendix J; and 10 CFR Part 21) would result in several million dollars in savings a year at STP Units 1 and 2. This estimate is probably an upper bound on the potential savings that can be realized by a given licensee (given STP's unique three-train design, which results in a larger number of SSCs whose special treatment requirements can be relaxed).

### 8.2 Regulatory Efficiency and Effectiveness

This regulatory approach is judged to enhance the NRC staff's efficiency and effectiveness by permitting a better safety focus. Fewer regulatory resources would be focused on special treatment issues for equipment that does not have more than a minimal contribution to plant safety. As a result, available resources can be focused on safety issues of greater importance. Licensees should see a similar benefit because they would not be utilizing resources to respond to regulatory action on such equipment and could, therefore, better focus resources in areas that are more important to plant safety.

### 8.3 Public Confidence

A key element of this rulemaking effort is to keep the public informed and invite its participation. Accordingly, to date the staff has held several meetings open to public participation to discuss this regulatory initiative. In addition to the opportunity the public will have to comment on the proposed rulemaking package, the staff is planning to issue an ANPR to invite public comments on the staff's rulemaking approach. The staff is also considering development of an Internet Web site as another vehicle to disseminate information to the public in a timely manner. Ultimately, if the staff is successful in this regulatory approach, which specifically means that safety is maintained while the costs of operating and maintaining commercial nuclear reactors is reduced, the public will be the chief beneficiary.

## **9.0 OGC Legal Analysis**

The proposed rulemaking would provide nuclear power plant licensees a voluntary alternative to complying with selected deterministic requirements in the Commission's regulations. These regulations currently set forth requirements with respect to design, quality assurance, construction and operation ("special treatment requirements") which are applicable to structures, systems, and components (SSCs) whose characteristics are defined in the selected

regulations<sup>6</sup>. These SSCs are denoted as “safety-related” and “important-to-safety.” The proposed rulemaking would permit licensees to redefine the scope of SSCs that are subject to the special treatment requirements, using risk-informed criteria as set forth in the amended rules. The staff expects that a significant number of SSCs currently deemed by licensees to be either “safety-related” or “important-to-safety” and therefore currently subject to special treatment requirements (RISC-3 SSCs) would not be “scoped in” under the alternative risk-informed criteria. Conversely, the staff expects that there would be a small number of SSCs currently not defined as “safety-related” or “important-to-safety,” but would be “scoped in” under the alternative risk-informed criteria and therefore would be subject to special treatment requirements (RISC-2 SSCs).

OGC has not identified any bases for legal objection to the contemplated rulemaking. The rulemaking provides an alternative method for assuring that the requirements of the Atomic Energy Act of 1954, as amended (AEA) are complied with, that there is reasonable assurance of adequate protection to public health and safety, that the operation of a nuclear power plant will not impose an undue risk to public health and safety, and that appropriate levels of protection are provided to minimize danger to life and property. Accordingly, OGC believes that Sections 103, 104, 161, 182 and 183 of the AEA provide the Commission with sufficient authority to promulgate the contemplated rule.

## **10.0 Category of Rulemaking**

The proposed rulemaking would provide nuclear power plant licensees a voluntary alternative to complying with selected deterministic requirements in the Commission’s regulations. This risk-informed regulatory alternative is judged by the staff to be a burden relief that would also minimize the need for exemptions.

## **11.0 Backfit Analysis**

The Office of General Council has concluded (based on the available information) that the rulemaking will not constitute a backfit as defined in §50.109(a)(1). This is because each of the rules being modified in this rulemaking would provide a voluntary alternative to licensees who wish to utilize risk-informed methods for selecting the SSCs that are subject to the “special treatment requirements.” Licensees who choose not to use risk-informed methods to select the applicable set of SSCs subject to the “special treatment requirements” can continue to rely upon their existing designations of “safety-related” and “important to safety” SSCs.

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<sup>6</sup>“Safety-related” structures, systems, and components (SSCs) are defined in 10 CFR 50.2. “Important-to-safety” SSCs are described in the introduction of 10 CFR Part 50, Appendix A.

## **12.0 Supporting Documents**

Currently, the staff intends to review an implementing document that the Nuclear Energy Institute (NEI) has indicated will be submitted by the end of 1999. The objective is to reach agreement with NEI concerning the implementation of risk-informed special treatment and be able to endorse the NEI guidance in a regulatory guide. Consequently, the staff does not currently plan to develop draft regulatory guidance to implement this rulemaking. There will be some staff effort required to update, as appropriate, current regulatory guides that address the current SSC categorization approach. Currently, the staff believes this task will be limited to revising the subject regulatory guides to indicate that another risk-informed alternative exists with the appropriate reference.

## **13.0 Issuance of the Rule by the EDO**

To date, the staff has communicated its recommendations regarding this regulatory effort to the Commission (SECY-98-300) and has received direction from the Commission in return. The staff concludes that this level of approval will continue to be needed for this rulemaking effort. Therefore, this rule will not be issued by the EDO.

## **14.0 Interoffice Management Steering Group**

Two interoffice Committees (containing members of NRR, OGC, RES, and Region II) are involved in advising the staff concerning the development of this rulemaking as discussed below.

### 14.1 Risk-Informed Licensing Panel

The Risk-Informed Licensing Panel (RILP) provides management oversight and direction, resolves conflicts on technical issues, and ensures that proper interaction with other offices is maintained. The members of the RILP are the NRR and RES Division Directors, and a representative from OGC and Region II. The NRR/DSSA Division Director is the RILP chairman.

### 14.2 PRA Steering Committee

The PRA steering committee provides oversight and addresses policy issues. The PRA steering committee members are the office directors and senior OGC management. The Director of RES is the PRA steering committee chairman.

## **15.0 Participation by the Public and the Industry**

There is significant public and industry interest in this rulemaking as evidenced in the public meetings held to date to discuss the staff's and the industry's efforts on this matter. The staff is considering the establishment of an Internet Web site for release of information in a more timely and convenient manner to the public to further facilitate public participation.

## 16.0 Organization

Figure 3 depicts the staff's organization for this rulemaking effort. This figure shows the NRR organization for the Option 2 rulemaking .

The members of the core team are Tom Bergman, Tim Reed, Mohammed Shuaibi, Tony Markley, Raj Auluck, Mike Cheok, Bob Palla, Goutam Bagchi, Pete Balmain, and Joe Williams.

Individuals who are providing support are S. Magruder, R. Young, S. Dinsmore, T. Eaton, F. Ashe, J. Knox, D. Fischer, E. McKenna, S. Ali, S. Hoffman, N. Gilles, K. Karwoski, and J. Pulsipher.

RES interface: M. Cunningham, M. Drouin, and R. Woods

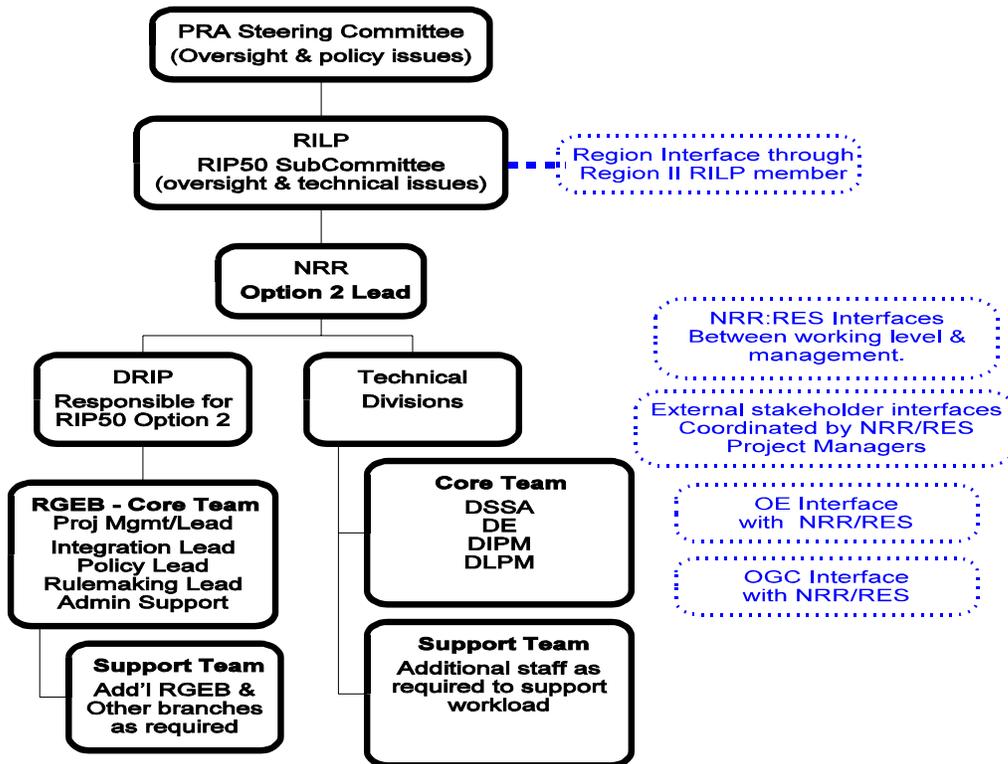
NMSS interface: S. Coplan

OGC interface: G. Mizuno and J. Moore

OE interface: T. Reis

Regional interface: B. Mallet and V. McCree

Figure 3: RIP50 Option 2 Organization



## 17.0 Schedule/Resources

The staff's proposed schedule is described below and is illustrated in Figure 4, "PERT Chart for Proposed Schedule" Figure 5, "Gantt Chart for Proposed Schedule." Explanatory notes for these figures are provided in Figure 6. The proposed schedule includes six major efforts: (1) STP Exemption, (2) ANPR, (3) Categorization Pilot Program, (4) NEI Guideline Review, (5) Proposed Rulemaking, and (6) Final Rulemaking. Some of these efforts are currently underway. The staff estimates that a final rulemaking can be provided to the Commission for approval in October 2001. The total resources for this effort are expected to be 47 full-time (FTE) equivalent positions and \$3.0 million in technical assistance.

1. STP Exemption: This effort ensures that the results of the exemption request review are factored into the proposed rulemaking package such that the two efforts are consistent. If the exemptions can be granted, it will demonstrate that a risk-informed approach can be implemented, at least as far as the STP approach is concerned. STP is not part of the categorization pilot program because it is too far ahead in implementation to effectively test the proposed Appendix T categorization method. In addition, some of the findings will be similar between the STP exemption and the basis for modifying the rules in the rulemaking.

The STP exemption is currently being reviewed, and the effort is currently projected to be completed in June 2000 and is expected to require about 3 FTE. The tasks included in this effort are:

- a. STP Exemption Request (Task STP.1): This task is a milestone (i.e., no associated NRC effort) reflecting that the STP exemption request was received on July 13, 1999.
- b. Staff Evaluation of STP Exemptions (Task STP.2): This task includes the staff effort to review the STP exemptions and to resolve all technical and legal issues. It is estimated to require 50 weeks to complete. To ensure consistency between the exemptions and the proposed rulemaking, this task must be completed prior to completing the proposed rulemaking task (Task PRM.2). This task is critical path work, hence any delays could delay the rulemaking.
- c. Issuance of STP Exemptions (Task STP.3): This task is a milestone to indicate completion of the STP exemption effort with respect to the rulemaking.

2. ANPR: This effort includes the issuance of the ANPR included as Attachment 2 to this Commission paper through the evaluation of public comments. The purposes of the ANPR include: (1) a description of the staff's proposed rulemaking approach, including draft regulatory text for the proposed Appendix T, and (2) early solicitation of public comments concerning rules considered for inclusion in the rulemaking effort, alternative regulatory approaches for accomplishing the same objectives, and issues associated with implementation of the rulemaking effort. The resolution of public comments received on the ANPR is expected to facilitate development of the proposed rulemaking package.

The ANPR has been developed and is scheduled to be issued in December 1999. The ANPR effort is scheduled to be complete in May 2000 and is estimated to require about 2 FTE. In the

event cumulative delays of the tasks in this effort exceed 5 weeks, the ANPR effort could become critical path work and impact the schedule for the final rulemaking.

- a. Negative Consent to Issue ANPR (Task ANPR.1): this task is a milestone indicating initiation of the ANPR effort. It assumes that the Commission will provide its negative consent to proceed with publishing of the ANPR (mid-November 1999).
  - b. Publication of ANPR (Task ANPR.2): This task includes staff efforts to address Commission comments on the ANPR and have it published in the *Federal Register*. It is estimated to require 4 weeks to complete.
  - c. ANPR Comment Period (Task ANPR.3): This task reflects a 75-day comment period for the ANPR, and is expected to be completed in February 2000.
  - d. Staff Evaluation of ANPR Comments (Task ANPR.4): This task provides 13 weeks for the staff to review and incorporate public comments received on the ANPR, as appropriate, and is expected to be completed in May 2000.
3. Categorization Pilot Program: This effort includes the implementation and evaluation of the pilot plant program that will demonstrate that the risk-informed categorization of SSCs utilizing the proposed Appendix T requirements and proposed NEI guideline can be performed in an acceptable manner. Included in this effort are the review and issuance of the exemptions for the pilot plants participating in this program.

This effort is underway and is expected to be completed (i.e., exemptions issued) in July 2001 and require about 9 FTE. Although not currently critical path, delays of more than 2 weeks in most tasks (exceptions noted below) would make them critical path and potentially delay the schedule.

- a. Request for Pilot Plants (Task CPP.1): This task is a milestone indicating that the staff has requested that the pilot plants for this effort be identified. This request was in the form of a letter to NEI dated October 19, 1999.
- b. Licensee Commitments to Pilot (Task CPP.2): This task is ongoing and assumes 13 weeks for licensees to commit to participating in the categorization pilot program. The appropriateness of this duration was discussed with NEI, which agreed it is reasonable. This task is expected to be completed in December 1999.
- c. Staff Acceptance of Pilot Plants (Task CPP.3): This task provides 4 weeks for the staff to evaluate the proposals for pilot plant participation and determine if any limitations or changes need to be made to the program. This task is estimated to begin in December 1999 and to be completed in January 2000.
- d. Pilot Plant Categorization Effort (Task CPP.4): This task assumes that licensees will need up to 52 weeks to complete the categorization of a number of systems to be included in their pilot effort. On the basis of discussions with NEI and some possible pilot program participants, this assumption appears reasonable, although the actual time required will vary among licensees. It also assumes that this task cannot begin until the

ANPR is published so that licensees can review the staff's proposed Appendix T. This task is estimated to begin in January 2000 and to be completed in January 2001.

- e. Submittal of Pilot Plant Exemptions (Task CPP.5): This task is a milestone to indicate that licensees will submit exemptions as they complete their categorization effort. It assumes that licensees will prepare the exemptions in parallel with the categorization. Since review and approval of the exemptions is not necessary to proceed with rulemaking, delays in this task would not affect the rulemaking schedule. This milestone should occur in January 2001.
- f. Staff Evaluation of Pilot Plant Categorization (Task CPP.6): This task provides the staff 52 weeks to evaluate the acceptability of pilot plant implementation of Appendix T and the associated NEI guideline. It can be accomplished in parallel with the categorization effort (Task CPP.4), but it is assumed that 26 weeks will be necessary for the staff to complete its review after the categorization efforts are complete. This task is expected to begin in July 2000 and to be completed in July 2001.
- g. Staff Review of Pilot Exemptions (Task CPP.7): This task assumes that the staff can complete its review in 13 weeks, and that this review can be performed in parallel with the staff's review of the categorization effort (Task CPP.6) but cannot be completed before completion of that task. Task CPP.7 also cannot begin until the exemptions are submitted. Since completion of this task is not necessary to proceed with rulemaking, delays in completion of this task will not affect the schedule. This task is expected to begin in April 2001 and to be completed in July 2001.
- h. Staff Issuance of Exemptions (Task CPP.8): This task is a milestone indicating that the categorization pilot program effort is expected to occur in July 2001.

4. NEI Guideline Review: This effort is to review an NEI guideline on the categorization of SSCs in a manner that will comply with the proposed Appendix T. This effort will factor in the experience of the categorization pilot program, which will utilize the NEI guideline. It also involves the development of a draft regulatory guide that would endorse the guideline and be part of the proposed rulemaking package.

This effort is on the critical path and therefore any delays may delay the entire schedule. NEI has already begun development of its guideline. This effort is projected for completion in July 2001, and is estimated to require about 3 FTE.

- a. Development of Draft NEI Categorization Guideline (Task NEI.1): This task is a milestone to indicate that NEI has already begun development of this guideline.
- b. NEI Submission of Draft to the Staff (Task NEI.2): This task is a milestone to indicate that NEI expects to submit the guideline at the end of December 1999. This milestone is on the critical path.
- c. Staff Review of NEI Draft Guideline (Task NEI.3): This task includes the staff effort to review, resolve comments on the guideline, and prepare a draft regulatory guide that proposes to endorse the NEI guideline. It is estimated to begin in December 1999 and be completed in June 2000. This is a critical path task.

- d. Categorization Approach Deemed Acceptable (Task NEI.4): This task is a milestone to capture the integration of the completion of the staff review of the guideline (Task NEI.3), Commission approval to publish the proposed rulemaking for comment (Task PRM.3), and completion of the staff's evaluation of the categorization pilot program (Task CPP.6). This milestone is estimated to occur in July 2001.

5. Proposed Rulemaking: This effort includes the development and issuance of the proposed rulemaking package for public comment. This effort includes resolution of all technical and legal issues and development of the associated regulatory guidance necessary to implement the proposed §50.69, including modifications to existing regulatory guidance for rules included in the rulemaking (except for the regulatory guide for Appendix T and the NEI guideline, which is included in the NEI guideline review effort). Since the proposed rulemaking may include changes in information collection requirements, the proposed rulemaking must also be submitted to the Office of Management and Budget at the same time the rule is forwarded to the Federal Register for publication.

This effort is on the critical path, and therefore any delays may delay the entire schedule. It is expected to begin in December 1999, and to be completed in December 2000, with a proposed rule to be submitted to the Commission in September 2000. Approximately 14 FTE and \$1.85 million in technical assistance are estimated for this effort.

- a. Initiation of Proposed Rulemaking (Task PRM.1): This task is a milestone indicating that the SRM for this Commission paper has been issued. It is estimated to occur in mid-December 1999; a delay in beginning this effort of more than 3 weeks (i.e., into January 2000) could delay the entire schedule.
- b. Preparation of Proposed Rulemaking (Task PRM.2): This task includes staff effort to resolve technical and legal issues associated with the rulemaking, and to develop proposed rule language, regulatory analyses, and associated regulatory guidance. The output of this task is a proposed rulemaking package submitted for Commission approval. In order to complete this task, the staff must have resolved technical and legal issues in common with the STP Exemption (Task STP.2), identified the scope of the categorization pilot program (Task CPP.3), and completed the review (and preparation of draft regulatory guide) of the NEI draft guideline (Task NEI.3). Task PRM.2 is a critical path task, and is estimated to begin in December 1999 and be completed in September 2000.
- c. Issuance of the SRM by the Commission for the Proposed Rulemaking (Task PRM.3): This task assumes that an SRM on the proposed rulemaking can be issued in 6 weeks. It is estimated to begin in September 2000 and be completed in November 2000. This is a critical path task.
- d. Publication of the Proposed Rulemaking for Comment (Task PRM.4): This task includes the staff effort to resolve Commission comments on the proposed rulemaking and to publish it in the *Federal Register*. It also includes the effort to submit the proposed rulemaking to the Office of Management and Budget as a result of any changes to information collection requirements. It assumes this task can be completed in 4 weeks, which is only reasonable if the staff prepares a proposed rulemaking package that does

not need substantive modification. This task is projected to begin in November 2000 and be completed in December 2000. This is a critical path task.

6. Final Rulemaking: This effort includes the development and issuance of the final rulemaking package, including resolution of public comments on the proposed rulemaking. To facilitate implementation, the final rulemaking should include final regulatory guidance as necessary to allow implementation of the rulemaking, in particular, regulatory guidance associated with §50.69, and Appendix T and the final NEI guideline.

This effort is estimated to begin in December 2000, have a final rulemaking package to the Commission in October 2001, and a final rule published in March 2002. This effort is estimated to require 14 FTE and \$1.15 million in technical assistance. All tasks in this effort are on the critical path and any delays could delay issuance of the final rulemaking.

- a. Initiation of Final Rulemaking (Task FRM.1): This task is a milestone to indicate completion of the proposed rulemaking effort and initiation of the final rulemaking effort. It is projected to occur in December 2000.
- b. Comment Period (Task FRM.2): This task allows for a 75-day public comment period. It is estimated to begin in December 2000 and be completed in February 2001.
- c. Evaluation of Public Comments (Task FRM.3): This task includes staff effort to resolve public comments, as appropriate, and modify the final rulemaking and associated guidance documents. Because the ANPR is expected to result in early identification of issues and reduction of the number raised as a result of the proposed rulemaking, it is assumed that only 13 weeks are necessary evaluate public comment at this point. This task is estimated to begin in February 2001 and be completed in May 2001.
- d. Endorsement of NEI Guideline in Final Regulatory Guide (Task FRM.4): This task includes staff effort to resolve staff concerns and public comments received on the NEI guideline. It assumes that 26 weeks are necessary for this task. It can be accomplished in parallel with the evaluation of public comments (Task FRM.3), although it is assumed that 13 weeks will be needed after completion of Task FRM.3 to conduct public meetings to discuss comments and achieve resolution. This task is projected to begin in February 2001 and be completed in August 2001.
- e. Preparation of Final Rulemaking (Task FRM.5): This task includes staff effort to refine the rulemaking package and associated regulatory guidance. It assumes that this effort will begin after public comments are evaluated (Task FRM.3) and partly in parallel with endorsement of the NEI guideline (Task FRM.4). The result of this task is a final rulemaking package for Commission approval. The task is estimated to require 26 weeks, beginning in April 2001 and ending in October 2001.
- f. Issuance of the SRM by the Commission on the Final Rulemaking (Task FRM.6): This task assumes that an SRM on the final rulemaking can be issued in 6 weeks. It is estimated to begin in October 2001 and be completed in December 2001.
- g. Publication of the Final Rule (Task FRM.7): This task includes staff effort to resolve Commission comments in the SRM and additional process considerations, such as an OMB clearance. It is assumed to require 13 weeks, and is projected to begin in December 2001 and be completed in March 2002. Upon completion of this task

licensees may begin implementation of the revised rules, and the rulemaking effort would be complete.

In addition to the these efforts, the staff will also conduct public meetings and workshops, and briefings of the Committee to Review Generic Requirements, the Advisory Committee on Reactor Safeguards, and the Commission. These interactions are estimated at 2 FTE.

