

in equipment or