Figure 4: PERT Chart for Proposed Schedule

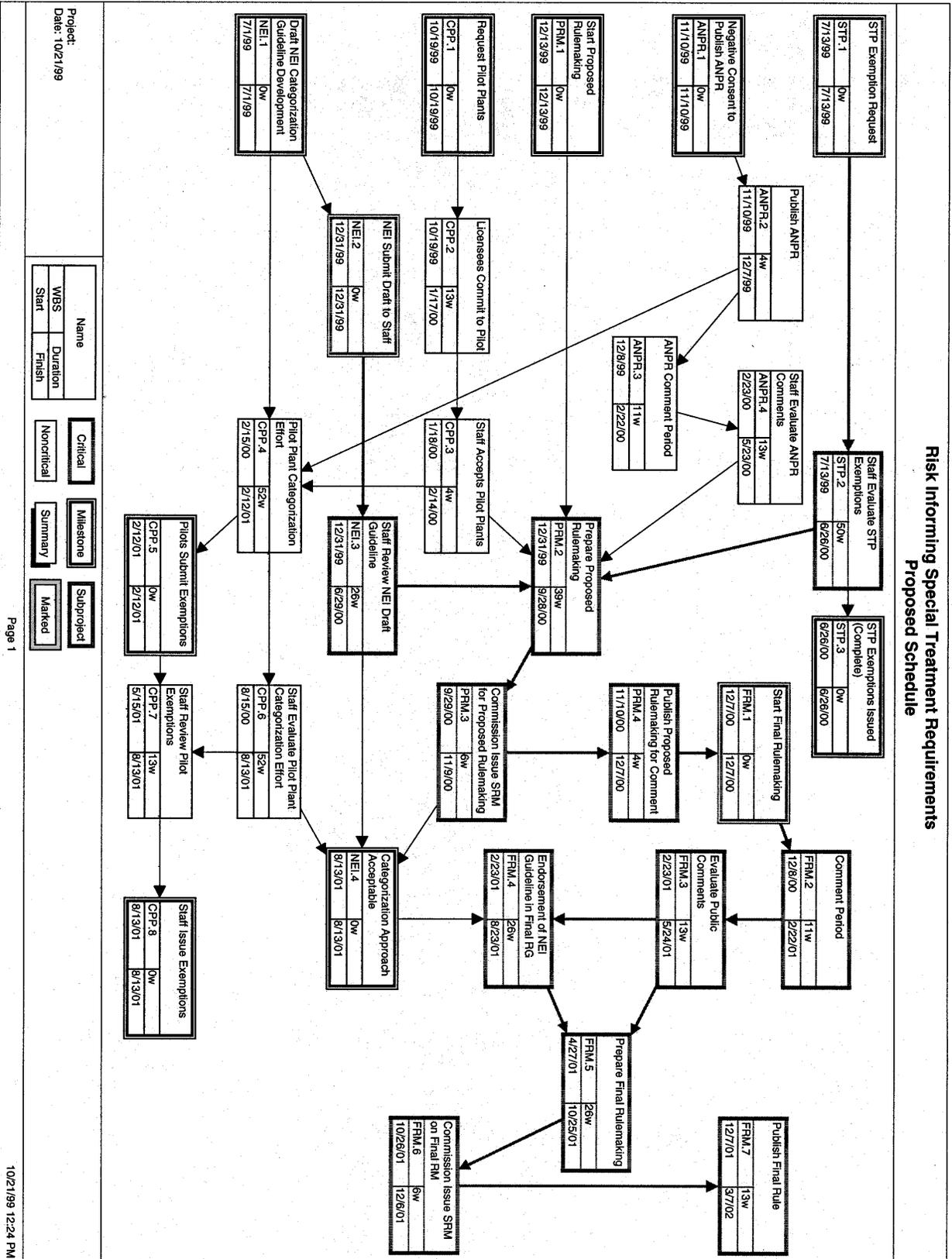


Figure 5: Gantt Chart for Proposed Schedule

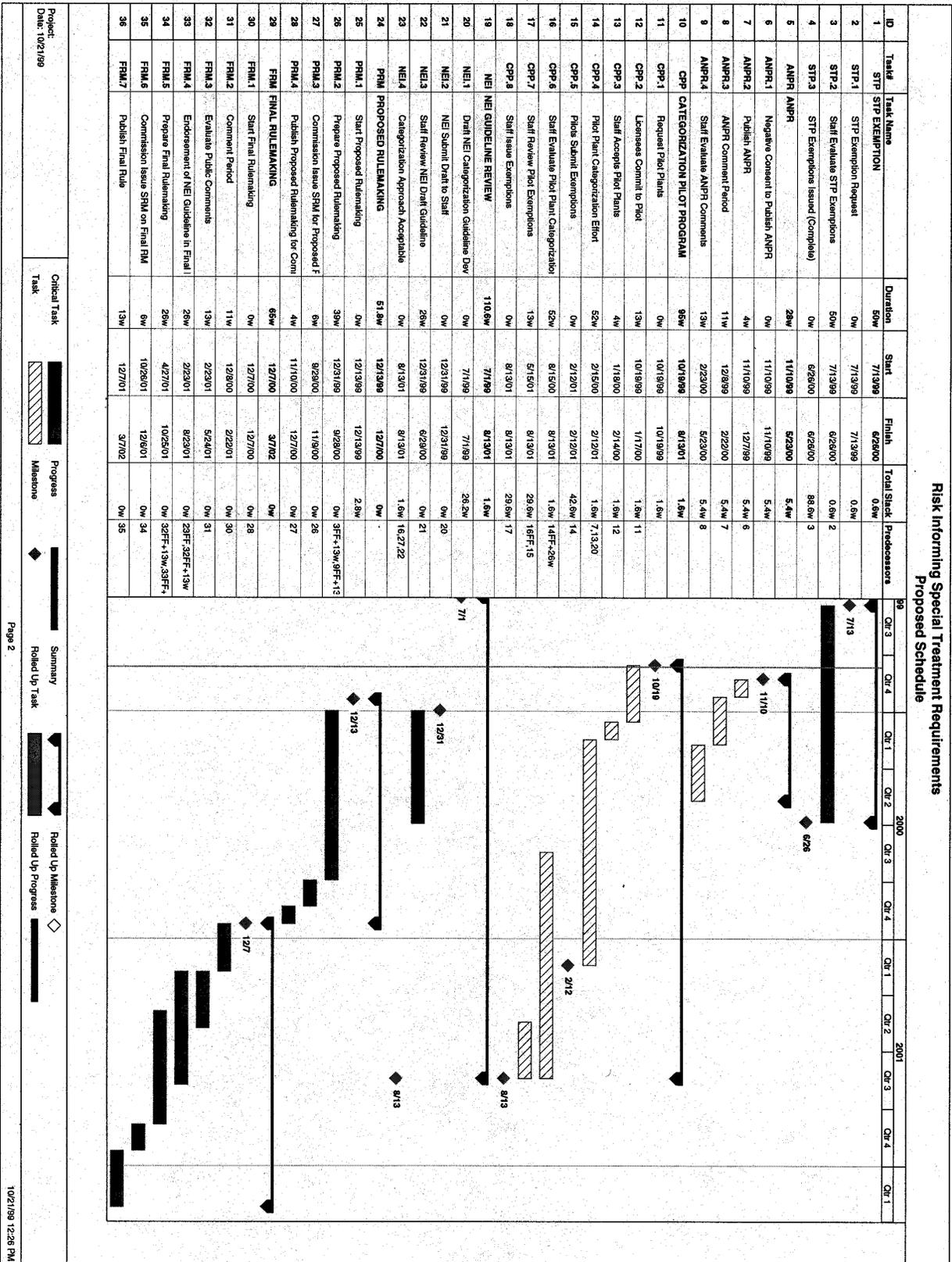


Figure 6: PERT and Gantt Chart Notes

<b>Risk Informing Special Treatment Requirements Proposed Schedule</b>	
2	STP Exemption Request
TASK STP_1	Milestone to indicate start of STP Exemption effort.
3	Staff Evaluate STP Exemptions
TASK STP_2	Staff review effort has already begun.
4	STP Exemptions Issued (Complete)
TASK STP_3	Time for this task is consistent with projected review schedule.
5	STP Exemptions Issued (Complete)
6	Milestone indicating completion of STP Exemption effort.
7	Consideration needs to be given as to extent of followup effort. That is, should STP be required to allow staff to test any inspection guidance as a condition of being a pilot plant (especially since the staff is proposing to waive fees).
8	Negative Consent to Publish ANPR
TASK ANPR_1	Assumes that effort to publish ANPR can begin within 10 days of paper issue date. If ANPR cannot be issued by negative consent, after about 5.5 weeks this would become a critical path task (9/14/1999 schedule).
9	Publish ANPR
TASK ANPR_2	Provided Commission does not require substantive changes to the ANPR, the staff should be able to publish within 4 weeks.
10	Assumption is that ANPR includes sufficient detail on categorization method that NEI & Licensees can develop Guideline and implement with high confidence that those efforts will not be undercut at proposed rulemaking phase.
11	ANPR Comment Period
TASK ANPR_3	Assumes a 75 day comment period.
12	Staff Evaluate ANPR Comments
TASK ANPR_4	Assumes the staff will need about a quarter of a year (13weeks) to review public comments.
13	Request Pilot Plants
TASK CPP_1	Milestone to indicate that the staff is likely to have initiated efforts to identify pilots in advance of the RM Plan SECY (assumes letter to NEI on 10/19/1999).
14	Licensees Commit to Pilot
TASK CPP_2	Licensees should become aware of staff expectations for pilot plants when the staff sends its letter to NEI. Appropriateness of this assumption (establishing link to task CPP_1) is based on discussions with NEI.
15	Time estimate for task is based on complexity of licensee decision (cost-benefit analysis).
16	Staff Accepts Pilot Plants
TASK CPP_3	Should be sufficient time for the staff to work with NEI to determine the final scope of the pilot plant in terms of number of plants and rules.
17	Pilot Plant Categorization Effort
TASK CPP_4	Assumes that plants cannot begin categorization effort until they see the language in the ANPR. Assumes that pilots will not begin categorization until staff confirms they are a pilot.
18	Pilots Submit Exemptions
TASK CPP_5	A milestone based on the assumption that Pilot Plants will be develop exemptions to the Phase 1 rules in conjunction with their categorization effort so that the exemptions can be issued as soon as possible.
19	Staff Evaluate Pilot Plant Categorization Effort
TASK CPP_6	25 weeks assigned to this task assumes that it can be done in parallel with pilot plant categorization to a certain extent.
20	Assumes that ~6-months needed for the staff to finalize its evaluation (presumably in a NUREG) on the acceptability of the categorization effort, the rule language & NEI guideline (a finish-to-finish link with 26 week lag).
21	Staff Review Pilot Exemptions
TASK CPP_7	This is additional effort beyond that to review categorization. That is, it is to conclude that exemptions to specifically requested rules can be implemented. This has a finish-to-finish link with categorization review with no lag.
22	Assumes that the categorization and exemption review work can be done in parallel.
23	Staff Issue Exemptions
TASK CPP_8	Milestone indicating that pilot plants can begin implementation of Option 2, phase 1 rules (effectively represents completion of demonstration pilot, although followup oversight may be conducted).
24	Draft NEI Categorization Guideline Development
TASK NEI_1	Milestone to indicate that NEI is developing a guideline to implement the categorization process.
25	NEI Submit Draft to Staff
TASK NEI_2	Substantial date based on phone call with Steve Floyd (NEI) on 8/19/1999, and confirmed with Adrian Heymer (NEI) on 9/13/1999.

Figure 6: PERT and Gantt Chart Notes (continued)

Risk Informing Special Treatment Requirements  
Proposed Schedule

- 22 Staff Review NEI Draft Guideline  
TASK NEI.3  
Assumes that about 6 months will be necessary for the staff to confirm that the NEI guideline appears to be one acceptable method of implementing the categorization process described in the ANPR.
- 23 Categorization Approach Acceptable  
TASK NEI.4  
Milestone to show that both the staff and Commission have determined that the categorization process, as implemented by the NEI guideline, are acceptable. This determination must be made to proceed with final rulemaking.
- 25 Start Proposed Rulemaking  
TASK FRM.1  
Milestone to indicate beginning of Option 2 rulemaking effort.  
Assumes that effort will not begin in earnest until the SRM for the Rulemaking Plan is issued, and that the SRM approves the staff's recommended approach without substantial modification.
- 26 Prepare Proposed Rulemaking  
TASK FRM.2  
Assumes about 9 months (39 weeks) to develop proposed rulemaking package for phase 1 rules.  
NOTE: NOT SHOWN ON THE PERT DIAGRAM IS DEVELOPMENT OF REGULATORY GUIDANCE FOR INDIVIDUAL RULEMAKINGS. THIS EFFORT COULD IMPACT SCHEDULE ASSUMPTION HERE IS THAT REG GUIDE DEVELOPMENT CAN BE HIGHLY PARALLEL, THUS SUFFICIENT RESOURCES CAN ACCOMPLISH IN TIMEFRAME ALLOWED.
- 28 Publish Proposed Rulemaking for Comment  
TASK FRM.4  
Assumes that SRM on proposed rulemaking approves the staff's recommendation without substantive modification.
- 30 Start Final Rulemaking  
TASK FRM.1  
Milestone to indicate beginning of final rulemaking effort.
- 31 Comment Period  
TASK FRM.2  
Assumes 75 day comment period for this rulemaking.
- 32 Evaluate Public Comments  
TASK FRM.3  
Extensive public comments could extend this period. However, ANPR and Pilot Programs and other communication forums for stakeholders should reduce the likelihood of comments that are exceptionally complex or require remedial action at this stage in the process.
- 33 Endorsement of NEI Guideline in Final RG  
TASK FRM.4  
Assumes about 6 months for NEI to submit a final guideline document and the staff to review it. Have assumed that need 13 weeks after completion of review of public comments (i.e., a finish-to-finish link with 13 week lag) to allow NEI to incorporate relevant comments in guideline instead of as exceptions in final RG (this is approach taken on UFSAR RG 1.181).  
Also assumes that staff must determine that the Categorization Pilot Program was acceptable for endorsing in final RG (this is a finish-to-finish link with no lag).
- 34 Prepare Final Rulemaking  
TASK FRM.5  
Assumes 6 months to prepare final rulemaking, and that this effort can be done partly in parallel with public comment evaluation and NEI guideline acceptance review.  
Assumes need 9 weeks (~2 months) after final RG prepared (finish-to-finish link with 9wk lag).  
Assumes need 17 weeks (~4months) after public comment period ends (finish-to-finish link with 17 wk lag).
- 36 Publish Final Rule  
TASK FRM.7  
Assumes SRM does not propose substantive changes.  
Time estimate based on need to get OMB clearance.  
The Option 2 rulemaking effort is considered complete at this point (assumes all rules addressed in a single rulemaking).

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 21, 50, 52, 54 and 100

RIN ###-###

Risk-Informing Special Treatment Requirements

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is considering promulgating new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations. This action is a result of the Commission's continuing efforts to risk-inform its regulations. The NRC invites comments, advice, and recommendations from interested parties on the contemplated approach for this rulemaking.

DATE: Comment period expires ###/###/####. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff.

You may also provide comments via the NRC's interactive rulemaking website through the NRC's home page (<http://ruleforum.llnl.gov>). This site provides the capability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415-5905; e-mail [CAG@nrc.gov](mailto:CAG@nrc.gov).

Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Thomas A. Bergman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: (301) 415-1021; e-mail: [tab@nrc.gov](mailto:tab@nrc.gov).

SUPPLEMENTARY INFORMATION:

I. Background.

II. Rulemaking Plan.

A. Vision.

B. Strategies.

C. Objectives.

D. Selection of Candidate Rules.

E. Rulemaking Alternatives.

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2. Redefine Current Terms.

3. Issue New Rule.

4. Comprehensive vs. Phased Rulemaking.

F. Implementation.

1. New Appendix vs. Regulatory Guide.

2. Additional Guidance.

G. Pilot Plant Program.

H. South Texas Exemption Request.

I. Schedule.

III. Specific Proposal.

A. Approach.

B. New Rule for Part 50.

C. New Appendix to Part 50.

IV. Issues.

- A. Selective Implementation.
- B. Impact on Other Regulations.
- C. Need for Prior NRC Review.
- D. Identification and Control of Attributes Requiring Special Treatment.

V. Specific Questions.

- A. Approach.
- B. Screening.
- C. Categorization Methodology.
- D. Pilot Plant Program.
- E. Identification and Control of Special Treatment Attributes.
- F. Selective Implementation.
- G. Impact on Other Regulations.
- H. Need for Prior NRC Review.

## I. Background.

On August 16<sup>th</sup>, 1995 (60 FR 42622), the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA). Since then, the Commission has issued guidance<sup>7</sup> on the use of risk information for reactor license amendments. This guidance is currently being used in processing license amendment applications that use risk information as part of their technical justification. However, fundamental reactor regulations remain largely deterministic. In addition, in meetings between the Commission and various stakeholders, a concern was expressed that the NRC is not placing enough emphasis on risk-informing its reactor requirements with the results of risk assessments. The Commission's current reactor regulatory framework (based largely upon design-basis events rather than on core-damage-accident scenarios) results in reasonable assurance of adequate protection to public health and safety but, in some cases, also results in unnecessary regulatory burden. In a staff requirements memorandum dated September 14, 1998, the Commission requested the NRC staff to present a set of options to make the requirements in the Commission's regulations risk-informed. The Commission expects that making the regulations risk-informed would result in a reduction of unnecessary regulatory burden while maintaining safety since there will be a better focus of the NRC's and industry's resources on the more safety significant SSCs and, therefore, address the expressed concern.

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998, the NRC staff

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<sup>7</sup> To date, this guidance includes Standard Review Plan (SRP) Chapter 19 and Related Regulatory Guide (RG) 1.174 on risk-informed decision making; SRP Section 3.9.7 and related RG 1.175 on risk-informed inservice testing; SRP Section 16.1 and related RG 1.177 on risk-informed technical specifications; RG 1.176 on risk-informed graded quality assurance; and SRP Section 3.9.8 and related RG 1.178 on risk-informed inservice inspection.

proposed three high-level options for making the NRC's regulations risk informed. In a staff requirements memorandum (SRM) dated June 8, 1999, the Commission approved the NRC staff's recommendations.

One of the options presented in SECY-98-300 was to make special treatment requirements (e.g., quality assurance, environmental qualifications, technical specifications, reporting) risk-informed. Special treatment as used here may be defined as --

*Current requirements imposed on structures, systems, and components (SSCs) that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.*

It should be noted that, this definition does not encompass functional design requirements; that is, an SSCs functional design requirement is ***not*** considered a special treatment requirement. The above-mentioned definition will apply, hereafter, when the term "special treatment" is used.

This advanced notice of proposed rulemaking presents the approaches that the Commission is contemplating to risk-inform special treatment requirements. Several public meetings have been held to obtain comments on the NRC's efforts related to this task. Comments and suggestions obtained from these meetings have been incorporated, to the extent possible, into these approaches.

## II. Rulemaking Plan.

### A. Vision.

Develop alternative regulations in 10 CFR Part 50 (and other applicable parts) that would modify the requirements for special treatment to focus on those SSCs that have been identified as important to protect public health and safety by using a risk-informed approach.

### B. Strategies.

Increase the use of risk-informed approaches to modify the special treatment requirements imposed on SSCs under existing Part 50 requirements (and those of other applicable parts).

Maintain overall safety provided by the existing Part 50 while reducing unnecessary burden associated with these requirements for licensee operational and licensing activities and for NRC oversight and licensing activities.

Risk-inform the special treatment requirements imposed on SSCs under Part 50 (and other applicable parts) in a manner that encourages public participation and results in public confidence in the product and process.

### C. Objectives.

Establish the criteria for acceptable methods for determining the SSCs that require special treatment in the regulations of Part 50. These criteria should be sufficiently clear and

robust such that if a licensee's program meets the criteria there is not a need for prior NRC review and approval of the plant-specific program.

Assign priorities to the rules to be modified, taking into consideration the maintenance of safety, the reduction of unnecessary burden for industry, the effect on NRC efficiency and effectiveness, public confidence, and the complexity of modifying each rule.

Ensure that the categorization process has been evaluated under a pilot program to verify that the requirements and their associated guidance can be implemented by industry, and that the results of licensee implementation provide reasonable assurance that public health and safety is maintained.

Issue a proposed rule for the initial set of rules to be modified within 1 year of the Commission's approval of the rulemaking plan, and a final rule within 1 year of the completion of the associated pilot program.

The proposed risk-informed regulatory alternatives should reduce unnecessary burden so that licensees with more than 10 years remaining on their license would find it beneficial to voluntarily implement the risk-informed alternative requirements.

#### D. Selection of Candidate Rules.

The Commission believes that the set of rules to be considered in this effort must be identified early so that rule-specific issues can be identified and addressed. Also, because implementation of any rules resulting from this effort is optional, the Commission does not intend to expend resources to modify rules that industry does not expect to implement, unless

the modifications are necessary to maintain safety. However, the Commission notes that the set of rules included in this effort should be chosen such that implementation of the rules will require little or no exemptions. Therefore, rules that may require exemptions before a licensee can implement changes in other rules (e.g., 10 CFR 50.59) should be considered in this rulemaking effort.

The NRC has developed and applied a systematic approach to identify the rules that should be included in this rulemaking effort. A scoping review of all the regulations in 10 CFR Parts 21, 50, 52, 54, and 100 identified a set of potential candidate rules that could be included. Screening criteria and a logic for applying these criteria were then developed to identify the subset of rules to which risk-informed changes can be made consistent with the intent of this effort. The screening criteria were based on the following elements: maintaining safety, improving NRC staff efficiency and effectiveness, reducing unnecessary regulatory burden, and increasing public confidence. In addition, and because this effort is focused solely on special treatment requirements, the NRC limited its selection to those rules that include special treatment requirements. Rules which would have to be modified in order to efficiently implement other rules included this effort were also included. The criteria and logic were then applied to the set of potential candidate rules identified by the scoping review. The screening process and results are illustrated in Figure 1. The results of the evaluations of the rules against each of the screening criteria are presented in Table 1. As a result of this screening process, the NRC has identified the following candidate rules for inclusion in this effort:

10 CFR Part 50 - Sections 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, and 50.73

10 CFR Part 50 - Appendix A (GDCs 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46), Appendix B, Appendix J, Appendix R, and Appendix S

10 CFR Parts 21, 52, 54, 100, and Appendix A to Part 100

E. Rulemaking Alternatives.

The NRC has evaluated alternatives to rulemaking and has concluded that, if sufficient industry interest exists, rulemaking is the most effective tool for implementing the type of generic changes encompassed by this effort. If sufficient interest does not exist, review and approval of a limited number of exemptions under 10 CFR 50.12 would be more efficient. Assuming industry interest does exist as has been indicated in public meetings, the NRC has evaluated several rulemaking alternatives to accomplish this task. These alternatives are discussed below.

1. Define New Term.

This alternative would entail the definition of a new term in 10 CFR 50.2 (e.g., “safety-significant”) that describes, for the purposes of special treatment requirements, which SSCs are safety-significant and, therefore, need to be within the scope of the special treatment requirements. This new term would then be incorporated into each rule that contains special treatment requirements to allow licensees to voluntarily revise the scope of SSCs that are subject to special treatment requirements. To determine which SSCs are safety significant, the Commission would issue a new Part 50 appendix that contains the requirements governing the categorization of SSCs consistent with the new term defined in §50.2. Alternatively, the Commission could issue a regulatory guide that contains the SSC categorization guidance.

Regulatory treatment requirements in addition to the special treatment requirements currently in the regulations may be necessary as a result of the risk categorization processes. These additional requirements would have to be added to the regulations and, therefore, additional changes to each affected rule may be required to ensure that the new regulatory treatment requirements are appropriately captured in the regulations. Since this alternative would result in duplicate changes to multiple rules, the NRC did not choose this alternative.

## 2. Redefine Current Terms.

This alternative would expand the definition of the term “safety-related ” in 10 CFR 50.2, or as an alternative, define the term “important to safety” such that the redefined term would contain a portion that allows special treatment requirements to be risk-informed. Licensees could then elect to risk-inform the scope of SSCs that are subject to special treatment in all the applicable rules. This approach would expand the definitions of the current terms (which reside in the existing rules) so there is no need to add new terms to the governing regulations. However, a significant effort would be required to review all the regulations to ensure that the Commission has not unintentionally revised any non-special treatment rules and to make appropriate changes to preclude such occurrences. In a similar fashion to the “new term” approach, this approach would also need to be supplemented with either a new Part 50 appendix that contains the requirements governing the risk-informed categorization of SSCs, or a regulatory guide that contains the SSC categorization guidance.

This alternative would introduce unnecessary complications and confusion in the application of the terms at plants that choose to implement the new scope for a subset of the special treatment requirements covered in this effort, or for some systems and not others. Such a situation would result in the use of similar language with different meanings in the

licensee's licensing basis documents and in the associated plant implementation documents. Furthermore, regulatory treatment requirements, in addition to those currently in the regulations, may be necessary as a result of the risk categorization processes. These requirements would have to be added to the regulations. Therefore, changes to other rules may still be required. The NRC did not choose this alternative.

### 3. Issue New Rule.

This approach entails the development of a new rule that would be added to Part 50. The rule would "list" the provisions that contain special treatment requirements that may have their scope risk-informed in accordance with the methodology requirements contained in either a new appendix that would also be added to Part 50, or in guidance contained in a regulatory guide (similar to above two alternatives in this respect). In addition to identifying which rules can be risk-informed for special treatment, the new rule would address rule specific issues resulting from this effort and contain new requirements concerning the type of regulatory treatment that SSCs would receive.

The NRC believes that this alternative is the simplest and most efficient regulatory approach because it appears to not require defining new terms which in turn requires subsequent revisions to each affected rule. In addition, this alternative has the benefit of integrating all the affected special treatment requirements into one rule which would make it easier for licensees and the NRC to implement. Therefore, the NRC has decided to proceed with this alternative.

### 4. Comprehensive vs. Phased Rulemaking.

The NRC considered whether it should proceed with a comprehensive rulemaking covering all special treatment requirements or a phased approach. The NRC's objective is to proceed with a comprehensive rulemaking. However, the NRC recognizes that this approach may prove problematic. Because of the uniqueness of the special treatment requirements, the potentially different effects that may result from modifying these requirements, and the inconsistencies that currently exist between the various special treatment requirements, the NRC notes that the comprehensive rulemaking approach would be a large and complex task. The comprehensive rulemaking approach appears to have a greater potential for delay because of the time required to review each of the affected requirements and the potential for issues to arise that can have impacts on the schedule. A comprehensive rulemaking must address all affected requirements and issues before the rulemaking may be completed. Consequently, this might delay implementation of some rules due to complications with others. If complications do arise, the NRC may elect to proceed with a phased approach that allows the NRC to issue some revised rules while continuing to address issues that arise on others.

#### F. Implementation.

##### 1. New Appendix vs. Regulatory Guide.

Each of the alternatives discussed in Section E include either the development of a new Appendix to Part 50 or the issuance of a regulatory guide that would contain the requirements governing the categorization of SSCs. The NRC has considered these two alternatives (a new appendix vs. a regulatory guide) and concluded that a new appendix approach is preferred since it would provide a more stable and predictable regulatory framework. Such a framework should result in the least burden on NRC and industry resources both from the standpoint of

any prior NRC review that is required and from the standpoint of the staff's inspection of this task. If an appendix can be constructed that when implemented by licensees yields consistent, objective, enforceable, and inspectable results, then this regulatory approach should allow for implementation of the resulting risk-informed special treatment requirements with little or no NRC review. On the other hand, putting categorization guidance into a regulatory guide would require that the staff review and approve licensee submittals prior to implementation because of the flexibility inherent in a regulatory guide. The NRC expects the pilot plant program to enable it to determine if development of an appendix in lieu of a regulatory guide is sufficient to support a no prior NRC review regulatory approach. If the pilot plant program reveals that development of the appendix does not minimize the need for NRC review, the NRC will reconsider whether an appendix remains the best approach.

## 2. Additional Guidance.

In addition to either an appendix or a regulatory guide, the Nuclear Energy Institutes (NEI) has indicated that it will submit an implementing document for this effort. The NRC intends to review this implementing document. The objective of this review will be to reach agreement with NEI concerning the implementation of risk-informed special treatment, and to be able to endorse the NEI guidance in a regulatory guide. Consequently, the Commission does not currently plan to develop draft regulatory guidance to implement this rulemaking. Additional NRC efforts would be required to update current regulatory guides that address the current SSC categorization approach, as appropriate.

G. Pilot Plant Program.

The Commission believes that the pilot plant program is an essential component of this rulemaking effort. The purpose of this program would be to demonstrate the viability of the requirements contained in the resulting rule and appendix before final rulemaking and the viability of the proposed NEI guidance for the implementation of the resulting rule and appendix. The program will also help the NRC identify the special treatment requirements that industry believes should be addressed.

The most important aspect of the pilot plant program will be to demonstrate the viability of risk categorization processes to establish alternative risk-informed special treatment requirements. These processes must be based on the requirements in the resulting rule and appendix in order to provide meaningful feedback on the rulemaking effort. In addition, the categorization processes must be evaluated against the set of special treatment requirements they are applied to so that critical attributes are appropriately evaluated. The categorization processes must also be applied to a variety of plant systems, including mechanical (active and passive), fluid, and electrical systems, and safety-related and nonsafety-related systems, so that technical aspects of the categorization processes and their implementation can be thoroughly exercised. The Commission may explicitly exclude any attributes that are not exercised by the pilot plant program from consideration in this effort.

The pilot plant program must be integrated with the rulemaking plan. It must agree on overall and plant-specific schedules and the rules to be piloted. Pilot plant program participants must commit to meet the resulting rulemaking requirements and proposed NEI guidance for categorization and implementation. In addition, pilot program submittals should address how design basis functions will be preserved when special treatment for safety-related SSCs is

reduced as a result of the risk categorization processes. The discussion should address how these SSCs will be treated by the licensee's design control and corrective action programs. Similarly, licensees should discuss how critical attributes identified by the risk categorization processes will be identified and controlled. This applies to safety-related and non-safety-related SSCs that are found to be significant as a result of the risk categorization processes. The processes established should be capable of reflecting changes to the facility and categorizing new and modified equipment as these changes are made.

#### H. South Texas Exemption Request.

In addition to the pilot plant program, the Commission notes that South Texas Project Nuclear Operating Company has submitted an extensive exemption request related to a number of special treatment requirements. This submittal was developed before initiation of this effort, and so was not coordinated with the development of the rulemaking plan. Presently, the NRC expects to complete review of this submittal before the proposed rulemaking stage of the effort would begin. The NRC believes that, if approved, the South Texas exemption request will serve as a proof-of-concept prototype which will provide useful information and experience when the rulemaking for this effort is developed.

#### I. Schedule.

The NRC has developed a schedule covering the following activities which influence this rulemaking: (1) the South Texas exemption request, (2) development and issuance of this advanced notice of proposed rulemaking, (3) the pilot plant program, (4) NRC review of the NEI implementation guidance, (5) development and issuance of the proposed rulemaking, and (6) development and issuance of the final rulemaking. The NRC estimates that a final rule can be

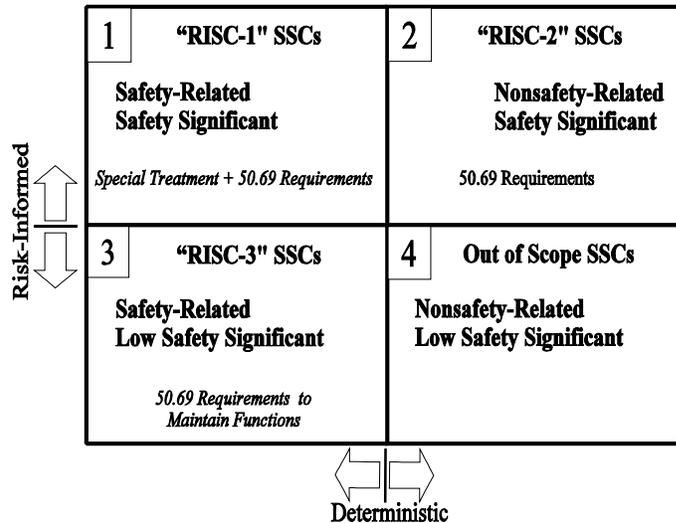
issued by March of 2002. This rulemaking includes milestones that depend significantly on NEI to develop implementation guidance and pilot plant program participants to develop and implement categorization processes.

### III. Specific Proposal.

#### A. Approach.

To effect the described changes, the Commission is considering an approach that consists of issuing a new rule (10 CFR 50.69) and a new appendix (Appendix T to 10 CFR Part 50). The new rule and appendix would allow licensees, for purposes of special treatment requirements, to categorize SSCs with regard to their importance to plant safety. The result of such a rulemaking, when combined with the current deterministic design basis, would result in SSCs being classified in two different manners. One would be consistent with the safety-related/non-safety-related philosophy that exists today for the deterministic design basis. The other would be consistent with a risk-informed philosophy. A graphical depiction of the results of the contemplated changes is illustrated in Figure 2. The figure is only intended to provide a conceptual understanding of the new SSC categorization process. The NRC's thinking is continuing to evolve on this matter. The NRC will explore the idea of more than two levels of safety significance. The NRC is requesting stakeholder feedback regarding safety significance categories in question C.3 of Section V. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme on the horizontal axis with an overlay of the new risk-informed categorization on the vertical axis. The risk-informed categorization would group SSCs into one of the four boxes.

Figure 2: Diagram of Categorization and Treatment



Box 1 of Figure 1 contains safety-related SSCs that a risk-informed categorization process concludes are significant contributors to plant safety. These SSCs are termed risk-informed safety class 1 (RISC-1) SSCs. SSCs in this box would continue to be subject to the current special treatment requirements. In addition, it is possible that some of these SSCs may have some additional requirements concerning reliability and availability if attributes which cause the SSC to be safety significant are not sufficiently controlled by current special treatment requirements. However, the NRC is not currently aware of any examples of this situation.

Box 2 depicts the SSCs that are nonsafety-related, and that the risk-informed categorization concludes make a significant contribution to plant safety. These SSCs are termed RISC-2 SSCs. Examples of RISC-2 SSCs could include the station blackout emergency diesel generator, the startup feedwater pump for pressurized water reactors (PWRs), and SSCs used for "feed and bleed" operations at PWRs. For RISC-2 SSCs, there will probably need to be requirements to maintain the reliability and availability of the SSCs

consistent with the PRA. It is currently envisioned that the new rule would contain the requirements regarding reliability and availability of RISC-1 and RISC-2 SSCs.

Box 3 depicts the currently safety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-3 SSCs. The rulemaking effort would revise 10 CFR Part 50 to contain alternative requirements such that RISC-3 SSCs would no longer be subject to the current special treatment requirements. For RISC-3 SSCs, it is not the intent of this rulemaking to allow such SSCs to be removed from the facility or to have their functional capability lost. Instead, the RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance. The NRC may determine that this level of assurance can be provided by licensees' commercial grade treatment programs. It is envisioned that the new rule would contain the regulatory treatments requirements for RISC-3 SSCs (e.g., the new rule may require commercial treatment for RISC-3 SSCs).

Box 4 depicts SSCs that are nonsafety-related and continue to be categorized as not being significant contributors to plant safety. These SSCs are out of scope of both the current special treatment regulations and of the new rule. The functional performance of these SSCs would be controlled under the licensee's commercial grade program (no change from the current requirements).

B. New Rule for Part 50.

The Commission expects that the new rule that would (1) identify the special treatment requirements in the current regulations whose scope could be modified consistent with the requirements resulting from this effort, (2) address rule-specific issues that arise as a result of the new scope by, for example, specifying, on a rule-by-rule basis, the applicability of the new scope, (3) specify all additional regulatory requirements that would result from this effort, and (4) reference the new appendix as providing the requirements governing the categorization of SSCs.

C. New Appendix to Part 50.

The Commission expects that the new appendix would contain the elements discussed below. The discussion consists of NRC expectations of the SSC categorization process and is not presented as proposed rule language. When finalized, the appendix would establish minimum requirements for the process and decision criteria for use in the categorization of SSCs into two groups — those that have safety significance and those that have low safety significance. This is consistent with the process to categorize SSCs into RISC classes as discussed above in which the safety significant and low safety significant categorization is used in the vertical axis.

## **Appendix T to Part 50 - Categorization of SSCs into Risk-Informed Safety Classes**

The principal activity required for the categorization of structures, systems and components (SSCs) into risk-informed safety classes is the categorization of the SSCs according to safety significance. Treatment requirements for SSCs will be dependent on this safety classification. This appendix establishes minimum requirements for the process and decision criteria for use in the categorization of SSCs.

### Process for Categorization

The determination of safety significance of SSCs must be performed as part of an integrated decision-making process which uses both risk insights and traditional engineering insights. In categorizing SSCs, it must be demonstrated that the defense-in-depth philosophy is maintained, that sufficient safety margin is maintained, and that increases in risk (if any) are small.

To accomplish these objectives, the process to categorize SSCs should consist of the following elements:

- (1) Identification of current treatment requirements for SSCs.
- (2) Assessment of the capability of the plant-specific Probabilistic Risk Assessment (PRA) to support the categorization process.

- (3) Use of the PRA to determine the relative importance of modeled SSCs to accident prevention and mitigation.
  
- (4) Use of an integrated decision-making panel (IDP) to determine the safety significance of SSCs. The categorization of SSCs as either safety significant or low safety significant must include considerations of:
  - b. Results of the PRA importance evaluation.
  
  - b. Deterministic and other traditional engineering analyses.
  
  - c. Maintenance of the defense-in-depth philosophy.
  
  - d. Maintenance of safety margins.
  
- (5) Evaluation of the change in risk resulting from reclassifying SSCs.
  - a. Determination of treatment requirements for SSCs based on their initial safety significance categorization.
  
  - b. Evaluation of the overall change in plant risk as a result of changes in treatment requirements, and readjustment (if necessary) of the categorization of SSCs based on this estimation of change in risk.

- (6) Documentation of the process and the decision criteria used for the categorization of SSCs.
  
- (7) Monitoring of the impact of the change in treatment requirements.

The remainder of this appendix discusses requirements and decision criteria for the above elements in more detail.

#### Requirements and Decision Criteria

##### Element (1): Identification of Current Treatment Requirements for SSCs.

All safety-related as well as non-safety-related SSCs in the plant are within the scope of this categorization process. For each SSC where changes to the treatment requirements are considered, current requirements must be identified and documented so that the effect of the changes can be more easily understood.

##### Element (2): Assessment of the Capability of the PRA to Support the Categorization Process.

**PRA scope.** At a minimum, a PRA modeling the internal initiating events at full power operations must be used for SSC importance analysis and determination of change in risk from the application. The PRA must be capable of quantifying

core damage frequency (CDF) and large early release frequency (LERF). When categorizing SSCs, the licensee shall also consider external event initiators, as well as the shutdown and low-power modes of operation, either by PRA modeling or by the integrated decision-making process. Element (4)(b) discusses the requirements for cases when PRA modeling is not available.

**PRA quality.** The PRA should conform to the consensus ASME/ANS PRA Standard documents as endorsed by the NRC. In addition to the technical requirements, the PRA shall conform to the requirements in the areas of documentation, configuration control, quality assurance, and peer review. Where elements of the Standard are not met, justification of why these elements are not important to the results must be documented and available for NRC review.

**PRA updates.** The PRA must reflect the as-built and as-operated plant. When used for SSC categorization, and as long as regulatory requirements are being dictated by this categorization, the PRA must be updated on a periodic basis, that is, annually or within six months after each refueling outage provided the interval between successive updates does not exceed 24 months. These updates are mandatory prior to implementation of changes to plant design or procedures if these changes affect the categorization of SSCs. A PRA update is also required upon receipt of new PRA information which would invalidate the results of the categorization process. Upon the completion of the PRA update, the SSC categorization shall be revisited in accordance with Elements 3 through 5 of this process with a focus on the impact of the changes on SSC categorization.

Element (3): Determination of Relative Importance of SSCs Using the PRA.

Relative importances of SSCs modeled in the PRA should be determined using PRA importance measures. The results of this process together with results of sensitivity studies will be used as inputs to the integrated decision-making process for the categorization of SSCs.

**Risk metrics and importance measures.** SSC importances must be determined based on both CDF and LERF. Importance measures should be chosen such that results can provide the IDP with information on the relative contribution of an SSC to total risk. Examples of importance measures that can accomplish this are the Fussell-Vesely (F-V) importance and the Risk Reduction Worth (RRW) importance. Importance measures should also be used to provide the IDP with information on the safety margin available should an SSC fail to function. The Risk Achievement Worth (RAW) importance and the Birnbaum importance are example measures that are suitable for this purpose.

**Screening criteria.** Importance measures do not directly relate to changes in the absolute value of risk. Therefore, the criteria for categorizing SSCs into the safety significant and the low safety significant categories shall be 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, see Element (5)(b). However, in the initial screening stages, an SSC with  $F-V < 0.005$  based on either CDF or LERF, and  $RAW < 2$  based on either CDF or

LERF can be considered as potentially low safety significant. Elements 4 and 5 must be carried out to confirm the low safety significance of these SSCs.

**Truncation limit.** The truncation value used for PRA model quantification must be set to a value that is sufficiently low so that the resultant minimal cutsets contain the significant contributors to risk and that at least 95 percent of the CDF and LERF is captured in the final solution.

**Sensitivity analyses.** The sensitivity of SSC importances to uncertainties in the parameter values for component availability/reliability and human error probabilities should be evaluated. Results of these sensitivity analyses should be provided to the IDP for deliberation.

**Combining models for different initiating events and plant operating modes.** The PRA models for external initiating events (e.g., events initiated by fires or earthquakes), and for low power and shutdown plant operating modes may be conservative with respect to those for internal initiating events. Use of conservative models can influence the calculation of importance measures by moving more SSCs into the low safety significance category. Therefore, when PRA models for external event initiators and for the low power and shutdown modes of operation are available, the importance measures shall be evaluated for each analysis separately, as well as integrally. Results of the analyses should be provided to the IDP for deliberation.

Element (4): SSC Categorization by the Integrated Decision-Making Panel.

An integrated decision-making panel, for example, an Expert Panel similar to the one used in implementing 10 CFR 50.65, must be used to determine the safety significance of SSCs. The categorization of SSCs as either safety significant or low safety significant must consider: results of the PRA importance analysis; deterministic and other traditional engineering analyses; maintenance of the defense-in-depth philosophy; and maintenance of safety margins. Elements (4)(a) through (4)(d) describe these requirements in more detail. Element (6) describes the requirements of the IDP process, and the documentation required of this process.

Element (4)(a): Use of PRA Insights.

Results of the PRA importance analysis, including results from sensitivity studies, and results from the external initiating events and the low power and shutdown modes of operation when available, should form the initial inputs to the categorization process:

- (i) For screening, an SSC with  $F-V < 0.005$  based on either CDF or LERF, and  $RAW < 2$  based on either CDF or LERF can be considered as potentially low safety significant.
- (ii) Results of sensitivity analyses shall be used to show that SSC categorization will not change for the expected range of values of SSC reliability/availability and human error probabilities.

- (iii) When PRA models are available, the importance measures for external event initiators and for the low power and shutdown mode of operation shall be evaluated for each analysis separately, as well as integrally, and only when an SSC is low safety significant for each of these analyses will it be assigned to the low safety significant category.

Application of the above guidelines will yield a list of SSCs that are determined to be safety significant by the PRA. These SSCs shall not be re-categorized as low safety significant by the IDP process.

#### **Verification of Low Safety Significance for SSCs Implicitly Modeled in the PRA.**

For SSCs which have not been identified as safety significant by PRA importance measures, the IDP must verify that these SSCs are not implicitly depended upon in the PRA. The IDP must determine if:

- (i) Failure of the SSC will significantly increase the frequency of an initiating event, including those initiating events originally screened out in the PRA.
- (ii) Failure of the SSC will fail a safety function, including SSCs that are assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems, and instrumentation and control systems).

- (iii) The SSC supports operator actions credited in the PRA.
  
- (iv) Failure of the SSC will result in failure of safety significant SSCs (e.g., through spatial interactions).

If any of the above conditions are true, the IDP should use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation should include identifying those failure modes for which the failure rate may increase, and those for which detection could become more difficult. The IDP can justify low safety significance of the SSC by demonstrating one or more of the following:

- The reclassification is consistent with the defense-in-depth philosophy and sufficient safety margin is maintained.
  
- Relaxing the requirements will have minimal impact on the failure rate increase.
  
- Historical data show that these failure modes are unlikely to occur.
  
- Such failure modes can be detected in a timely fashion.

Element (4)(b): Use of Deterministic and Other Engineering Analyses.

For SSCs identified in Element (4)(a) as low safety significant by the PRA as well as those SSCs outside the scope of the PRA, the IDP must verify low safety significance based on deterministic and other engineering analyses and insights, operational experience, and information from licensing basis documents and design basis accident analyses.

### **Initiating Events and Plant Operating Modes not Modeled in the PRA**

When initiating events with frequencies of greater than  $10^{-6}$  per year are not modeled in the PRA, or when the low power and shutdown plant operating modes are not modeled, the IDP shall demonstrate that the relaxation of regulatory requirements will not unacceptably degrade plant response capability and will not introduce risk vulnerabilities for the unmodeled initiating events or plant operating modes. For these unmodeled events, the IDP assessment must consider whether an SSC has an impact on the plant's capability to:

- (i) Prevent or mitigate accident conditions,
- (ii) Reach and/or maintain safe shutdown conditions,
- (iii) Preserve the reactor coolant system pressure boundary integrity,
- (iv) Maintain containment integrity, and
- (v) Allow monitoring of post-accident conditions.

In determining the importance of SSCs for each of these functions, the following factors must be considered:

- Safety function being satisfied by SSC operation
- Level of redundancy existing at the plant to fulfill the SSC's function
- Ability to recover from a failure of the SSC
- Performance history of the SSC
- Use of the SSC in the Emergency Operating Procedures or Severe Accident Management Guidelines
- Cumulative impacts of combinations of SSC unavailability which could impact an entire system or critical safety function

### **Risk Indices Outside the Scope of the PRA**

In addition to being safety significant in terms of CDF and LERF, SSCs can also be safety significant in terms of other risk metrics. Therefore, when an SSC is not identified as safety significant by the PRA, the IDP must verify low safety significance by determining if:

- (i) The SSC is a part of a system that acts as a barrier to fission product release during severe accidents.
- (ii) The SSC is depended upon in the Emergency Operating Procedures or the Severe Accident Management Guidelines.
- (iii) Failure of the SSC will result in unintentional releases of radioactive material even in the absence of severe accident conditions.

If any of the above conditions are true, the IDP should use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation should include identifying those failure modes for which the failure rate may increase, and those for which detection could become more difficult. The IDP can justify low safety significance of the SSC by demonstrating one or more of the following:

- The reclassification is consistent with the defense-in-depth philosophy and sufficient safety margin is maintained.
- Relaxing the requirements will have minimal impact on the failure rate increase.
- Historical data show that these failure modes are unlikely to occur.
- Such failure modes can be detected in a timely fashion.

Element (4)(c): Maintaining the Defense-in-Depth Philosophy.

When categorizing SSCs as low safety significant, the IDP must demonstrate that the defense-in-depth philosophy is maintained. Defense-in-depth is considered adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure the risk acceptance guidelines provided in Element (5)(b) are met, and that:

- Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release
  
- System redundancy, independence, and diversity is preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters
  
- There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design, and
  
- Potential for common cause failures is taken into account

Element (4)(d): Maintenance of Safety Margins.

When categorizing SSCs as low safety significant, the IDP shall demonstrate that there is sufficient safety margins to account for uncertainty in the engineering analysis and in the supporting data. Safety margin shall be incorporated when determining performance characteristics and parameters (e.g., component, system, and plant capability) or when defining mission success criteria (e.g., the number of system trains required to mitigate an initiating event or the ability of an SSC to perform in a certain environment). The amount of margin should depend on the uncertainty associated with the performance parameters in question, the availability of alternatives to compensate for adverse performance, and the consequences of failure to meet the performance goals. Demonstration of available safety margins shall be accomplished by use of data from plant operations or research studies, or by use of analyses using established engineering codes and standards or NRC-approved alternatives.

Element (5): Evaluation of the Change in Risk Resulting from Reclassifying SSCs.

The change in risk from reclassifying SSCs shall be quantified. Elements (5)(a) and (5)(b) provide the requirements for this quantification.

Element (5)(a): Determination of Treatment Requirements Based on Safety Significance.

Where regulatory requirements are to be relaxed for SSCs categorized as low safety significant or where regulatory requirements are increased for SSCs categorized as safety significant, the IDP must document the functional requirements for the SSCs and describe the process to assure that these requirements are preserved. Based on the revised requirements, the IDP must document and justify the target SSC reliability and availability.

Element (5)(b): Assessment of the Change in Risk.

The potential impact of relaxing treatment requirements on SSCs must be evaluated in an integrated manner. Changes in CDF and LERF must be estimated by calculations where the failure likelihood of SSCs is changed to the level corresponding to the failure likelihood for the revised treatment requirements.

Changes to CDF and LERF must be small. Plants with total baseline CDFs of  $10^{-4}$  per year or less will be permitted CDF increases of  $10^{-5}$  per year, and plants with total baseline CDFs greater than  $10^{-4}$  per year will be permitted CDF increases of  $10^{-6}$  per year. Plants with total baseline LERFs of  $10^{-5}$  per year or less will be permitted LERF increases of  $10^{-6}$  per year, and plants with total baseline LERFs greater than  $10^{-5}$  per year will be permitted LERF increases of  $10^{-7}$  per year.

If a PRA model is not available to evaluate the change in risk from an external initiating event or plant operating mode, the IDP must provide justification, on the

basis of bounding analyses or qualitative considerations, that the risk will not be significantly impacted.

Subsequent changes to the categorization of SSCs for the purpose of further modifying regulatory requirements must be performed in such a manner where plant performance and previous changes to the licensing basis are taken into account. There must not be a pattern of systematic increases in risk as a result of repeated applications of the SSC categorization process.

Element (6): Documentation of the Integrated Decision-Making Process and the Decision Criteria Used.

**Requirements of the Integrated Decision-Making Panel**

Plant procedure. The IDP shall be described in a formal plant procedure which includes:

- (i) The designated chairman, panel members, and panel alternates;
- (ii) Required training and qualifications for the chairman, members and alternates;
- (iii) Requirements for a quorum, attendance records, agendas, and meeting minutes;
- (iv) The decision-making process;
- (v) Documentation and resolution of differing opinions; and
- (vi) Implementation of feedback/corrective actions.

Membership. There shall be at least five experts designated as members of the IDP. Expertise in the following fields shall be represented on the IDP: plant operations, design engineering, systems engineering, safety analysis engineering, quality assurance, plant licensing, and probabilistic risk assessment. Members may be experts in more than one field, however excessive reliance on any one member's judgement should be avoided.

Expertise: The licensee shall establish and document specific requirements for ensuing adequate expertise levels of IDP members, and shall ensure that expertise levels are maintained. There shall be at least three members of the IDP with a minimum of five years experience at the plant, and there shall be at least one member of the IDP who has worked on the modeling and updating of the plant-specific PRA for a minimum of five years.

Training: The IDP shall be trained in the specific technical aspects and requirements related to the categorization process. Training shall address, at a minimum,

- (I) The purpose of the categorization,
- (II) Present treatment requirements for SSCs including requirements for design basis events,
- (III) PRA fundamentals,
- (IV) Details of the plant-specific PRA including the modeling scope and assumptions,
- (V) The role risk importance measures including the use of sensitivity studies,

- (VI) The assessment of SSC failure modes and effects,
- (VII) The role of and the use of risk thresholds, and
- (VIII) The defense-in-depth philosophy and requirements to maintain this philosophy. Each of these topics shall be covered to the extent necessary to provide the IDP with a level of knowledge sufficient to evaluate and approve SSC categorization using both probabilistic and deterministic information.

Decision-making: IDP decision criteria for categorizing SSCs as safety significant or low safety significant shall be documented. Decisions of the IDP shall be arrived at by consensus. Differing opinions shall be documented and resolved, if possible. If a resolution cannot be achieved concerning the safety significance of an SSC, then the SSC shall be classified as safety significant.

Feedback and corrective actions: SSC categorization shall be revisited by the IDP when the PRA is updated or when the other criteria used by the IDP are affected by changes in plant operational data or changes in plant design or plant procedures.

### **Documentation of the IDP Process**

The following shall be documented and available for NRC review:

- Results of the relative risk importance of SSCs modeled in the PRA including the results of sensitivity analyses. This should include separate

SSC importances for the external events initiators and for low power and shutdown operations when these events are modeled in the PRA.

- Results of the final SSC categorization including a summary of IDP deliberations for each SSC classified as low safety significant and each non-safety-related SSC classified as safety significant. Decision criteria in terms of qualitative assessments, assessments for initiating events and plant operating modes not modeled in the PRA, defense-in-depth, and safety margins must be included. Technical basis documents used to support the categorization shall also be available.
- Functional requirements for each SSC receiving revised treatment, the original treatment requirements for these SSCs, the revised requirements for these SSCs, target values for SSC reliability and availability, and the process that will be used to assure these functional requirements and target values will be preserved/met.
- The overall change in plant risk as a result of changes in treatment requirements, including the baseline CDF and LERF and the change in this CDF and LERF. Changes to plant risk from all previous changes to treatment requirements shall also be included.
- Requirements for the IDP including, the plant procedure, expertise, membership, training, and decision-making guidelines. Meeting minutes should also be included.

- The PRA used and the supporting analyses, together with a description of conformance of this PRA to the PRA Standards documents.

Element (7): Monitoring of the Impact of the Change in Requirements.

A performance monitoring and corrective action program must be implemented so that early indication of SSC degradation can be obtained, and corrective actions can be implemented. This program shall include safety significant SSCs and safety-related SSCs classified as low safety-significant. A mechanism for changing SSC categorization based on operating experience must be included in the program. SSC performance must be consistent with the level of performance allocated in the risk analysis or credited in the integrated decision-making process. Monitoring of the safety-significant SSCs is expected to be addressed by the Maintenance Rule as described in 10 CFR 50.65.

Results of the monitoring program must be documented and available for NRC review. Results of the monitoring program must also be incorporated into the PRA update process described in Element (2).

IV. Issues.

A. Selective Implementation.

“Selective implementation” is defined as implementing the changes resulting from this effort for a subset of the affected special treatment requirements or implementing the changes for a subset of SSCs at a facility, or both. The NRC is considering the argument that selective implementation would tend only to reduce unnecessary regulatory burden and would not yield safety benefits where the risk importance of SSCs had not been recognized by the current regulatory framework. However, selective implementation may be possible and even necessary to some degree.

The South Texas Project experience with the Graded Quality Assurance program has demonstrated that implementation of the resulting changes for only 10 CFR 50, Appendix B, is not beneficial from a burden reduction perspective without exemptions from other regulations. The South Texas Project experience has further shown that implementation for a minimum set of rules, in combination with 10 CFR 50, Appendix B, must occur before sufficient benefits are realized. The NRC believes that this feedback applies to most of the current set of regulations. However, even with the experience that South Texas Project had with 10 CFR 50, Appendix B, the licensee did not request exemption from the full set of regulations identified as candidates for this effort. In addition, none of the potential pilot plant program participants have expressed interest in implementing the full set of rules being considered. As a result, the NRC currently believes that a sufficient amount of burden reduction can be achieved with selective implementation.

The NRC intends to make rule changes so that exemptions will not be required for licensees wishing to implement the risk-informed regulatory regime that would result

from this effort. Therefore, the NRC currently believes that it should not issue exemptions to allow for selective implementation after final rulemaking.

With regard to safety, the NRC believes that, if the exemption request submitted by South Texas Project can be found acceptable, the NRC would have, in effect, determined that an adequate level of safety could be preserved without having to adopt all changes resulting from this effort. Therefore, the NRC will depend, in part, on the results of the South Texas exemption effort to decide this issue.

Selective implementation of alternative regulatory treatment requirements would introduce additional complexity into the regulatory process and the NRC will need to assess the practicality of the approach. In addressing this issue, the NRC will need to establish an implementation approach which recognizes all of the NRC's outcome oriented goals, not just reducing unnecessary regulatory burden. The NRC is continuing to evaluate this issue and is seeking stakeholder feedback in Section V.F. of this advance notice of proposed rulemaking.

Another selective implementation issue is whether licensees should be allowed to implement the alternative for certain systems and not others. The NRC expects that licensees would look at a comprehensive set of systems and components as it applies any individual risk-informed regulation. If a comprehensive scope of equipment is not considered, the NRC does not believe that licensees can develop an appropriate risk-ranking process or identify risk-significant characteristics of equipment which may warrant additional control. For example, licensees would be expected to review systems and components outside current safety-related boundaries to identify the need for additional equipment qualification for risk-significant SSCs at the same time that it

reviews the current equipment qualification scope for relaxation opportunities. The NRC does recognize, however, that implementation would take place through a phased approach by licensees.

The NRC recognizes that licensees may elect to exclude certain systems from the detailed risk-ranking process based on their prior understanding of the importance of those systems to overall safety. Some systems, such as the reactor protection system, can be shown to be very important without an extensive risk evaluation. Other systems may not be relevant to facility safety at all. Licensees may determine that there is little benefit from a detailed risk categorization process for such systems. However, to ensure that this effort is implemented correctly, such systems may still need evaluation to assess the risk-significant attributes from a risk-informed perspective.

The Commission is continuing to evaluate this issue and is seeking stakeholder feedback on this issue in Section V.F. of this advance notice of proposed rulemaking.

#### B. Impact on Other Regulations.

The NRC has determined that implementation of risk-informed alternatives in Part 50 may affect implementation of other regulations. For example, the NRC has determined that changes to Part 54 may be required to accommodate license renewal for a facility that had implemented risk-informed changes encompassed by this effort. The scope of Part 54 is explicitly defined using the traditional deterministic approach. Therefore, Part 54 does not, without change, accommodate the alternative the risk-informed scope that would result from this effort. The goal of the license renewal program is to establish a stable, predictable, and efficient license renewal process. The

NRC believes that a revision to Part 54 at this time will have a significant effect on the stability and consistency of the processes being established for preparation of license renewal applications and for NRC review. Allowing a voluntary alternate scoping criteria would necessitate the development of an alternate license renewal process. Guidance would need to be developed regarding format and content of a renewal application, NRC review criteria, and inspection guidance for conducting onsite scoping inspections.

In other cases, such as operator licensing (Part 55), rule changes may not be necessary. Nevertheless, licensees may need to make changes to programs implementing these regulations in order to ensure compliance.

The Commission would like to identify all such impacts early in this effort and is, therefore, seeking stakeholder input on this issue in Section V.G. of this advance notice of proposed rulemaking.

#### C. Need For Prior NRC Review.

The preferred approach for this effort is to avoid the need for prior NRC review and approval of either the licensee's categorization process or the results of that process. The Commission intends on achieving this by issuing a detailed and enforceable appendix which would yield consistent, objective, and inspectable results. This appendix is being developed, in part, from existing guidance such as RG 1.174 and from experience gained by review of the South Texas Graded Quality Assurance methodology. Several significant aspects of the proposed categorization technique rely upon subjective and qualitative judgement. For example, it is expected that an expert panel will consider defense-in-depth and margin of safety as part of the assessment of

the significance of SSCs. However, these terms are often defined only in a qualitative, not quantitative, sense. Such terms are difficult to translate into enforceable regulations yielding consistent, objective, and inspectable results. Therefore, use of these concepts within an appendix creates a significant challenge to the NRC. If the NRC cannot develop criteria which result in consistent, objective, and enforceable results, some level of NRC review and approval will be necessary.

No prior NRC review of a licensee's categorization process may affect the public participation process concerning the implementation. With no prior NRC review, public participation would be limited to the rulemaking process. For example, the public could participate by providing input on this advanced notice of proposed rulemaking, on the notice of proposed rulemaking, in public meetings, etc.. However, public participation allowed by the licensing amendment process (i.e., for implementation), including hearing rights on the licensing action, would not be part of the implementation of this effort because no licensing action would need to take place.

The Commission is seeking comment on this issue in Section V.H. of this advance notice of proposed rulemaking.

D. Identification and Control of Attributes Requiring Special Treatment.

The NRC anticipates some SSCs that are not presently subject to special treatment requirements to be identified as significant to plant safety (i.e, RISC-2 SSCs). The NRC further anticipates to find that the existing special treatment requirements do not fully address some risk-significant characteristics of SSCs that are significant to plant safety (RISC-1 and RISC-2 SSCs). This is anticipated to occur because the risk-

informed categorization processes will address some severe accident concerns that are not currently addressed by the special treatment requirements. The Commission expects to develop regulatory controls for RISC-1 and RISC-2 SSCs to ensure risk-significant characteristics of these SSCs are adequately preserved.

The Commission expects some SSCs that are presently subject to special treatment requirements to be identified as being of low significance to plant safety (i.e., RISC-3 SSCs). However, it is not the intent of this effort to redefine the design basis events that a plant must analyze to demonstrate compliance with the regulations. Therefore, this effort will not allow for elimination of these components from the plant. In addition, these components must remain functional to meet the design basis. Accordingly, the Commission expects to develop regulatory controls for RISC-3 to ensure that they would be maintained functional.

The Commission is considering how to identify the risk-significant attributes for RISC-1 and RISC-2 SSCs and what regulatory controls to establish for them to ensure that they are adequately preserved. The Commission is also considering what regulatory controls to establish for RISC-3 SSCs to ensure that they would be maintained functional. The Commission is seeking comment on this issue in Section V.E. of this advance notice of proposed rulemaking.

V. Specific Questions.

Comments, advice, and recommendations on a proposed rule reflecting the features presented above and any other pertinent points are invited from all interested persons. Particularly, comments and supporting reasons are requested on the following questions arranged by topic:

A. Approach.

- A.1. If the NRC elects to pursue a a phased rulemaking approach, how should the rules identified be prioritized/phased?
- 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.
- A.3. Please provide an estimate of the expected costs and benefits of implementing risk-informed special treatment requirements.
- A.4. Please comment of the benefits of risk-informing 10 CFR 50.36?

B. Screening.

B.1. Are the screening criteria reasonable and have the rules that have been evaluated (see Table 1) 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).

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 believe should be considered and the reasons for recommending their inclusion.

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.

C. Categorization Methodology.

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?

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?

- C.3. What are the benefits of defining more than two categories of safety significance?
- C.4. Importance measures are strongly affected by the scope and quality of the PRA. For example, incomplete assessments of risk contributions from low-power and shutdown operations, fires, and human performance will distort the importance rankings. What should be the requirements for assuring PRA quality? What should the scope of the PRA be in terms of initiating events and plant operating modes? If modeled in a PRA, how should the contributions from external event initiators and low power and shutdown operating modes be factored into the results (taking into account that modeling for these events is usually not as complete as that for the internal events)?
- C.5. Even with a full-scope, high quality PRA, the importance measures have limitations. How should these limitations be addressed in Appendix T? What is the role of sensitivity and uncertainty analyses? What is the role of delta risk measures and absolute risk measures?
- C.6. It is essential that the implementation of 10 CFR 50.69 and Appendix T be scrutable and auditable. What requirements are needed to ensure that this is the case? What documents should be available for NRC inspection (e.g., the risk assessment, technical bases documents, inputs to and deliberations of the expert panel) Please provide a discussion to support your comments.

C.7 Does the proposal provide adequate guidance on the use of expert judgement in the form of the integrated decision-making panel to ensure consistent categorization of SSCs across the industry?

D. Pilot Plant Program.

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

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

E. Identification and Control of Special Treatment Attributes.

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?

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

E.3. 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?

- E.4. To what degree should severe accidents be incorporated into the licensing basis under the regulatory effort to risk-inform special treatment requirements?

F. Selective Implementation.

- F.1. What are the potential advantages and disadvantages of selective implementation with regard to selection of rules and selection of systems?
- 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?
- F.3. What limits should be placed on the set of rules for implementation? Should licensees be required to implement all risk-informed rules? If not, what limitations are appropriate?
- F.4. How can the NRC ensure that additional attention is given to risk significant components if selective implementation is allowed?

G. Impact on Other Regulations.

- G.1. What regulations may be affected by risk-informed changes to special treatment requirements in Part 50 and how are these regulations affected?
- G.2. What changes should be considered to provide consistency between affected regulations and risk-informed scope of special treatment?
- G.3. Please comment on the need and appropriateness of applying a risk-informed scope to license renewal (i.e., Part 54)?

H. Need for Prior NRC Review.

- 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?
- H.2. What level of NRC review is appropriate for a facility making the transition to a risk-informed regulatory regime?
- H.3. What regulatory controls need to be placed on licensees to implement risk-informed changes to special treatment without prior NRC approval?

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

The preliminary views expressed in this document may change in light of comments received. In any case, there will be another opportunity for additional public comment in connection with any proposed rule that may be developed by the Commission.

The authority citation for this document is: 42 U.S.C. 2201; 42 U.S.C. 5841.

Dated at Rockville, Maryland, this \_\_\_\_ day of \_\_\_\_\_ 1999.

For the Nuclear Regulatory Commission.

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Annette Vietti-Cook,  
Secretary of the Commission.

Figure 1. Screening Process and Results.

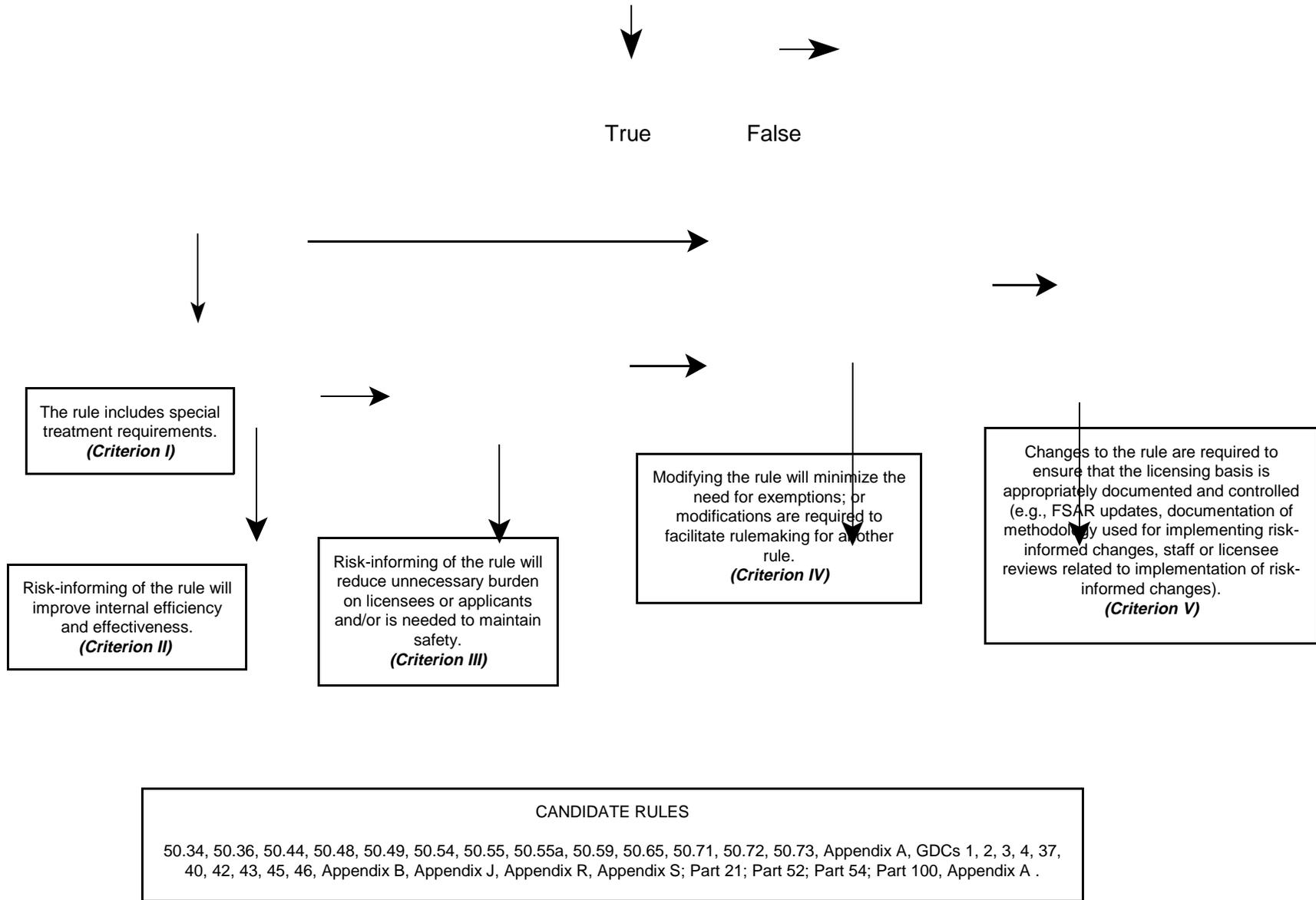




Table 1. Rule Evaluation Matrix (Page 1 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
50.2	Definitions.						
50.4	Written communications.						
50.8	Information collection requirements: OMB approval.						
50.10	License required.						
50.34	Contents of applications; technical information.	x				x	x
50.35	Issuance of construction permits.						
50.36	Technical specifications.	x	x	x			x
50.44	Standards for combustible gas control system in light-water-cooled power reactors.	x	x	x	x		x
50.48	Fire protection.	x	x	x		x	x
50.49	Environmental qualification of electric equipment important to safety for nuclear power plants.	x	x	x	x	x	x
50.54	Conditions of licenses.		x	x	x	x	x
50.55	Conditions of construction permits.	x	x	x	x	x	x
50.55a	Codes and standards.	x	x	x		x	x
50.59	Changes, tests and experiments.	x	x	x	x	x	x
50.62	Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.						
50.65	Requirements for monitoring the effectiveness of maintenance at nuclear power plants.	x	x	x			x
50.71	Maintenance of records, making of reports.	x				x	x
50.72	Immediate notification requirements for operating nuclear power reactors.	x	x	x			x
50.73	License event report system.	x	x	x			x
App. A Intro.	General Design Criteria for Nuclear Power Plants				x		x

Table 1. Rule Evaluation Matrix (Page 2 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
GDC 1	Quality Standards and Records.	x	x	x	x	x	x
GDC 2	Design Bases for Protection Against Natural Phenomena.	x	x	x	x		x
GDC 3	Fire Protection.	x	x	x	x		x
GDC 4	Environmental and Dynamic Effects Design Bases.	x	x	x	x		x
GDC 5	Sharing of Structures, Systems, and Components.						
GDC 14	Reactor Coolant Pressure Boundary.	x					
GDC 16	Containment Design.						
GDC 17	Electric Power Systems.	x					1
		1					
GDC 18	Inspection and Testing of Electric Power Systems.	1					1
GDC 20	Protection System Functions.						
GDC 21	Protection System Reliability and Testability.	1					1
GDC 22	Protection System Independence.	x					
GDC 30	Quality of Reactor Coolant Pressure Boundary.	x					
GDC 32	Inspection of Reactor Coolant Pressure Boundary.	x					1
		1					
GDC 36	Inspection of Containment Heat Removal System.	1					1
GDC 37	Testing of Emergency Core Cooling System.	x	x	x	x		x
		1					1
		2					2
GDC 39	Inspection of Containment Heat Removal System.	1					1

Table 1. Rule Evaluation Matrix (Page 3 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
GDC 40	Testing of Containment Heat Removal System.	x	x	x	x		x
		1					1
		2					2
GDC 42	Inspection of Containment Atmosphere Cleanup Systems.	x	x	x	x		x
		1					1
		2					2
GDC 43	Testing of Containment Atmosphere Cleanup Systems.	x	x	x	x		x
		1					1
		2					2
GDC 44	Cooling Water.						
GDC 45	Inspection of Cooling Water System.	x	x	x	x		x
		1					1
		2					2
GDC 46	Testing of Cooling Water System.	x	x	x	x		x
		1					1
		2					2
GDC 52	Capability for Containment Leakage Rate Testing.	1					1
GDC 53	Provisions for Containment Testing and Inspection.	1					1
GDC 54	Systems Penetrating Containment.	1					1
GDC 55	Reactor Coolant Pressure Boundary Penetrating Containment.	x					
GDC 61	Fuel Storage and Handling and Radioactivity Control.	1					1
App. B	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	x	x	x	x	x	x

Table 1. Rule Evaluation Matrix (Page 4 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
App. E	Emergency Planning and Preparedness for Production and Utilization Facilities						
App. J	Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors	x	x	x			x
App. M	Standardization of Design; Manufacture of Nuclear Power Reactors; Construction and Operation of Nuclear Power Reactors Manufactured Pursuant to Commission License						
App. N	Standardization of Nuclear Power Plant Designs: Licenses to Construct and Operate Nuclear Power Reactors of Duplicate Design at Multiple Sites						
App. R	Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979	x	x	x		x	x
App. S	Earthquake Engineering Criteria for Nuclear Power Plants	x	x	x	x		x
Part 21	REPORTING OF DEFECTS AND NONCOMPLIANCE	x	x	x	x		x
Part 52	EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 54	REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 100 & App. A	REACTOR SITE CRITERIA	x	x	x	x		x

NOTES:

A.9 Includes requirements that components be designed to permit inspection and/or testing.

A.10 Includes requirements that components be designed to permit inspection and/or testing **to assure** the capability of the components. The staff has treated the words **to assure** as requiring actual periodic testing.

## IDENTIFICATION OF CANDIDATE RULES

### 1.0 Introduction

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,'" dated December 23, 1998, the staff proposed three high level options for making the Nuclear Regulatory Commission's (NRC's) regulations risk informed. In a staff requirements memorandum (SRM) dated June 8, 1999, the Commission approved the staff's recommendation. NRR is leading the effort to make the special treatment requirements risk-informed. This paper describes the approach developed by NRR for identifying the rules that should be included in this effort. Several public meetings were held with stakeholders to obtain comments on the staff's efforts, including the approach described in this paper for identifying the rules that should be included. Comments from stakeholders were explicitly solicited during these meetings and extensively utilized throughout this effort.

### 2.0 Scoping Review

Existing regulations require that "special treatment" be applied to "safety-related" and "important to safety" structures, systems, and components (SSCs) and "basic components." Safety-related SSCs are currently defined in 10 CFR 50.2 as --

*Structures, systems and components that are relied upon to remain functional during and following design basis events 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 potential offsite exposures comparable to the applicable guideline exposures set forth in §50.34(a)(1) or §100.11 of this chapter, as applicable.*

Basic component was defined in Section 223.b of the Energy Reorganization Act as --

A facility structure, system, component or part thereof necessary to assure -

- (1) the integrity of the reactor coolant pressure boundary,
- (2) the capability to shut-down the facility and maintain it in a safe shut-down condition, or
- (3) the capability to prevent or mitigate the consequences of accidents which could result in an unplanned offsite release of quantities of fission products in excess of the limits established by the Commission.

Basic component is also defined in 10 CFR Part 21 as --

A.1. (i) *When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure: (A) The integrity of the reactor coolant pressure boundary; (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of this chapter, as applicable.*

*(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, appendix B, or commercial grade items which have successfully completed the dedication process.*

*(2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.*

*(3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.*

A similar definition for basic component is also provided in 10 CFR 50.2.

In addition, the introduction section of Appendix A to 10 CFR Part 50 defines important to safety SSCs as --

*Structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.*

Special treatment is not currently defined in the regulations. However, for purposes of this effort, the following broad definition is used:

*Special treatment requirements are requirements imposed on SSCs that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment*

*requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.*

This definition does not encompass functional design requirements (i.e., a component's functional design requirement is ***not*** considered a special treatment requirement). The above-mentioned definition will apply, hereafter, whenever the term "special treatment" is used.

The above definitions for "safety-related," "important to safety" and "basic component" are deterministically based and stem primarily from the evaluation of selected design basis events. To date, this regulatory framework has provided reasonable assurance of adequate protection of (i.e., no undue risk to) the health and safety of the public. However, recent advances in probabilistic risk assessment technology, coupled with operating reactor experience, have suggested that a better approach, one that maintains safety and reduces unnecessary burden, is possible. It is envisioned that the new approach would utilize a risk-informed process for evaluating the safety significance of SSCs, which would, in turn, result in an improved determination of which SSCs should receive special treatment. It is further envisioned that this new process would help identify the type of special treatment appropriate for the different SSCs. This revised regulatory framework should enable a better focus of both NRC staff and industry resources on issues that are important to plant safety.

In order to identify candidate rules for consideration in this effort, the staff performed a scoping review of all the regulations in 10 CFR Part 50 and other selected parts (Parts 21, 52, 54, and 100). During this review, a rule was selected as a candidate rule if (1) the rule contained “safety-related” or “important to safety” type language, (2) the rule included special treatment requirements, and/or (3) a modification to the rule was judged to be needed in order to facilitate rulemaking or implementation of another rule identified by items (2) and (3). As a result of this review, the following rules were identified:

- 10 CFR Part 50, Sections 50.2, 50.4, 50.8, 50.10, 50.34, 50.35, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.62, 50.65, 50.71, 50.72, and 50.73
- 10 CFR Part 50, Appendix A (General Design Criteria [GDCs] 1, 2, 3, 4, 5, 14, 16, 17, 18, 20, 21, 22, 30, 32, 36, 37, 39, 40, 42, 43, 44, 45, 46, 52, 53, 54, 55, and 61), Appendix B, Appendix E, Appendix J, Appendix M, Appendix N, Appendix R, and Appendix S
- 10 CFR Parts 21, 52, 54, 100, and Appendix A to Part 100

A matrix of these rules and related text was generated and is provided as Table 1, “Rule Text Matrix.” The matrix includes the part and/or section number in the first column, related text in the second column, and general comments related to this

task in the third column. Rules that were specifically identified in SECY-98-300 and the Commission's SRM on SECY-98-300 were not reviewed as part of this task but were included in Table 1 for completeness. These rules (10 CFR 50.36, 50.49, 50.55a, 50.59, 50.65, and Appendix B) were included by the Commission's direction in the SRM.

The above list of rules constitutes the complete set evaluated in the sections that follow.

### 3.0 Development of Screening Criteria and Methodology

Section 2.0 identified a complete set of candidate rules that could be modified by the effort to make the special treatment requirements risk-informed. However, the staff recognizes that changes to some rules may not be warranted nor beneficial from either a stakeholder or a regulatory perspective. Therefore, to implement this effort in an efficient and effective manner, the staff developed a systematic process, including screening criteria and a logic for their application, for selecting the rules that the staff believes should be modified. The screening criteria were based on the following elements: maintaining safety, improving staff efficiency and effectiveness, reducing unnecessary regulatory burden, and increasing public confidence. In addition, and because this effort is focused solely on special treatment requirements, the staff limited its selection to those rules that include special treatment requirements. Rules that would have to be modified in order to efficiently implement rules

identified by the criteria were also included. This resulted in five criteria. A discussion of each criterion follows. A basis for why each criterion was selected and a measure of how the criterion will be applied are included.

Criterion I. The rule includes special treatment requirements.

a. Basis: SECY-98-300 and the SRM in response to SECY-98-300, both indicated that this effort would make changes to rules requiring special treatment. Therefore, this criterion captures the rules that were intended by the staff (in SECY-98-300) and the Commission (in the SRM) to be modified as part of this effort.

b. Measure: Special treatment is defined as follows:

Special treatment requirements are requirements imposed on SSCs that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design

considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.

Therefore, any rule that specifies such requirements satisfies this criterion.

Criterion II. Risk-informing of the rule will improve internal efficiency and effectiveness.

- a. Basis: It is essential that the staff continue to find ways to improve its efficiency and effectiveness as a regulator. This goal can be accomplished by focusing staff resources on safety and risk-significant matters and allowing licensees to address other matters with reduced staff involvement. By developing a risk-informed regulatory framework, the staff will ease the burden (on itself) of regulations that add little to overall safety. This approach will, in turn, allow the staff to focus its efforts on safety-significant issues. This approach should also increase public confidence because a risk-informed regulatory framework will allow the staff to expend more of its resources on significant issues that could potentially affect the public.

- b. Measure: The staff can make a judgment on the amount of internal review and inspection related to a rule and the relationship of such efforts to safety. A rule satisfies this criterion if it is judged that risk-informing of the rule will result in a reduction in unnecessary staff review and inspection.

Criterion III. Risk-informing of the rule will reduce unnecessary burden on licensees or applicants and/or is needed to maintain safety.

- a. Basis: Given that implementation is voluntary, if the risk-informed alternative of a rule results in a net increase in burden to licensees, it is unlikely that the rule will be implemented. Therefore, a rule should only be modified if a reduction in unnecessary burden is anticipated, unless a change to the rule is necessary to allow implementation of another rule (Criterion IV) or is necessary to ensure that safety is maintained.
- b. Measure: The staff can make a preliminary analysis to assess whether risk-informing of a rule represents a reduction or an increase in unnecessary burden. Therefore, a rule satisfies this criterion if the staff judges that risk-informing of the rule will reduce unnecessary burden on licensees. The staff considers industry identification of pilot plants for a specific rule prima facie evidence that risk-informing of the

rule reduces burden. Therefore, the identification of pilot plants for the rule will be considered in the staff's evaluation<sup>8</sup>. A rule also satisfies this criterion if modifications are judged necessary for safety reasons.

Criterion IV. Modifying the rule will minimize the need for exemptions, or modifications are required to facilitate rulemaking for another rule.

- a. Basis: The finding to establish the acceptability of an exemption is similar to the finding necessary to demonstrate the acceptability of an alternative voluntary rule. Therefore, if implementation of a risk-informed alternative to one rule necessitates an exemption from a second rule, the second rule should be included and appropriately modified in this effort. This approach would avoid unnecessary plant-specific submittals and staff reviews of exemption requests. In addition, once a complete set of risk-informed regulations is issued, licensees would be able to implement the rules in combinations that would avoid the need for exemptions. This will (1) increase public confidence by ensuring that the move to a risk-informed regulatory framework involves processes that maximize public participation

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<sup>8</sup>The staff recognizes that industry input on the burden reduction aspect of this criterion should weigh heavily in the final decision with respect to burden reduction. Stakeholder input was explicitly solicited and utilized for evaluating rules against burden reduction. Further evaluation of rules against this criterion may be necessary following formal receipt of comments on this effort.

and (2) reduce industry and staff burden that could result from submittals for exemptions or approvals required to implement a risk-informed regulatory framework.

- b. Measure: A rule satisfies this criterion if it is judged that an exemption to the rule would be necessary in order to implement any of the other rule being modified by this effort.

Criterion V. Changes to the rule are required to ensure that the licensing basis is appropriately documented and controlled (e.g., final safety analysis report (FSAR) updates, documentation of methodology used for implementing risk-informed changes, staff or licensee reviews related to implementation of risk-informed changes).

- a. Basis: This criterion is necessary in order to identify those rules that are related to the control and documentation of the licensing basis so that the staff can determine whether existing rule language is appropriate, inadequate, or excessively burdensome. It is essential that the processes and plant-specific methodologies for the transition be established and documented early in the transition. This step will ensure that the basis for early work in this area is not lost. This step will also ensure that safety is maintained in the long term by providing the risk-informed basis for decisions made in this

process. Ensuring that the licensing basis is appropriately documented and controlled also increases public confidence.

b. Measure: A rule satisfies this criterion if it is related to the control or documentation of the licensing basis.

The above criteria were combined using the following logic for evaluating the candidate rules identified in Section 2.0. This logic is illustrated in Figure 1, "Screening Process and Results."

((I and (II or III)) or IV or V)

#### 4.0 Evaluation of Rules

Following is a rule-by-rule evaluation of the rules identified in Section 2.0 against the criteria presented in Section 3.0.

#### **10 CFR 50.2**

The staff has decided to promulgate new regulations to make the current special treatment requirements contained in 10 CFR Parts 21, 50, 52, 54, and 100, risk informed. The new regulations are expected to include a rule and an appendix, both of which would be included in 10 CFR Part 50. The new rule would identify the special treatment requirements modified by this effort and would specify any additional requirements that would need to be imposed as a result of implementing this rule. Additional clarification of how the current requirements are affected would also be included as necessary. The new appendix would contain elements that a method must meet to be acceptable for categorizing SSCs in a risk-informed manner. The new rule would reference the appendix as necessary to establish the regulatory nature of the elements contained in the appendix. This approach does not require that new terms be defined, and, therefore, no new definition will be added to 10 CFR 50.2.

10 CFR 50.2 does not meet Criterion I, II, III, IV, or V because it does not, in itself, contain any regulatory requirements. Therefore, because it does not meet Criterion I, II, III, IV, or V, the staff concludes that 10 CFR 50.2 should not be included as a candidate.

**10 CFR 50.4 and 50.8**

These rules were identified by the scoping review to flag requirements other than special treatment requirements that may need consideration. These sections do not impose the types of special treatment requirements intended to be risk informed by this effort. However, they do include requirements that may need to be addressed during rulemaking to ensure that changes made by this the rulemaking are consistent with the requirement of these sections. For example, if the rulemaking effort results in recordkeeping or reporting requirements, 10 CFR 50.4 may need to be modified to provide direction on how to make and submit such records or reports. In addition, action may need to be taken by the staff to obtain Office of Management and Budget (OMB) approval for the recordkeeping and reporting requirements imposed by this effort. If such OMB approval is deemed necessary, 10 CFR 50.8 would need to be amended to reflect such an approval.

As discussed above, this effort may result in changes to these sections. However, because such changes are specifically addressed by the rulemaking process and because these sections do not meet Criterion I, II, III, IV, or V, the staff concludes that these sections should not be included as candidates. If the need arises to include these rules, the rulemaking process would ensure that they would be included.

**10 CFR 50.10, 50.35, 50.62, and 10 CFR Part 50, Appendices E, M, and N**

The subject sections include words similar to important to safety and safety-related (e.g., 10 CFR 50.10 includes “structures, systems, and components [SSCs] which prevent or mitigate the consequences of postulated accidents,” 10 CFR 50.35 includes “major features or components incorporated therein for the protection of the health and safety of the public,” 10 CFR 50.62 includes “non-safety-related,” Appendix E includes “safety system,” Appendix M includes “major features or components incorporated therein for the protection of the health and safety of the public,” and “safety features or components,” Appendix N includes “structures, systems, and components important to radiological health and safety”). However, these sections do not contain any ongoing operational requirements applicable to such SSCs. Therefore, they do not impose any special treatment requirements (Criterion I). Since these sections do not impose special treatment requirements, they also do not meet Criterion II or III. This follows because the changes envisioned as part of this effort will only deal with special treatment requirements and their implementation.

The subject sections do not meet Criterion IV because changes to or exemptions from these sections will not be necessary in order to implement rule changes for other rules (i.e., changes to the other rules will not create inconsistencies with these sections). They also do not meet Criterion V.

The staff concludes that 10 CFR 50.10, 10 CFR 50.62, and 10 CFR Part 50, Appendices E, M, and N, should not be included as candidates because they do not meet Criterion I, II, III, IV or V.

**10 CFR 50.34**

Section 50.34 requires that an applicant describe the facility and includes specific documentation requirements for SSCs that are important to safety. These include documentation of the adequacy of SSCs provided for the prevention of accidents and mitigation on the consequences of accidents, documentation of potential hazards to SSCs important to safety from construction activities, and documentation of conformance with or justification for deviation from the standard review plan. These requirements are considered to include special treatment attributes (Criterion I).

Risk-informing of 10 CFR 50.34 may not result in a reduction of burden on the staff or licensees. Risk-informing of 10 CFR 50.34 may, in fact, result in an increased but necessary burden to ensure that the basis for classification of equipment under the risk-informed regulatory framework is captured (Criteria II and III).

Risk-informing of other rules in this effort is not expected to necessitate an exemption from 10 CFR 50.34 (Criterion IV). Appropriate documentation of the methods and governing processes for classification of SSCs is essential to ensuring that the licensing basis is maintained and understood. Accordingly, the staff should evaluate the requirements in 10 CFR 50.34 to determine whether existing rule language is appropriate, inadequate, or excessively burdensome (Criterion V).

The staff concludes that 10 CFR 50.34 should be included as a candidate because it meets Criterion V.

### **10 CFR 50.36**

Section 50.36 imposes surveillance and monitoring requirements that are considered special treatments (Criterion I). It is expected that in the long run risk-informing of 10 CFR 50.36 will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to be included in the technical specifications (TS). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities. Risk-informing of 10 CFR 50.36 is also expected to improve staff efficiency and effectiveness and reduce unnecessary burden as related to applicants for the same reasons discussed above.

The staff recognizes that burden reduction for existing licensees would come only after applications for TS amendments to remove such equipment from the current TS are submitted by the licensees and reviewed and approved by the staff, as required by Sections 50.90 and 50.92. Therefore, an initial increase in burden, in addition to that required for implementing the remainder of this effort, is expected before the benefits from a risk-informed 50.36 can be realized. This makes judgment on staff efficiency and burden reduction for licensees from including 50.36 in this effort difficult.

However, risk-informing of 50.36 would ensure that safety is maintained by ensuring that SSCs of high safety significance are included in the TS (Criterion III). In addition, highlighting the importance of such SSCs will allow the staff to implement regulatory measures to activities related to these SSCs, thereby allowing for improvements in staff effectiveness (Criterion II). Therefore, risk-informing of 10 CFR 50.36 would allow the NRC staff and licensees to focus attention on matters significant to safety.

Risk-informing of other rules in this effort is not expected to necessitate exemptions from 10 CFR 50.36 because changes to the other rules are not affected by the specific requirements in Section 50.36 (Criterion IV). In addition, changes to Section 50.36 are not needed to ensure that the risk-informed licensing basis is appropriately documented and controlled. Such requirements that ensure that changes to the licensing basis are documented and controlled are included in others rules, not in Section 50.36 (Criterion V).

The staff concludes that 10 CFR 50.36 should be included as a candidate because it meets Criteria I, II and III.

#### **10 CFR 50.44**

Section 50.44 includes equipment qualification requirements for SSCs necessary to establish and maintain safe shutdown and to maintain containment integrity. These requirements are considered special treatment requirements (Criterion I). It is

expected that risk-informing of this rule will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive this special treatment (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

In addition, licensees could have demonstrated compliance with the requirements in 10 CFR 50.44 on the basis of meeting similar or bounding requirements of other rules (e.g., 10 CFR 50.49). Therefore, changes to other rules may result in the need for exemptions from 10 CFR 50.44 (Criterion IV). Section 50.44 does not require documentation of the licensing basis and, therefore, does not meet Criterion V.

The staff concludes that 10 CFR 50.44 should be included as a candidate because it meets Criteria I, II, III, and IV.

#### **10 CFR 50.48 and 10 CFR Part 50, Appendix R**

The subject rules impose equipment protection requirements that are considered special treatments (Criterion I). It is not clear at this time if risk-informing of the scope of these rules will reduce staff or licensee burden. However, industry feedback during public meetings indicates that experience in the application of risk information to this area has identified SSCs that may otherwise not be classified as safety significant. Accordingly, risk-informing of these rules will ensure that safety is

maintained by ensuring that such SSCs are included in their scope (Criterion III). In addition, highlighting the importance of such SSCs will allow the staff to implement regulatory measures to activities related to these SSCs, thereby allowing for improvements in staff effectiveness (Criterion II).

Risk-informing of other rules is not expected to necessitate exemptions from 10 CFR 50.48 or 10 CFR Part 50, Appendix R (Criterion IV). However, changes to these rules may be needed to ensure that the risk-informed licensing basis is appropriately documented and controlled. This need arises from requirements in these rules for documentation of the fire protection plan (Criterion V).

The staff concludes that 10 CFR 50.48 and 10 CFR Part 50, Appendix R, should be included as candidates because they meet Criteria I, II, III, and V.

#### **10 CFR 50.49**

Section 50.49 imposes environmental qualification requirements that are considered special treatments (Criterion I). It is expected that risk-informing of 10 CFR 50.49 will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff

to focus its resources on more risk-significant activities (Criterion II). In addition, the specific requirements for environmental qualification of SSCs stem from the general requirements contained in GDC 4. Therefore risk-informing of GDC 4 may necessitate exemptions from 10 CFR 50.49 (Criterion IV).

Changes to 10 CFR 50.49 may be needed to ensure that the risk-informed licensing basis is appropriately documented and controlled. This need arises from the requirement in this rule for documentation of a licensee's program for meeting this rule (Criterion V).

The staff concludes that 10 CFR 50.49 should be included as a candidate because it meets all five criteria.

#### **10 CFR 50.54**

Section 50.54(a) requires staff review and approval of any reduction in commitments in the licensee's quality assurance program that the licensee committed to in compliance with 10 CFR Part 50, Appendix B. Because Section 50.54(a) is a programmatic change requirement, it is not considered a special treatment requirement (Criterion I). However, because this programmatic change requirement is directly related to special treatment requirements, risk-informing of this requirement (i.e., limiting its scope to changes that affect SSCs that are significant to the safety of the plant) is expected to result in less staff effort being expended to review such changes (Criterion II). Furthermore, by reducing the scope of this requirement, a

licensee would be able to make such risk-informed downgrades without having to first submit applications and obtain staff approval for the downgrade (Criterion III). In addition, 10 CFR 50.54 imposes license conditions that stem directly from and invoke specific requirements of other rules (e.g., 10 CFR 50.34, 50.71, and 50.72). Therefore, changes to the specific requirements in these rules may result in a need for exemptions from 10 CFR 50.54 (Criterion IV). In addition, 10 CFR 50.54 imposes license conditions on the documentation and control of the licensing basis, which may need to be modified to ensure that the justifications for decisions related to special treatment requirements, that result from this effort, are captured (Criterion V).

The staff concludes that 10 CFR 50.54 should be included as a candidate because it meets Criteria II, III, IV, and V.

### **10 CFR 50.55**

Section 50.55 requires holders of a construction permit subject to this part to adopt procedures to identify and report defects and failures of a basic component to comply with any rule, regulation, order, or license relating to a substantial safety hazard. This rule imposes reporting requirements (i.e., special treatment requirements) on certain SSCs (Criterion I). It is expected that risk-informing of 10 CFR 50.55 would reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

Similar requirements for identifying and reporting defects and failures of a basic component are also contained in 10 CFR Part 21. Risk-informing of 10 CFR 50.55 would be appropriate in order to minimize the need for exemptions that may result from implementation of risk-informed requirements under 10 CFR Part 21 (Criterion IV). In addition, changes to 10 CFR 50.55 may be needed to ensure that the risk-informed licensing basis is appropriately documented and controlled. This need arises from the requirement in this rule for documentation of a licensee's quality assurance program for meeting this rule (Criterion V).

The staff concludes that 10 CFR 50.55 should be included as a candidate because it meets all five criteria.

#### **10 CFR 50.55a**

Section 50.55a imposes inspection, testing, and American Society of Mechanical Engineers Boiler and Pressure Vessel Code (ASME Code) special treatment and design requirements on certain SSCs (Criterion I). It is expected that risk-informing of 10 CFR 50.55a will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

Risk-informing of other rules in this effort is not expected to necessitate an exemption from 10 CFR 50.55a (Criterion IV). Section 50.55a, through endorsement of the ASME Code, requires documentation of licensee programs for meeting the special treatment requirements imposed by this section. Changes to the scope of such programs as a result of risk-informed processes may need to be justified in the documentation of these programs. Therefore, documentation requirements imposed by 10 CFR 50.55a should be evaluated for their adequacy under the risk-informed regulatory framework (Criterion V).

The staff concludes that 10 CFR 50.55a should be included as a candidate because it meets Criterion I, II, III, and V.

#### **10 CFR 50.59**

Any change to SSCs or procedures described in the FSAR must be evaluated in accordance with the specific requirement of 10 CFR 50.59. Therefore, for a licensee to exclude any SSC or procedure from the scope of other special treatment rules, the licensee must either establish that the SSC or procedure is not described in the FSAR or that the change does not involve an unreviewed safety question. Otherwise, the licensee must obtain NRC approval before the change. This is considered a special treatment requirement (Criterion I).

In this effort, the staff will promulgate regulations that, when implemented, would, in part, allow licensees to redefine the scope of special treatment requirements in a risk-informed manner. Implementation of such rules would only be allowed for licensees that have acceptable categorization methods. Therefore, since the staff is, in effect, approving a licensee's categorization process for establishing the scope of special treatment rules, it may not be necessary for the staff to review every change that results from the process. Risk-informing of 10 CFR 50.59 to accomplish this goal would reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II). In addition, Risk-informing of 10 CFR 50.59 would reduce the efforts expended by licensees on generating applications for staff reviews (Criterion III). It should be noted that licensee efforts for evaluating the specific changes may not be reduced but may take a different form than is specified in the current 10 CFR 50.59.

The need for the special treatment requirements in 10 CFR 50.59 should be evaluated further for SSCs when the change results from a process that meets the risk-informed rules that will be promulgated by this effort. If the 10 CFR 50.59 requirements are determined unnecessary because of the acceptability of the licensee's process, exemptions would be appropriate from 10 CFR 50.59. To efficiently implement the rules resulting from this effort, exemptions should be minimized and, therefore, 10 CFR 50.59 should be considered for modification to address such situations (Criterion IV). In addition, 10 CFR 50.59 imposes requirements for documentation of changes performed under this section. Changes to take SSCs out of the scope of other special treatment rules (e.g., Sections 50.34 and 50.71) can lead to taking these SSCs out of the scope of

the requirement in 10 CFR 50.59. The staff needs to evaluate the appropriate level and type of documentation necessary for removal of equipment out of the scope of special treatment rules, including 10 CFR 50.59 (Criterion V).

The staff concludes that 10 CFR 50.59 should be included as a candidate because it meets all five criteria.

### **10 CFR 50.65**

This rule imposes performance monitoring and risk assessment requirements for SSCs within its scope. Such requirements are considered special treatments (Criterion I). It is expected that risk-informing of 10 CFR 50.65 will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II). Risk-informing of other rules is not expected to necessitate exemptions from 10 CFR 50.65 (Criterion IV). In addition, 10 CFR 50.65 does not include requirements for the type of documentation addressed by Criterion V and, therefore, does not meet this criterion.

The staff concludes that 10 CFR 50.65 should be included as a candidate because it meets Criteria I, II, and III.

**10 CFR 50.71**

Section 50.71 imposes documentation and update requirements for records and reports required by license conditions and other regulations, including FSAR updates. One such example is 10 CFR 50.34, which requires that an applicant describe the facility and includes specific documentation requirements for SSCs that are important to safety. These requirements include documentation of the adequacy of SSCs provided for the prevention of accidents and mitigation on the consequences of accidents, documentation of potential hazards to SSCs important to safety from construction activities, and documentation of conformance with or justification for deviation from the standard review plan. These requirements in 10 CFR 50.34 are considered to include special treatment attributes. Accordingly, the documentation and update of these reports in accordance with the requirements in 10 CFR 50.71 are also considered to include special treatment attributes (Criterion I).

Risk-informing of 10 CFR 50.71 may not result in a reduction of burden on the staff or licensees. Risk-informing of 10 CFR 50.71 may, in fact, result in increased but necessary burden to ensure that the basis for change under the risk-informed regulatory framework is captured (Criteria II and III).

Risk-informing of other rules is not expected to necessitate an exemption from 10 CFR 50.71 (Criterion IV). Appropriate documentation of the methods and governing processes for classification of SSCs is essential to ensuring that the licensing

basis is maintained and understood. Accordingly, the staff should evaluate the requirements in 10 CFR 50.71 to determine whether existing rule language is appropriate, inadequate, or excessively burdensome (Criterion V).

The staff concludes that 10 CFR 50.71 should be included as a candidate because it meets Criterion V.

### **10 CFR 50.72 and 10 CFR 50.73**

Sections 50.72 and 50.73 impose notification and reporting requirements for events affecting certain SSCs. These notification and reporting requirements are considered special treatments (Criterion I). Risk-informing of 10 CFR 50.72 and 50.73 is expected to reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

Risk-informing of other rules is not expected to necessitate exemption from 10 CFR 50.72 and 50.73 (Criterion IV). In addition, these sections do not include requirements for the type of documentation addressed by Criterion V and, therefore, do not meet this criterion.

The staff concludes that 10 CFR 50.72 and 50.73 should be included as candidates because they meet Criteria I, II, and III.

**10 CFR Part 50, Appendix A, Introduction**

The introduction section of 10 CFR Part 50, Appendix A, includes the words “important to safety” and a definition for important to safety SSCs. “Important to safety” is used throughout Appendix A. Some GDCs and other rules that impose special treatment requirements use this term in defining their scope. Therefore, while the introduction section of Appendix A does not, in itself, impose special treatment requirements (Criterion I), it does, in effect, define the scope of GDCs and rules that do impose such requirements. Therefore, because of the interdependence of the introduction and some special treatment requirements, the introduction section of Appendix A meets Criterion IV.

Since this section does not impose special treatment requirements, it does not, by itself, meet Criterion II or III. This section does not require documentation of the licensing basis and, therefore, does not meet Criterion V.

The staff concludes that the introduction section to 10 CFR Part 50, Appendix A, should be included as a candidate because it meets Criterion IV.

**10 CFR Part 50, Appendix A, GDC 1, and 10 CFR Part 50, Appendix B**

The subject rules impose quality assurance requirements (i.e., special treatment requirements) on certain SSCs (Criterion I). It is expected that risk-informing of these rules will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

In addition, licensees could have demonstrated compliance with the requirements in one rule (e.g., 10 CFR Part 50, Appendix A, GDC 1) because it meets similar or bounding requirements of another rule (e.g., 10 CFR Part 50, Appendix B). Therefore, changes to the scope of the second rule may result in the need for exemptions from the first (Criterion IV).

These rules require documentation of licensee programs related to the licensing basis and, therefore, meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDC 1, and 10 CFR Part 50, Appendix B, should be included as candidates because they meet all the criteria.

**10 CFR Part 50, Appendix A, GDCs 2 and 4; 10 CFR Part 50, Appendix S; and 10 CFR Part 100, Appendix A**

The subject rules impose equipment qualification requirements with respect to natural phenomena (10 CFR Part 50, Appendix A, GDC 2), environmental and dynamic events (10 CFR Part 50, Appendix A, GDC 4), and seismic events (10 CFR Part 50, Appendix S, and 10 CFR Part 100, Appendix A). These requirements are considered special treatment requirements (Criterion I). It is expected that risk-informing of the scopes of these rules will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

In addition, licensees could have demonstrated compliance with requirements in one rule (e.g., 10 CFR Part 50, Appendix A, GDC 4) because it meets similar or bounding requirements of another rule (e.g., 10 CFR 50.49). Therefore, changes to the scope of the second rule may result in the need for exemptions from the first (Criterion IV).

These rules do not, in themselves, require documentation of the licensing basis and, therefore, do not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDCs 2 and 4; 10 CFR Part 50, Appendix S; and 10 CFR Part 100, Appendix A, should be included as candidates because they meet Criteria I, II, III, and IV.

**10 CFR Part 50, Appendix A, GDC 3**

The specific requirements in 10 CFR 50.48 and 10 CFR Part 50, Appendix R, stem from the general requirements in 10 CFR Part 50, Appendix A, GDC 3. Therefore, the subject GDC meets Criteria I, II, and III in the same manner as was discussed earlier for 10 CFR 50.48 and 10 CFR Part 50, Appendix R.

GDC 3 should be evaluated further to determine if it would need modification to allow implementation of a risk-informed 10 CFR 50.48 and 10 CFR Part 50, Appendix R (Criterion IV). GDC 3 does not include requirements for documentation and therefore does not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDC 3, should be included as a candidate because it meets Criteria I, II, III, and IV.

**10 CFR Part 50, Appendix A, GDCs 5, 16, 20, and 44**

The subject GDCs set forth design requirements for SSCs that are important to safety. However, these GDCs do not contain any ongoing operational requirements for such SSCs. Therefore, they do not impose any special treatment requirements (Criterion I). Since the GDCs do not impose special treatment requirements, they also do not meet Criterion II or III. This follows because the changes envisioned as part of this effort will only deal with the implementation of special treatment requirements.

The subject GDCs do not meet Criterion IV because changes to or exemptions from the GDCs will not be necessary in order to implement rule changes resulting from this effort (i.e., changes resulting from this effort will not create inconsistencies with these GDCs). The subject GDCs do not include requirements for documentation and, therefore, do not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDCs 5, 16, 20, and 44, should not be included as candidates because these GDCs do not meet Criterion I, II, III, IV or V.

**10 CFR Part 50, Appendix A, GDCs 14, 17, 22, 30, 32, and 55**

The subject GDCs impose quality assurance, environmental qualification, and/or testing special treatment requirements on the associated SSCs (Criterion I). However, it was judged that these GDCs do not meet Criterion II or III because it is not expected that a risk-informed process would alleviate any of the requirements imposed by these GDCs on the associated SSCs. The subject GDCs do not meet Criterion IV because changes to or exemptions from the GDCs will not be necessary in order to implement rule changes resulting from this effort (i.e., changes resulting from this effort will not create inconsistencies with these GDCs). The subject GDCs do not include requirements for documentation and, therefore, do not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDCs 14, 17, 22, 30, 32, and 55, should not be included as candidates because these GDCs do not meet Criterion II, III, IV or V.

**10 CFR Part 50, Appendix A, GDCs 18, 21, 36, 39, 52, 53, 54, and 61**

The subject GDCs require that associated SSCs be designed to permit inspection and/or testing. However, these GDCs do not contain inspection or testing requirements for the SSCs. Therefore, the GDCs do not impose special treatment requirements (Criterion I). Since the GDCs do not impose special treatment requirements, they also do not meet Criterion II or III. This follows because the changes envisioned as part of this effort will only deal with the implementation of special treatment requirements.

The subject GDCs do not meet Criterion IV because changes to or exemptions from the GDCs will not be necessary in order to implement rule changes resulting from this effort (i.e., changes resulting from this effort will not create inconsistencies with these GDCs). The subject GDCs do not include requirements for documentation and, therefore, do not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDCs 18, 21, 36, 39, 52, 53, 54, and 61, should not be included as candidate rules because these GDCs do not meet Criterion I, II, III, IV or V.

**10 CFR Part 50, Appendix A, GDCs 37, 40, 42, 43, 45, and 46**

The subject GDCs require that associated SSCs be designed to permit inspection and/or testing to assure the functional capability of these SSCs throughout the term of operation. The staff has treated the words “to assure” as requiring testing of the SSCs. These GDCs are, therefore, considered to include special treatment requirements (Criterion I). It is expected that risk-informing of these GDCs will reduce unnecessary burden on licensees because the scope of SSCs that would be required to be tested would be reduced (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to such testing and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II). Risk-informing of rules or licensee programs that implement such testing requirements would necessitate exemptions from these GDCs. Therefore, these GDCs also meet Criterion IV.

The subject GDCs do not require documentation of the licensing basis and, therefore, do not meet Criterion V.

The staff concludes that 10 CFR Part 50, Appendix A, GDCs 37, 40, 42, 43, 45, and 46, should be included as candidates because these GDCs meet Criteria I, II, III, and IV.

**10 CFR Part 50, Appendix J**

Appendix J imposes testing requirements that are considered special treatments (Criterion I). The staff judges that risk-informing of this appendix may lead to less testing and, therefore, reduce unnecessary burden on the licensees (Criterion III). In addition, risk-informing of Appendix J could also lead to improvements in staff efficiency and effectiveness (Criterion II) by allowing the staff to focus its inspection efforts on more significant activities. Although the 1995 revision to Appendix J was labeled as being “risk-informed,” the changes were not as extensive as those expected in this effort. The revision primarily decreased testing frequencies, whereas redefining the scope of this appendix may remove some SSCs from testing altogether.

Risk-informing of other rules included in this effort is not expected to necessitate exemption from Appendix J (Criterion IV). In addition, changes to Appendix J are not needed to ensure that the risk-informed licensing basis is appropriately documented and controlled (Criterion V). Such requirements that ensure that changes to the licensing basis are documented and controlled are included in other rules.

The staff concludes that 10 CFR Part 50, Appendix J, should be included as a candidate because it meets Criteria I, II, and III.

**10 CFR Part 21**

Part 21 imposes reporting and documentation requirements on certain SSCs. These reporting and documentation requirements are considered special treatments (Criterion I). It is expected that risk-informing of this part will reduce unnecessary burden on licensees by reducing the scope of SSCs that would be required to receive these special treatments (Criterion III). This step would also reduce the efforts expended by the staff for reviewing and inspecting licensee actions related to these requirements and would, therefore, allow the staff to focus its resources on more risk-significant activities (Criterion II).

Basic components, to which the requirements in 10 CFR Part 21 apply, by definition include items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, Appendix B. Therefore, risk-informing of the scope of 10 CFR Part 50, Appendix B, may necessitate exemptions from Part 21 in order to allow an SSC designated by Part 21 as a basic component to not be designed and manufactured under a quality assurance program complying with 10 CFR Part 50, Appendix B. Otherwise, the current 10 CFR Part 50, Appendix B, may still be required by Part 21 to apply to all basic components. Therefore, risk-informing of Part 21 is necessary to minimize the need for such exemptions (Criterion IV).

Part 21 does not include requirements for the type of documentation addressed by Criterion V and, therefore, does not meet this criterion.

The staff concludes that 10 CFR Part 21 should be included as a candidate because it meets Criteria I, II, III, and IV.

### **10 CFR Parts 52 and 54**

Parts 52 and 54 include, by reference, rules from other parts of Chapter 10 of the Code of Federal Regulations, including all of Part 50 and its appendices. Therefore, as a result of inclusion of rules that, when taken together, satisfy Criteria I, II, III, IV, and V, Parts 52 and 54 also satisfy these criteria.

The staff concludes that 10 CFR Parts 52 and 54 should be included as candidates because they meet all five criteria.

Table 2, "Rule Evaluation Matrix," summarizes the results of these evaluations. The table presents (1) each of the rules identified in Section 2.0, (2) the results of the evaluation of each rule against each of the five screening criteria developed in Section 3.0, and (3) the staff's conclusions on inclusion of the rules in this effort. An "x" in any of the screening criteria columns of the table represents an answer of "true" to the corresponding screening criterion. An "x" in the last (far right) column represents a conclusion that the rule should be included as a candidate rule in this effort.

Table 2 includes two notes. Note 1 indicates that the corresponding GDC includes a requirement that the subject components be designed to permit inspection and/or testing. Note 2 indicates that the corresponding GDC includes requirements for periodic testing of the associated components.

As a result of the staff's evaluations of the candidate rules identified in Section 2.0 in accordance with the evaluation process described in Section 3.0, the staff has identified the following rules as candidates for this effort:

- 10 CFR Part 50, Sections 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, and 50.73
- 10 CFR Part 50, Appendix A (GDCs 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46), Appendix B, Appendix J, Appendix R, and Appendix S
- 10 CFR Parts 21, 52, 54, 100, and Appendix A to Part 100

The results of the evaluations are also shown in Figure 1. The bottom-most box in Figure 1 presents the rules that have been identified as candidates for this effort.

A more detailed evaluation of each candidate rule and the specific requirements within each rule will be conducted for the proposed rulemaking. The review at that time will be conducted in a manner to evaluate contemplated changes with respect to their effects on safety.

## 5.0 Summary and Conclusions

The staff has developed and applied a systematic approach to identify the rules that should be included in this effort. The staff first conducted a scoping review of all the regulations in 10 CFR Part 50 and other selected parts and identified a set of candidate rules for inclusion in this effort (Section 2.0). The staff then developed screening criteria and a logic for applying these criteria in order to identify the subset of rules to which risk-informed changes can be made consistent with the intent of this effort (Section 3.0). The screening criteria were based on the following elements: maintaining safety, improving staff efficiency and effectiveness, reducing unnecessary regulatory burden, and increasing public confidence. In addition and because this effort is focused solely on special treatment requirements, the staff limited its selection to those rules that include special treatment requirements and those in which changes would be necessary in order to efficiently implement changes to rules that include such requirements. The criteria and logic were then applied to the set of candidate rules for this effort (Section 4.0). As a result, the staff concludes that the following list of candidate rules should be included in this effort:

- 10 CFR Part 50, Sections 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, and 50.73

- 10 CFR Part 50, Appendix A (GDCs 1, 2, 3, 4, 37, 40, 42, 43, 45, and 46), Appendix B, Appendix J, Appendix R, and Appendix S
- 10 CFR Parts 21, 52, 54, 100, and Appendix A to Part 100

RULE	RELATED TEXT	COMMENTS
50.2	<p><b>Basic component</b> means, for the purposes of §50.55(e) of this chapter: (1) When applied to nuclear power reactors, any plant structure, system, component, or part thereof necessary to assure (i) The integrity of the reactor coolant pressure boundary, (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of this chapter, as applicable. (2) When applied to other types of facilities or portions of such facilities for which construction permits are issued under §50.23, a component, structure, system or part thereof that is directly procured by the construction permit holder for the facility subject to the regulations of this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. (3) In all cases, <b>basic component</b> includes <b>safety related</b> design, analysis, inspection, testing, fabrication, replacement parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.</p>	
50.2	<p>Construction or constructing means, for the purposes of §50.55(e), 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 <b>safety related</b>.</p>	
50.2	<p>Defect means, for the purposes of §50.55(e) of this chapter: (1) A deviation in a <b>basic component</b> delivered to a purchaser for use in a facility or activity subject to a construction permit under this part, if on the basis of an evaluation, the deviation could create a substantial safety hazard; or (2) The installation, use, or operation of a <b>basic component</b> containing, a defect as defined in paragraph (1) of this definition; or (3) A deviation in a portion of a facility subject to the construction permit of this part provided the deviation could, on the basis of an evaluation, create a substantial safety hazard.</p>	

Table 1. Rule Text Matrix (Page 2 of 1)

RULE	RELATED TEXT	COMMENTS
50.2	Deviation means, for the purposes of §50.55(e) of this chapter, a departure from the technical or quality assurance requirements defined in procurement documents, safety analysis report, construction permit, or other documents provided for <b>basic components</b> installed in a facility subject to the regulations of this part.	
50.2	Procurement document means, for the purposes of §50.55(e) of this chapter, a contract that defines the requirements which facilities or <b>basic components</b> must meet in order to be considered acceptable by the purchaser.	
50.2	<b>Safety-related</b> structures, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events 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 potential offsite exposures comparable to the applicable guideline exposures set forth in §50.34(a)(1) or §100.11 of this chapter, as applicable.	
50.2	Station blackout means the complete loss of alternating current (ac) electric power to the <b>essential</b> and <b>nonessential</b> switchgear buses in a nuclear power plant (i.e., loss of offsite electric power system concurrent with turbine trip and unavailability of the onsite emergency ac power system).	
50.4		May need to modify to include potentially new documentation/reporting requirements.
50.8		May need approval for collection of information.

Table 1. Rule Text Matrix (Page 3 of 1)

RULE	RELATED TEXT	COMMENTS
50.10(e)(1)(v)	<p>The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to §51.20(b) of this chapter, and is of the type specified in §50.21(b) (2) or (3) or §50.22 or is a testing facility to conduct the following activities: ... and (v) the construction of <b><u>structures, systems and components which do not prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.</u></b></p>	
50.10(e)(3)(i)	<p>The Director of Nuclear Reactor Regulation may authorize an applicant for a construction permit for a utilization facility which is subject to §51.20(b) of this chapter, and is of the type specified in §50.21(b) (2) or (3) or §50.22 or is a testing facility to conduct, in addition to the activities described in paragraph (e)(1) of this section, the installation of structural foundations, including any necessary subsurface preparation, for <b><u>structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.</u></b></p>	
50.34(a)(1)(i)	<p>The assessment must contain an analysis and evaluation of the <b><u>major structures, systems and components of the facility which bear significantly on the acceptability of the site under the site evaluation factors identified in part 100 of this chapter.</u></b></p>	
50.34(a)(1)(ii)(D)	<p><b><u>The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents.</u></b></p>	
50.34(a)(4)(ii)	<p>...the adequacy of <b><u>structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.</u></b></p>	
50.34(a)(11)	<p>On or after February 5, 1979, applicants who apply for construction permits for nuclear powerplants to be built on multiunit sites shall identify potential hazards to the structures, systems and components <b><u>important to safety</u></b> of operating nuclear facilities from construction activities.</p>	

Table 1. Rule Text Matrix (Page 4 of 1)

RULE	RELATED TEXT	COMMENTS
50.34(b)(2)(i)	For nuclear reactors, such items as the reactor core, reactor coolant system, instrumentation and control systems, electrical systems, containment system, <b><u>other engineered safety features, auxiliary and emergency systems,</u></b> power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent.	
50.34(b)(2)(ii)	For facilities other than nuclear reactors, such items as the chemical, physical, metallurgical, or nuclear process to be performed, instrumentation and control systems, ventilation and filter systems, electrical systems, <b><u>auxiliary and emergency systems,</u></b> and radioactive waste handling systems shall be discussed insofar as they are pertinent.	
50.34(b)(4)	A final analysis and evaluation of the design and performance of <b><u>structures, systems, and components with the objective stated in paragraph (a)(4)</u></b> of this section and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report.	
50.34(b)(6)(ii)	Managerial and administrative controls to be used to assure safe operation. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for such controls for nuclear power plants and fuel reprocessing plants. The information on the controls to be used for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied.	Included in the South Texas exemption request.
50.34(b)(6)(vii)	On or after February 5, 1979, applicants who apply for operating licenses for nuclear power plants to be operated on multiunit sites shall include an evaluation of the potential hazards to the structures, systems, and components <b><u>important to safety</u></b> of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multiunit sites.	

Table 1. Rule Text Matrix (Page 5 of 1)

RULE	RELATED TEXT	COMMENTS
50.34(b)(11)	On or after January 10, 1997, stationary power reactor applicants who apply for an operating license pursuant to this part, or a combined license pursuant to part 52 of this chapter, shall provide a description and safety assessment of the site and of the facility as in §50.34(a)(1)(ii) of this part. However, for either an operating license applicant or holder whose construction permit was issued prior to January 10, 1997, the reactor site criteria in part 100 of this chapter and the seismic and geologic siting criteria in Appendix A to part 100 of this chapter continues to apply.	Included in the South Texas exemption request.
50.34(f)(1)(x)	Perform a study to ensure that the Automatic Depressurization System, valves, accumulators, and associated equipment and instrumentation will be capable of performing their intended functions during and following an accident situation, taking no credit for <b>non-safety related</b> equipment or instrumentation, and accounting for normal expected air (or nitrogen) leakage through valves. (Applicable to BWR's only). (II.K.3.28)	
50.34(f)(2)(ix)(C)	<b><u>Equipment necessary for achieving and maintaining safe shutdown of the plant and maintaining containment integrity</u></b> will perform its safety function during and after being exposed to the environmental conditions attendant with the release of hydrogen generated by the equivalent of a 100% fuel-clad metal water reaction including the environmental conditions created by activation of the hydrogen control system.	
50.34(f)(2)(xiv)	Provide containment isolation systems that: (II.E.4.2) (A) Ensure all <b>non-essential</b> systems are isolated automatically by the containment isolation system, (B) For each <b>non-essential</b> penetration (except instrument lines) have two isolation barriers in series,	
50.34(f)(2)(xx)	Provide power supplies for pressurizer relief valves, block valves, and level indicators such that: (A) Level indicators are powered from vital buses; (B) motive and control power connections to the emergency power sources are through devices qualified in accordance with requirements applicable to systems <b>important to safety</b> and (C) electric power is provided from emergency power sources. (Applicable to PWR's only). (II.G.1)	
50.34(f)(3)(ii)	Ensure that the quality assurance (QA) list required by Criterion II, app. B, 10 CFR part 50 includes all structures, systems, and components <b>important to safety</b> . (I.F.1)	

Table 1. Rule Text Matrix (Page 6 of 1)

RULE	RELATED TEXT	COMMENTS
50.35(a)(1)	...and has identified the <b><u>major features or components incorporated therein for the protection of the health and safety of the public;</u></b>	
50.36		Included in SECY-98-300.
50.44(c)(3)(iv)(E)	If the hydrogen control system relies on post-accident inerting, the <b><u>systems and components required to establish and maintain safe shutdown and containment integrity</u></b> must be designed and qualified for the environment caused by such inerting. Furthermore, inadvertent full inerting during normal plant operations must not adversely affect <b><u>systems and components needed for safe operation of the plant.</u></b>	Environmental qualification.
50.44(c)(3)(v)(A)	Each licensee with a boiling light-water nuclear power reactor with a Mark III type of containment and each licensee with a pressurized light-water nuclear power reactor with an ice condenser type of containment issued a construction permit before March 28, 1979, for a reactor that does not rely upon an inerted atmosphere to control hydrogen inside the containment, shall provide its nuclear power reactor with <b><u>systems and components necessary to establish and maintain safe shutdown and to maintain containment integrity. These systems and components must be capable of performing their functions during and after exposure to the environmental conditions created by the burning of hydrogen.</u></b> Environmental conditions caused by local detonations of hydrogen must also be included, unless such detonations can be shown unlikely to occur.	Environmental qualification.
50.44(c)(3)(vi)(B)(5)(ii)	<b><u>Systems and components necessary to establish and maintain safe shutdown and to maintain containment integrity</u></b> will be capable of performing their functions during and after exposure to the environmental conditions created by the burning of hydrogen, including the effect of local detonations, unless such detonations can be shown unlikely to occur.	Environmental qualification.

Table 1. Rule Text Matrix (Page 7 of 1)

RULE	RELATED TEXT	COMMENTS
50.48(a)	The plan must also describe specific features necessary to implement the program described above, such as administrative controls and personnel requirements for fire prevention and manual fire suppression activities, automatic and manually operated fire detection and suppression systems, and the means to limit fire damage to structures, systems, or components <b>important to safety</b> so that the capability to safely shut down the plant is ensured. <sup>(3)</sup>	Environmental qualification and protection of equipment.
50.49		Included in SECY-98-300.  Included in the South Texas exemption request.
50.54(a)(3)	Each licensee described in paragraph (a)(1) of this section <b><u>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.</u></b>  <b><u>Changes to the quality assurance program description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:</u></b>	Included in the South Texas exemption request.

Table 1. Rule Text Matrix (Page 8 of 1)

RULE	RELATED TEXT	COMMENTS
50.55(e)(1)(iii)	<p>Ensure that a director or responsible officer of the holder of a facility construction permit subject to this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (e)(1)(i) or (e)(1)(ii) of this section, if the construction of a facility or activity, or a <b>basic component</b> supplied for such facility or activity -- (A) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, (B) Contains a defect, or (C) Undergoes any significant breakdown in any portion of the quality assurance program conducted pursuant to the requirements of appendix B to 10 CFR part 50 which could have produced a defect in a <b>basic component</b>. Such breakdowns in the quality assurance program are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction or installation.</p>	
50.55(e)(8)	<p>The written notification required by paragraph (e)(6)(ii) of this section must clearly indicate that the written notification is being submitted under §50.55(e) and include the following information, to the extent known-- (i) Name and address of the individual or individuals informing the Commission. (ii) Identification of the facility, the activity, or the <b>basic component</b> supplied for the facility or the activity within the United States which contains a defect or fails to comply. (iii) Identification of the firm constructing the facility or supplying the <b>basic component</b> which fails to comply or contains a defect. (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply. (v) The date on which the information of such defect or failure to comply was obtained. (vi) In the case of a <b>basic component</b> which contains a defect or fails to comply, the number and location of all the components in use at the facility subject to the regulations in this part. (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action. (viii) Any advice related to the defect or failure to comply about the facility, activity, or <b>basic component</b> that has been, is being, or will be given to other entities.</p>	

Table 1. Rule Text Matrix (Page 9 of 1)

RULE	RELATED TEXT	COMMENTS
50.55(e)(9)	The holder of a construction permit must prepare and maintain records necessary to accomplish the purposes of this section, specifically -- (i) Retain procurement documents, which define the requirements that facilities or <b><u>basic components</u></b> must meet in order to be considered acceptable, for the lifetime of the <b><u>basic component</u></b> .	
50.55(f)(3)	After March 11, 1983, each construction permit holder described in paragraph (f)(1) of this section <b><u>may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC.</u></b>  <b><u>Changes to the quality assurance program description that do reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:</u></b>	Should be consistent with changes to 50.54(a)(3).
50.55a		Included in SECY-98-300.  Included in the South Texas exemption request.
50.59		Included in SECY-98-300.  Included in the South Texas exemption request.

Table 1. Rule Text Matrix (Page 10 of 1)

RULE	RELATED TEXT	COMMENTS
50.62(d)	Implementation. By 180 days after the issuance of the QA guidance for <b>non-safety related</b> components, each licensee shall develop and submit to the Commission, as specified in §50.4, a proposed schedule for meeting the requirements of paragraphs (c)(1) through (c)(5) of this section. Each shall include an explanation of the schedule along with a justification if the schedule calls for final implementation later than the second refueling outage after July 26, 1984, or the date of issuance of a license authorizing operation above 5 percent of full power. A final schedule shall then be mutually agreed upon by the Commission and licensee.	
50.65		Included in SECY-98-300.  Included in the South Texas exemption request.
50.71(e)	<b><u>The updated FSAR shall be revised to include the effects of: all changes made in the facility or procedures as described in the FSAR; all safety evaluations performed by the licensee either in support of requested license amendments or in support of conclusions that changes did not involve an unreviewed safety question; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request.</u></b>	
50.71(e)(2)	<b><u>The submittal shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of §50.59 but not previously submitted to the Commission.</u></b>	

Table 1. Rule Text Matrix (Page 11 of 1)

RULE	RELATED TEXT	COMMENTS
50.72(b)(2)(iii)	(iii) Any event or condition that alone could have prevented the fulfillment of the safety function of the <b><u>structures or systems that are needed to: (A) Shut down the reactor and maintain it in a safe shutdown condition, (B) Remove residual heat, (C) Control the release of radioactive material, or (D) Mitigate the consequences of an accident.</u></b>	Included in SECY-98-300.
50.72(b)(2)(vii)(A)	(vii) Any instance of: (A) A defect in any spent fuel storage cask structure, system, or component which is <b><u>important to safety;</u></b>	See above.
50.73(a)(2)(v)	Any event or condition that alone could have prevented the fulfillment of the safety function of <b><u>structures or systems that are needed to: (A) Shut down the reactor and maintain it in a safe shutdown condition; (B) Remove residual heat; (C) Control the release of radioactive material; or (D) Mitigate the consequences of an accident.</u></b>	Included in SECY-98-300.
50.73(a)(2)(vii)	Any event where a single cause or condition caused at least one independent train or channel to become inoperable in <b><u>multiple systems</u></b> or two independent trains or channels to become inoperable in a <b><u>single system designed to: (A) Shut down the reactor and maintain it in a safe shutdown condition; (B) Remove residual heat; (C) Control the release of radioactive material; or (D) Mitigate the consequences of an accident.</u></b>	See above.
50.73(b)(2)(ii)(H)	For failure that rendered a train of a <b><u>safety system</u></b> inoperable, an estimate of the elapsed time from the discovery of the failure until the train was returned to service.	See above.
50.73(b)(2)(ii)(K)	Automatically and manually initiated <b><u>safety system</u></b> responses.	See above.
App. A Intro.	The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for <b><u>structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public.</u></b>	Definition of important to safety.

Table 1. Rule Text Matrix (Page 12 of 1)

RULE	RELATED TEXT	COMMENTS
<p>App. A Intro.</p>	<p>Also, some of the specific design requirements for structures, systems, and components <b><u>important to safety</u></b> have not as yet been suitably defined. Their omission does not relieve any applicant from considering these matters in the design of a specific facility and satisfying the necessary safety requirements. These matters include:</p> <p>(1) Consideration of the need to design against single failures of passive components in fluid systems <b><u>important to safety</u></b>. (See Definition of Single Failure.)</p> <p>(2) Consideration of redundancy and diversity requirements for fluid systems <b><u>important to safety</u></b>. A "system" could consist of a number of subsystems each of which is separately capable of performing the specified system safety function. The minimum acceptable redundancy and diversity of subsystems and components within a subsystem, and the required interconnection and independence of the subsystems have not yet been developed or defined. (See Criteria 34, 35, 38, 41, and 44.)</p> <p>(3) Consideration of the type, size, and orientation of possible breaks in components of the reactor coolant pressure boundary in determining design requirements to suitably protect against postulated loss-of-coolant accidents. (See Definition of Loss of Coolant Accidents.)</p> <p>(4) Consideration of the possibility of systematic, nonrandom, concurrent failures of redundant elements in the design of <b><u>protection systems and reactivity control systems</u></b>. (See Criteria 22, 24, 26, and 29.)</p>	
<p>App. A Definition</p>	<p>Nuclear power unit. A nuclear power unit means a nuclear power reactor and associated equipment necessary for electric power generation and includes those <b><u>structures, systems, and components required to provide reasonable assurance the facility can be operated without undue risk to the health and safety of the public.</u></b></p>	<p>Definition of important to safety.</p>

Table 1. Rule Text Matrix (Page 13 of 1)

RULE	RELATED TEXT	COMMENTS
GDC 1	<p>Structures, systems, and components <u>important to safety</u> shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed.</p> <p>Appropriate records of the design, fabrication, erection, and testing of structures, systems, and components <u>important to safety</u> shall be maintained by or under the control of the nuclear power unit licensee throughout the life of the unit.</p>	<p>Qualification, testing, and protection of equipment.</p> <p>Included in the South Texas exemption request.</p>
GDC 2	<p>Structures, systems, and components <u>important to safety</u> shall be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches without loss of capability to perform their safety functions.</p>	<p>Qualification and protection of equipment.</p> <p>Included in the South Texas exemption request.</p>
GDC 3	<p>Structures, systems, and components <u>important to safety</u> shall be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.</p> <p>Fire detection and fighting systems of appropriate capacity and capability shall be provided and designed to minimize the adverse effects of fires on structures, systems, and components <u>important to safety</u>.</p>	<p>Environmental qualification and protection of equipment.</p> <p>Should modify at the same time as 50.48.</p>

Table 1. Rule Text Matrix (Page 14 of 1)

RULE	RELATED TEXT	COMMENTS
GDC 4	Structures, systems, and components <b><u>important to safety</u></b> shall be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents, including loss-of-coolant accidents.	Environmental qualification and protection of equipment.  Included in the South Texas exemption request.
GDC 5	Structures, systems, and components <b><u>important to safety</u></b> shall not be shared among nuclear power units unless it can be shown that such sharing will not significantly impair their ability to perform their safety functions, including, in the event of an accident in one unit, an orderly shutdown and cooldown of the remaining units.	
GDC 14	The reactor coolant pressure boundary shall be designed, fabricated, erected, and tested so as to have an extremely low probability of abnormal leakage, of rapidly propagating failure, and of gross rupture.	Requires testing.
GDC 16	Reactor containment and associated systems shall be provided to establish an essentially leak-tight barrier against the uncontrolled release of radioactivity to the environment and to assure that the containment <b><u>design conditions important to safety</u></b> are not exceeded for as long as postulated accident conditions require.	
GDC 17	An onsite electric power system and an offsite electric power system shall be provided to permit functioning of structures, systems, and components <b><u>important to safety</u></b> .	
GDC 18	Electric power systems <b><u>important to safety</u></b> shall be designed to permit appropriate periodic inspection and testing of <b><u>important areas and features</u></b> , such as wiring, insulation, connections, and switchboards, to assess the continuity of the systems and the condition of their components.	Design with capability to inspect/test.  Included in the South Texas exemption request.

Table 1. Rule Text Matrix (Page 15 of 1)

RULE	RELATED TEXT	COMMENTS
GDC 20	The protection system shall be designed to: ... (2) to sense accident conditions and to initiate the operation of systems and components <b>important to safety</b> .	
GDC 21	The protection system shall be designed for high functional reliability and inservice testability commensurate with the safety functions to be performed. Redundancy and independence designed into the protection system shall be sufficient to assure that (1) no single failure results in loss of the protection function and (2) removal from service of any component or channel does not result in loss of the required minimum redundancy unless the acceptable reliability of operation of the protection system can be otherwise demonstrated. The protection system shall be designed to permit periodic testing of its functioning when the reactor is in operation, including a capability to test channels independently to determine failures and losses of redundancy that may have occurred.	Design with capability to inspect/test.
GDC 22	The protection system shall be designed to assure that the effects of natural phenomena, and of normal operating, maintenance, testing, and postulated accident conditions on redundant channels do not result in loss of the protection function, or shall be demonstrated to be acceptable on some other defined basis.	Environmental qualifications.
GDC 30	Components which are part of the reactor coolant pressure boundary shall be designed, fabricated, erected, and tested to the highest quality standards practical. Means shall be provided for detecting and, to the extent practical, identifying the location of the source of reactor coolant leakage.	Requires testing.
GDC 32	Components which are part of the reactor coolant pressure boundary shall be designed to permit (1) periodic inspection and testing of important areas and features to assess their structural and leaktight integrity, and (2) an appropriate material surveillance program for the reactor pressure vessel.	Requires testing.
GDC 36	The emergency core cooling system shall be designed to permit appropriate periodic inspection of important components, such as spray rings in the reactor pressure vessel, water injection nozzles, and piping, to assure the integrity and capability of the system.	Design with capability to inspect/test.

Table 1. Rule Text Matrix (Page 16 of 1)

RULE	RELATED TEXT	COMMENTS
GDC 37	The emergency core cooling system shall be designed to permit appropriate periodic pressure and functional testing to assure ....	Requires testing.
GDC 39	The containment heat removal system shall be designed to permit appropriate periodic inspection of important components, such as the torus, sumps, spray nozzles, and piping to assure the integrity and capability of the system.	Design with capability to inspect/test.
GDC 40	The containment heat removal system shall be designed to permit appropriate periodic pressure and functional testing to assure ....	Requires testing.
GDC 42	The containment atmosphere cleanup systems shall be designed to permit appropriate periodic inspection of important components, such as filter frames, ducts, and piping to assure the integrity and capability of the systems.	Requires testing.
GDC 43	The containment atmosphere cleanup systems shall be designed to permit appropriate periodic pressure and functional testing to assure ....	Requires testing.
GDC 44	A system to transfer heat from structures, systems, and components <b>important to safety</b> , to an ultimate heat sink shall be provided. The system safety function shall be to transfer the combined heat load of these structures, systems, and components under normal operating and accident conditions.	
GDC 45	The cooling water system shall be designed to permit appropriate periodic inspection of important components, such as heat exchangers and piping, to assure the integrity and capability of the system.	Requires testing.
GDC 46	The cooling water system shall be designed to permit appropriate periodic pressure and functional testing to assure ....	Requires testing.
GDC 52	The reactor containment and other equipment which may be subjected to containment test conditions shall be designed so that periodic integrated leakage rate testing can be conducted at containment design pressure.	Design with capability to inspect/test.
GDC 53	The reactor containment shall be designed to permit (1) appropriate periodic inspection of all important areas, such as penetrations, (2) an appropriate surveillance program, and (3) periodic testing at containment design pressure of the leaktightness of penetrations which have resilient seals and expansion bellows.	Design with capability to inspect/test.

Table 1. Rule Text Matrix (Page 17 of 1)

RULE	RELATED TEXT	COMMENTS
GDC 54	Piping systems penetrating primary reactor containment shall be provided with leak detection, isolation, and containment capabilities having redundancy, reliability, and performance capabilities which reflect the <b><u>importance to safety</u></b> of isolating these piping systems. Such piping systems shall be designed with a capability to test periodically the operability of the isolation valves and associated apparatus and to determine if valve leakage is within acceptable limits.	Design with capability to inspect/test.
GDC 55	Other appropriate requirements to minimize the probability or consequences of an accidental rupture of these lines or of lines connected to them shall be provided as necessary to assure adequate safety. Determination of the appropriateness of these requirements, such as higher quality in design, fabrication, and testing, additional provisions for inservice inspection, protection against more severe natural phenomena, and additional isolation valves and containment, shall include consideration of the population density, use characteristics, and physical characteristics of the site environs.	Requires testing.
GDC 61	These systems shall be designed (1) with a capability to permit appropriate periodic inspection and testing of components <b><u>important to safety</u></b> , (2) with suitable shielding for radiation protection, (3) with appropriate containment, confinement, and filtering systems, (4) with a residual heat removal capability having reliability and testability that reflects the <b><u>importance to safety</u></b> of decay heat and other residual heat removal, and (5) to prevent significant reduction in fuel storage coolant inventory under accident conditions.	Design with capability to inspect/test.
App. B		Included in SECY-98-300  Included in the South Texas exemption request.

Table 1. Rule Text Matrix (Page 18 of 1)

RULE	RELATED TEXT	COMMENTS
App. E VI.2.a.	While it is recognized that ERDS is not a <b>safety system</b> , it is conceivable that a licensee's ERDS interface could communicate with a <b>safety system</b> . In this case, appropriate isolation devices would be required at these interfaces.	
App. J Option A III	<p>A program consisting of a schedule for conducting Type A, B, and C tests shall be developed for leak testing the primary reactor containment and related systems and components penetrating primary containment pressure boundary.</p> <p>Upon completion of construction of the primary reactor containment, including installation of all portions of mechanical, fluid, electrical, and instrumentation systems penetrating the primary reactor containment pressure boundary, and prior to any reactor operating period, preoperational and periodic leakage rate tests, as applicable, shall be conducted in accordance with the following: ....</p>	Requires testing.
App. J Opt. B III.B	Type B pneumatic tests to detect and measure local leakage rates across pressure retaining, leakage-limiting boundaries, and Type C pneumatic tests to measure containment isolation valve leakage rates, must be conducted (1) prior to initial criticality, and (2) periodically thereafter at intervals based on the safety significance and historical performance of each boundary and isolation valve to ensure the integrity of the overall containment system as a barrier to fission product release to reduce the risk from reactor accidents.	Requires testing.  Included in the South Texas exemption request.
App. M 5(a)	...and has identified the <b>major features or components incorporated therein for the protection of the health and safety of the public.</b>	
App. M 5(c)	(c) <b>Safety features or components</b> , if any, which require research and development have been described by the applicant and the applicant has identified, and there will be conducted a research and development program reasonably designed to resolve any safety questions associated with such features or components;	

Table 1. Rule Text Matrix (Page 19 of 1)

RULE	RELATED TEXT	COMMENTS
App. N Footnote 2	As used in this appendix, the design of a nuclear power reactor included in a single referenced safety analysis report means the design of those <b><u>structures, systems and components important to radiological health and safety and the common defense and security.</u></b>	
App. R I	Criterion 3 of Appendix A to this part specifies that "Structures, systems, and components <b><u>important to safety</u></b> shall be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions."	Environmental qualification and protection of equipment.  Should modify at the same time as 50.48.
App. R I	When considering the effects of fire, <b><u>those systems associated with achieving and maintaining safe shutdown conditions assume major importance to safety</u></b> because damage to them can lead to core damage resulting from loss of coolant through boiloff.	See above.
App. R I	The phrases " <b><u>important to safety,</u></b> " or " <b><u>safety-related,</u></b> " will be used throughout this Appendix R as applying to all <b><u>safety functions.</u></b> The phrase "safe shutdown" will be used throughout this appendix as applying to both hot and cold shutdown functions.	See above.
App. R I	Because fire may affect <b><u>safe shutdown systems</u></b> and because the loss of function of <b><u>systems used to mitigate the consequences of design basis accidents</u></b> under postfire conditions does not per se impact public safety, the need to limit fire damage to systems required to achieve and maintain safe shutdown conditions is greater than the need to limit fire damage to those <b><u>systems required to mitigate the consequences of design basis accidents.</u></b> Three levels of fire damage limits are established according to the safety functions of the structure, system, or component:	See above.

Table 1. Rule Text Matrix (Page 20 of 1)

RULE	RELATED TEXT	COMMENTS
<p>App. R I</p>	<p>Safety function                      Fire damage limits</p> <p>Hot Shutdown.                      One train of <b><u>equipment necessary to achieve hot shutdown</u></b> from either the control room or emergency control station(s) must be maintained free of fire damage by a single fire, including an exposure fire.<sup>1</sup></p> <p>Cold Shutdown                      Both trains of <b><u>equipment necessary to achieve cold shutdown</u></b> may be damaged by a single fire, including an exposure fire, but damage must be limited so that at least one train can be repaired or made operable within 72 hours using onsite capability.</p> <p>Design Basis Accidents              Both trains of equipment <b><u>necessary for mitigation of consequences following design basis accidents</u></b> may be damaged by a single exposure fire.</p>	<p>See above.</p>
<p>App. R I</p>	<p>1 Exposure Fire. An exposure fire is a fire in a given area that involves either in situ or transient combustibles and is external to any structures, systems, or components located in or adjacent to that same area. The effects of such fire (e.g., smoke, heat, or ignition) can adversely affect those structures, systems, or components <b><u>important to safety</u></b>. Thus, a fire involving one train of <b><u>safe shutdown equipment</u></b> may constitute an exposure fire for the redundant train located in the same area, and a fire involving combustibles other than either redundant train may constitute an exposure fire to both redundant trains located in the same area.</p>	<p>See above.</p>
<p>App. R I</p>	<p>The most stringent fire damage limit shall apply for those systems that fall into more than one category. <b><u>Redundant systems used to mitigate the consequences of other design basis accidents but not necessary for safe shutdown may be lost to a single exposure fire. However, protection shall be provided so that a fire within only one such system will not damage the redundant system.</u></b></p>	<p>See above.</p>

Table 1. Rule Text Matrix (Page 21 of 1)

RULE	RELATED TEXT	COMMENTS
App. R II	The program shall establish the fire protection policy for the protection of structures, systems, and components <b><u>important to safety</u></b> at each plant and the procedures, equipment, and personnel required to implement the program at the plant site.	See above.
App. R II	The fire protection program shall extend the concept of defense-in-depth to fire protection in fire areas <b><u>important to safety</u></b> , with the following objectives:	See above.
App. R II	To provide protection for structures, systems, and components <b><u>important to safety</u></b> so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.	See above.
App. R II	(3) specify measures for fire prevention, fire detection, fire suppression, and fire containment and alternative shutdown capability as required for each fire area containing structures, systems, and components <b><u>important to safety</u></b> in accordance with NRC guidelines and regulations.	See above.
App. R II	C. Fire prevention features. Fire protection features shall meet the following general requirements for all fire areas that contain or present a fire hazard to structures, systems, or components <b><u>important to safety</u></b> .	See above.
App. R II	4. Fire barriers or automatic suppression systems or both shall be installed as necessary to protect <b><u>redundant systems or components necessary for safe shutdown</u></b> .	See above.
App. R III	Each supply of the fire water distribution system shall be capable of providing for a period of 2 hours the maximum expected water demands as determined by the fire hazards analysis for <b><u>safety-related areas or other areas that present a fire exposure hazard to safety-related areas</u></b> .	See above.
App. R III	C. Hydrant isolation valves. Valves shall be installed to permit isolation of outside hydrants from the fire main for maintenance or repair without interrupting the water supply to automatic or manual fire suppression systems in any <b><u>area containing or presenting a fire hazard to safety-related or safe shutdown equipment</u></b> .	See above.

Table 1. Rule Text Matrix (Page 22 of 1)

RULE	RELATED TEXT	COMMENTS
<p>App. R III</p>	<p>D. Manual fire suppression. Standpipe and hose systems shall be installed so that at least one effective hose stream will be able to reach any location that contains or presents an exposure fire hazard to structures, systems, or components <b><u>important to safety.</u></b></p> <p>Access to permit effective functioning of the fire brigade shall be provided to all areas that contain or present an exposure fire hazard to structures, systems, or components <b><u>important to safety.</u></b></p>	<p>See above.</p>
<p>App. R III</p>	<p>F. Automatic fire detection. Automatic fire detection systems shall be installed in all areas of the plant that contain or present an exposure fire hazard to <b><u>safe shutdown or safety-related systems or components.</u></b> These fire detection systems shall be capable of operating with or without offsite power.</p>	<p>See above.</p>

Table 1. Rule Text Matrix (Page 23 of 1)

RULE	RELATED TEXT	COMMENTS
<p>App. R</p> <p>III</p>	<p>G. Fire protection of safe shutdown capability.</p> <p>1. Fire protection features shall be provided for structures, systems, and components <b><u>important to safe shutdown</u></b>. These features shall be capable of limiting fire damage so that: a. One train of <b><u>systems necessary to achieve and maintain hot shutdown conditions</u></b> from either the control room or emergency control station(s) is free of fire damage; and b. <b><u>Systems necessary to achieve and maintain cold shutdown</u></b> from either the control room or emergency control station(s) can be repaired within 72 hours.</p> <p>2. Except as provided for in paragraph G.3 of this section, where cables or equipment, including associated <b><u>non-safety</u></b> circuits that could prevent operation or cause maloperation due to hot shorts, open circuits, or shorts to ground, of redundant trains of <b><u>systems necessary to achieve and maintain hot shutdown conditions</u></b> are located within the same fire area outside of primary containment, one of the following means of ensuring that one of the redundant trains is free of fire damage shall be provided: a. Separation of cables and equipment and associated <b><u>non-safety</u></b> circuits of redundant trains by a fire barrier having a 3-hour rating. Structural steel forming a part of or supporting such fire barriers shall be protected to provide fire resistance equivalent to that required of the barrier; b. Separation of cables and equipment and associated <b><u>non-safety</u></b> circuits of redundant trains by a horizontal distance of more than 20 feet with no intervening combustible or fire hazards. In addition, fire detectors and an automatic fire suppression system shall be installed in the fire area; or c. Enclosure of cable and equipment and associated <b><u>non-safety</u></b> circuits of one redundant train in a fire barrier having a 1-hour rating, In addition, fire detectors and an automatic fire suppression system shall be installed in the fire area; Inside noninerted containments one of the fire protection means specified above or one of the following fire protection means shall be provided: d. Separation of cables and equipment and associated <b><u>non-safety</u></b> circuits of redundant trains by a horizontal distance of more than 20</p>	<p>See above.</p>

Table 1. Rule Text Matrix (Page 24 of 1)

RULE	RELATED TEXT	COMMENTS
App. R III	<p>H. Fire brigade. A site fire brigade trained and equipped for fire fighting shall be established to ensure adequate manual fire fighting capability for all areas of the plant containing structures, systems, or components <b><u>important to safety</u></b>. The fire brigade shall be at least five members on each shift. The brigade leader and at least two brigade members shall have sufficient training in or knowledge of plant <b><u>safety-related</u></b> systems to understand the effects of fire and fire suppressants on safe shutdown capability. The qualification of fire brigade members shall include an annual physical examination to determine their ability to perform strenuous fire fighting activities. The shift supervisor shall not be a member of the fire brigade. The brigade leader shall be competent to assess the potential safety consequences of a fire and advise control room personnel. Such competence by the brigade leader may be evidenced by possession of an operator's license or equivalent knowledge of plant <b><u>safety-related</u></b> systems.</p>	See above.
App. R III	<p>J. Emergency lighting. Emergency lighting units with at least an 8-hour battery power supply shall be provided in all areas needed for operation of <b><u>safe shutdown equipment</u></b> and in access and egress routes thereto.</p>	See above.
App. R III	<p>K. Administrative controls. Administrative controls shall be established to minimize fire hazards in areas containing structures, systems, and components <b><u>important to safety</u></b>. These controls shall establish procedures to: 1. Govern the handling and limitation of the use of ordinary combustible materials, combustible and flammable gases and liquids, high efficiency particulate air and charcoal filters, dry ion exchange resins, or other combustible supplies in <b><u>safety-related</u></b> areas. 2. Prohibit the storage of combustibles in <b><u>safety-related</u></b> areas or establish designated storage areas with appropriate fire protection. 3. Govern the handling of and limit transient fire loads such as combustible and flammable liquids, wood and plastic products, or other combustible materials in buildings containing <b><u>safety-related</u></b> systems or equipment during all phases of operating, and especially during maintenance, modification, or refueling operations.</p>	See above.

Table 1. Rule Text Matrix (Page 25 of 1)

RULE	RELATED TEXT	COMMENTS
App. R III	8. Control the use of specific combustibles in <b><u>safety-related</u></b> areas. All wood used in <b><u>safety-related</u></b> areas during maintenance, modification, or refueling operations (such as lay-down blocks or scaffolding) shall be treated with a flame retardant. Equipment or supplies (such as new fuel) shipped in untreated combustible packing containers may be unpacked in <b><u>safety-related</u></b> areas if required for valid operating reasons. However, all combustible materials shall be removed from the area immediately following the unpacking.	See above.
App. R III	12. Define the strategies for fighting fires in all <b><u>safety-related</u></b> areas and areas presenting a hazard to <b><u>safety-related</u></b> equipment. These strategies shall designate:	See above.
App. R III	6. Shutdown systems installed to ensure postfire shutdown capability need not be designed to meet seismic Category I criteria, single failure criteria, or other design basis accident criteria, except where required for other reasons, e.g., because of interface with or impact on existing <b><u>safety systems</u></b> , or because of adverse valve actions due to fire damage.	See above.
App. R III	7. The <b><u>safe shutdown equipment and systems</u></b> for each fire area shall be known to be isolated from associated <b><u>non-safety</u></b> circuits in the fire area so that hot shorts, open circuits, or shorts to ground in the associated circuits will not prevent operation of the <b><u>safe shutdown equipment</u></b> .	See above.
App. R III	4 An acceptable method of complying with this alternative would be to meet Regulatory Guide 1.75 position 4 related to associated circuits and IEEE Std 384 - 1974 (Section 4.5) where trays from redundant <b><u>safety divisions</u></b> are so protected that postulated fires affect trays from only one <b><u>safety division</u></b> .	See above.

Table 1. Rule Text Matrix (Page 26 of 1)

RULE	RELATED TEXT	COMMENTS
App. S I(a)	Each applicant for a construction permit, operating license, design certification, or combined license is required by §50.34 (a)(12), (b)(10), and General Design Criterion 2 of Appendix A to this part to design nuclear power plant structures, systems, and components <b>important to safety</b> to withstand the effects of natural phenomena, such as earthquakes, without loss of capability to perform their safety functions.	Applicable to applicants for a design certification, combined license, construction permit, or operating license on or after 1/10/1997.
App. S I(b)	These criteria implement General Design Criterion 2 insofar as it requires structures, systems, and components <b>important to safety</b> to withstand the effects of earthquakes.	See above.
App. S III	The Operating Basis Earthquake Ground Motion (OBE) is the vibratory ground motion for which those features of the nuclear power plant <b>necessary for continued operation without undue risk to the health and safety of the public</b> will remain functional.	See above.
App. S III	The structures, systems, and components required to withstand the effects of the Safe Shutdown Earthquake Ground Motion or surface deformation <b>are those 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 that could result in potential offsite exposures comparable to the guideline exposures of §50.34(a)(1).</b>	See above.
App. S IV(a)(1)(ii)	The nuclear power plant must be designed so that, if the Safe Shutdown Earthquake Ground Motion occurs, certain structures, systems, and components will remain functional and within applicable stress, strain, and deformation limits. In addition to seismic loads, applicable concurrent normal operating, functional, and accident-induced loads must be taken into account in the design of these <b>safety-related</b> structures, systems, and components.	See above.

Table 1. Rule Text Matrix (Page 27 of 1)

RULE	RELATED TEXT	COMMENTS
<p>App. S IV(a)(1)(iv)</p>	<p>The evaluation must take into account soil-structure interaction effects and the expected duration of vibratory motion.</p> <p>It is permissible to design for strain limits in excess of yield strain in some of these <b>safety-related</b> structures, systems, and components during the Safe Shutdown Earthquake Ground Motion and under the postulated concurrent loads, provided the necessary safety functions are maintained.</p>	<p>See above.</p>
<p>App. S IV(a)(2)(i)(I)</p>	<p>When subjected to the effects of the Operating Basis Earthquake Ground Motion in combination with normal operating loads, all structures, systems, and components of the nuclear power plant <b>necessary for continued operation without undue risk to the health and safety of the public</b> must remain functional and within applicable stress, strain, and deformation limits.</p>	<p>See above.</p>
<p>App. S IV(a)(3)</p>	<p>If systems, structures, or components <b>necessary for the safe shutdown</b> of the nuclear power plant are not available after the occurrence of the Operating Basis Earthquake Ground Motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the nuclear power plant. Prior to resuming operations, the licensee must demonstrate to the Commission that no functional damage has occurred to those <b>features necessary for continued operation without undue risk to the health and safety of the public</b> and the licensing basis is maintained.</p>	<p>See above.</p>
<p>App. S IV(a)(4)</p>	<p>Required Seismic Instrumentation. Suitable instrumentation must be provided so that the seismic response of nuclear power plant <b>features important to safety</b> can be evaluated promptly after an earthquake.</p>	<p>See above.</p>
<p>App. S IV(b)</p>	<p>In addition to surface deformation induced loads, the design of <b>safety features</b> must take into account seismic loads and applicable concurrent functional and accident-induced loads.</p>	<p>See above.</p>

Table 1. Rule Text Matrix (Page 28 of 1)

RULE	RELATED TEXT	COMMENTS
21.1	<p>The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or <b><u>basic component</u></b> supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or <b><u>basic component</u></b> supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.</p>	
21.2(a)	<p>The regulations in this part apply also to each individual, corporation, partnership or other entity doing business within the United States, and each director and responsible officer of such organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation pursuant to part 50 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, a MRS for the storage of spent fuel or high level radioactive waste pursuant to part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 of this chapter; or supplies <b><u>basic components</u></b> for a facility or activity licensed, other than for export, under parts 30, 40, 50, 60, 61, 70, 71, or part 72 of this chapter.</p>	
21.2(d)	<p>NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear <b><u>safety-related problems</u></b>.</p>	

Table 1. Rule Text Matrix (Page 29 of 1)

RULE	RELATED TEXT	COMMENTS
21.3	<p><b>Basic component.</b> (1)(i) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure: (A) The integrity of the reactor coolant pressure boundary; (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in §50.34(a)(1) or §100.11 of this chapter, as applicable. (ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR Part 50, appendix B, or commercial grade items which have successfully completed the dedication process. (2) When applied to other facilities and when applied to other activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard. (3) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.</p>	<p>Included in the South Texas exemption request.</p>

Table 1. Rule Text Matrix (Page 30 of 1)

RULE	RELATED TEXT	COMMENTS
21.3	<p><b>Commercial grade item.</b> (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, <b>commercial grade item</b> means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a <b>basic component</b>. <b>Commercial grade items</b> do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).</p> <p>(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, commercial grade item means an item that is: (i) Not subject to design or specification requirements that are unique to those facilities or activities; (ii) Used in applications other than those facilities or activities; and (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).</p>	
21.3	<p>Constructing or construction means the analysis, design, manufacture, fabrication, 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 <b>safety related</b>.</p>	
21.3	<p>Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a <b>commercial grade item</b> that, once verified, will provide reasonable assurance that the item will perform its intended safety function.</p>	
21.3	<p>Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to §21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the <b>dedicated item</b>, and maintaining auditable records of the dedication process.</p>	

Table 1. Rule Text Matrix (Page 31 of 1)

RULE	RELATED TEXT	COMMENTS
21.3	<p>Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedication is an acceptance process undertaken to provide reasonable assurance that a <b>commercial grade item</b> to be used as a <b>basic component</b> will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a <b>basic component</b>. (2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a <b>basic component</b>.</p>	
21.3	<p>Defect means: (1) A deviation in a <b>basic component</b> delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard; or (2) The installation, use, or operation of a <b>basic component</b> containing a defect as defined in this section; or (3) A deviation in a portion of a facility subject to the construction permit or manufacturing licensing requirements of part 50 of this chapter provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance; or (4) A condition or circumstance involving a <b>basic component</b> that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued pursuant to part 50 of this chapter.</p>	
21.3	<p>Operating or operation means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to <b>operations that are safety related</b>.</p>	

Table 1. Rule Text Matrix (Page 32 of 1)

RULE	RELATED TEXT	COMMENTS
21.3	Procurement document means a contract that defines the requirements which facilities or <b><u>basic components</u></b> must meet in order to be considered acceptable by the purchaser.	
21.3	Supplying or supplies means contractually responsible for a <b><u>basic component</u></b> used or to be used in a facility or activity which is subject to the regulations in this part.	
21.7	Suppliers of <b><u>commercial grade items</u></b> are exempt from the provisions of this part to the extent that they supply <b><u>commercial grade items.</u></b>	
21.21(a)	Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to -- ... (3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in §21.21(a)(1) or §21.21(a)(2) if the construction or operation of a facility or activity, or a <b><u>basic component</u></b> supplied for such facility or activity -- (i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to a substantial safety hazard, or (ii) Contains a defect.	
21.21(b)	If the deviation or failure to comply is discovered by a supplier of <b><u>basic components</u></b> , or services associated with <b><u>basic components</u></b> , and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to §21.21(a).	
21.21(c)	A dedicating entity is responsible for -- (1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for <b><u>dedicated items</u></b> ; and (2) Maintaining auditable records for the dedication process.	

Table 1. Rule Text Matrix (Page 33 of 1)

RULE	RELATED TEXT	COMMENTS
21.21(d)(1)	<p>A director or responsible officer subject to the regulations of this part or a person designated under §21.21(c)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting -- (ii) A <b>basic component</b> that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 60, 61, 70, 71, or 72 of this chapter.</p>	
21.21(d)(4)	<p>The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known: (i) Name and address of the individual or individuals informing the Commission. (ii) Identification of the facility, the activity, or the <b>basic component</b> supplied for such facility or such activity within the United States which fails to comply or contains a defect. (iii) Identification of the firm constructing the facility or supplying the <b>basic component</b> which fails to comply or contains a defect. (iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply. (v) The date on which the information of such defect or failure to comply was obtained. (vi) In the case of a <b>basic component</b> which contains a defect or fails to comply, the number and location of all such components in use at, supplied for, or being supplied for one or more facilities or activities subject to the regulations in this part. (vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action. (viii) Any advice related to the defect or failure to comply about the facility, activity, or <b>basic component</b> that has been, is being, or will be given to purchasers or licensees.</p>	
21.31	<p>Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a <b>basic component</b> issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.</p>	

Table 1. Rule Text Matrix (Page 34 of 1)

RULE	RELATED TEXT	COMMENTS
21.41	Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and <b><u>basic components</u></b> as necessary to accomplish the purposes of this part.	
21.51(a)	Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically -- (1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation; (2) Suppliers of <b><u>basic components</u></b> must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification. (3) Suppliers of <b><u>basic components</u></b> must retain a record of the purchasers of <b><u>basic components</u></b> for 10 years after delivery of the <b><u>basic component</u></b> or service associated with a <b><u>basic component</u></b> .	
21.51(b)	Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to <b><u>basic components</u></b> that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a <b><u>basic component</u></b> .	
Part 52		Part 52 includes, by reference, Part 21, Part 50 and its Appendices, and Part 100 and its Appendix A.

Table 1. Rule Text Matrix (Page 35 of 1)

RULE	RELATED TEXT	COMMENTS
54.4	<p>(a) Plant systems, structures, and components within the scope of this part are --</p> <p>(1) <b>Safety-related</b> systems, structures, and components which are those relied upon to remain functional during and following design-basis events (as defined in 10 CFR 50.49 (b)(1)) to ensure the following functions -- (i) The integrity of the reactor coolant pressure boundary; (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (iii) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in §50.34(a)(1) or §100.11 of this chapter, as applicable.</p> <p>(2) All <b>nonsafety-related systems, structures, and components whose failure could prevent satisfactory accomplishment of any of the functions identified in paragraphs (a)(1)(i), (ii), or(iii) of this section.</b></p> <p>(3) <b>All systems, structures, and components relied on in safety analyses or plant evaluations to perform a function that demonstrates compliance with the Commission's regulations for fire protection (10 CFR 50.48), environmental qualification (10 CFR 50.49), pressurized thermal shock (10 CFR 50.61), anticipated transients without scram (10 CFR 50.62), and station blackout (10 CFR 50.63).</b></p>	<p>Applicable to issuance of renewed operating licenses.</p>
100.1(d)	<p><b><u>The Commission intends to carry out a traditional defense-in-depth approach with regard to reactor siting to ensure public safety.</u></b></p>	
100.10(a)(4)	<p><b><u>The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur.</u></b></p>	<p>Design, testing, qualification, and documentation.</p>

Table 1. Rule Text Matrix (Page 36 of 1)

RULE	RELATED TEXT	COMMENTS
100.23(d)(4)	Siting factors for other design conditions that must be evaluated include soil and rock stability, liquefaction potential, natural and artificial slope stability, cooling water supply, and remote <b>safety-related</b> structure siting.	Applicable to applicants on or after January 10, 1997.
Part 100 App. A I	General Design Criterion 2 of Appendix A to part 50 of this chapter requires that nuclear power plant structures, systems, and components <b>important to safety</b> be designed to withstand the effects of natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches without loss of capability to perform their safety functions.	Testing, environmental qualification, and documentation.
Part 100 App. A III(c)	The Safe Shutdown Earthquake(1) is that earthquake which is based upon an evaluation of the maximum earthquake potential considering the regional and local geology and seismology and specific characteristics of local subsurface material. It is that earthquake which produces the maximum vibratory ground motion for which certain structures, systems, and components are designed to remain functional. <b><u>These structures, systems, and components are those necessary to assure: (1) The integrity of the reactor coolant pressure boundary, (2) The capability to shutdown 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 potential offsite exposures comparable to the guideline exposures of this part.</u></b>	See above.
Part 100 App. A III(d)	The Operating Basis Earthquake is that earthquake which, considering the regional and local geology and seismology and specific characteristics of local subsurface material, could reasonably be expected to affect the plant site during the operating life of the plant; it is that earthquake which produces the vibratory ground motion for which <b><u>those features of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public</u></b> are designed to remain functional.	See above.

Table 1. Rule Text Matrix (Page 37 of 1)

RULE	RELATED TEXT	COMMENTS
Part 100 App. A V(d)(4)	Distant structures. Those structures which are not located in the immediate vicinity of the site but which are <b>safety related</b> shall be designed to withstand the effect of the Safe Shutdown Earthquake and the design basis for surface faulting determined on a comparable basis to that of the nuclear power plant, taking into account the material underlying the structures and the different location with respect to that of the site.	See above.
Part 100 App. A VI(a)(1)	The nuclear power plant shall be designed so that, if the Safe Shutdown Earthquake occurs, certain structures, systems, and components will remain functional. <b><u>These structures, systems, and components are those necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the guideline exposures of this part.</u></b> In addition to seismic loads, including aftershocks, applicable concurrent functional and accident-induced loads shall be taken into account in the design of these <b>safety-related</b> structures, systems, and components.	See above.  Included in the South Texas exemption request.
Part 100 App. A VI(a)(1)	It is permissible to design for strain limits in excess of yield strain in some of these <b>safety-related</b> structures, systems, and components during the Safe Shutdown Earthquake and under the postulated concurrent conditions, provided that the necessary safety functions are maintained.	See above.  Included in the South Texas exemption request.
Part 100 App. A VI(a)(2)	All <b><u>structures, systems, and components of the nuclear power plant necessary for continued operation without undue risk to the health and safety of the public</u></b> shall be designed to remain functional and within applicable stress and deformation limits when subjected to the effects of the vibratory motion of the Operating Basis Earthquake in combination with normal operating loads.	See above.  Included in the South Texas exemption request.
Part 100 App. A VI(a)(3)	Required Seismic instrumentation. Suitable instrumentation shall be provided so that the seismic response of nuclear power plant features <b>important to safety</b> can be determined promptly to permit comparison of such response with that used as the design basis.	See above.

Table 1. Rule Text Matrix (Page 38 of 1)

RULE	RELATED TEXT	COMMENTS
Part 100 App. A VI(b)(3)	These <u>structures, systems, and components are those necessary to assure (i) the integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shutdown condition, or (iii) the capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the guideline exposures of this part.</u> In addition to seismic loads, including aftershocks, applicable concurrent functional and accident-induced loads shall be taken into account in the design of such <u>safety features.</u>	See above.

Table 2. Rule Evaluation Matrix (Page 1 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
50.2	Definitions.						
50.4	Written communications.						
50.8	Information collection requirements: OMB approval.						
50.10	License required.						
50.34	Contents of applications; technical information.	x				x	x
50.35	Issuance of construction permits.						
50.36	Technical specifications.	x	x	x			x
50.44	Standards for combustible gas control system in light-water-cooled power reactors.	x	x	x	x		x
50.48	Fire protection.	x	x	x		x	x
50.49	Environmental qualification of electric equipment important to safety for nuclear power plants.	x	x	x	x	x	x
50.54	Conditions of licenses.		x	x	x	x	x
50.55	Conditions of construction permits.	x	x	x	x	x	x
50.55a	Codes and standards.	x	x	x		x	x
50.59	Changes, tests and experiments.	x	x	x	x	x	x
50.62	Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.						
50.65	Requirements for monitoring the effectiveness of maintenance at nuclear power plants.	x	x	x			x
50.71	Maintenance of records, making of reports.	x				x	x
50.72	Immediate notification requirements for operating nuclear power reactors.	x	x	x			x
50.73	License event report system.	x	x	x			x

Table 2. Rule Evaluation Matrix (Page 2 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
App. A Intro.	General Design Criteria for Nuclear Power Plants				x		x
GDC 1	Quality Standards and Records.	x	x	x	x	x	x
GDC 2	Design Bases for Protection Against Natural Phenomena.	x	x	x	x		x
GDC 3	Fire Protection.	x	x	x	x		x
GDC 4	Environmental and Dynamic Effects Design Bases.	x	x	x	x		x
GDC 5	Sharing of Structures, Systems, and Components.						
GDC 14	Reactor Coolant Pressure Boundary.	x					
GDC 16	Containment Design.						
GDC 17	Electric Power Systems.	x 1					1
GDC 18	Inspection and Testing of Electric Power Systems.	1					1
GDC 20	Protection System Functions.						
GDC 21	Protection System Reliability and Testability.	1					1
GDC 22	Protection System Independence.	x					
GDC 30	Quality of Reactor Coolant Pressure Boundary.	x					
GDC 32	Inspection of Reactor Coolant Pressure Boundary.	x 1					1
GDC 36	Inspection of Containment Heat Removal System.	1					1

Table 2. Rule Evaluation Matrix (Page 3 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
GDC 37	Testing of Emergency Core Cooling System.	x	x	x	x		x
		1					1
		2					2
GDC 39	Inspection of Containment Heat Removal System.	1					1
GDC 40	Testing of Containment Heat Removal System.	x	x	x	x		x
		1					1
		2					2
GDC 42	Inspection of Containment Atmosphere Cleanup Systems.	x	x	x	x		x
		1					1
		2					2
GDC 43	Testing of Containment Atmosphere Cleanup Systems.	x	x	x	x		x
		1					1
		2					2
GDC 44	Cooling Water.						
GDC 45	Inspection of Cooling Water System.	x	x	x	x		x
		1					1
		2					2
GDC 46	Testing of Cooling Water System.	x	x	x	x		x
		1					1
		2					2
GDC 52	Capability for Containment Leakage Rate Testing.	1					1

Table 2. Rule Evaluation Matrix (Page 4 of 1)

RULE	TITLE	SCREENING CRITERIA					CANDIDATE RULES
		I	II	III	IV	V	(I and (II or III)) or IV or V
GDC 53	Provisions for Containment Testing and Inspection.	1					1
GDC 54	Systems Penetrating Containment.	1					1
GDC 55	Reactor Coolant Pressure Boundary Penetrating Containment.	x					
GDC 61	Fuel Storage and Handling and Radioactivity Control.	1					1
App. B	Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	x	x	x	x	x	x
App. E	Emergency Planning and Preparedness for Production and Utilization Facilities						
App. J	Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors	x	x	x			x
App. M	Standardization of Design; Manufacture of Nuclear Power Reactors; Construction and Operation of Nuclear Power Reactors Manufactured Pursuant to Commission License						
App. N	Standardization of Nuclear Power Plant Designs: Licenses to Construct and Operate Nuclear Power Reactors of Duplicate Design at Multiple Sites						
App. R	Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979	x	x	x		x	x
App. S	Earthquake Engineering Criteria for Nuclear Power Plants	x	x	x	x		x
Part 21	REPORTING OF DEFECTS AND NONCOMPLIANCE	x	x	x	x		x
Part 52	EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 54	REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS	x	x	x	x	x	x
Part 100 & App. A	REACTOR SITE CRITERIA	x	x	x	x		x

## Table 2. Rule Evaluation Matrix (Page 5 of 1)

### NOTES:

- Includes requirements that components be designed to permit inspection and/or testing.
- Includes requirements that components be designed to permit inspection and/or testing **to assure** the capability of the components. The staff has treated the words **to assure** as requiring actual periodic testing.

Figure 1. Screening Process and Results.

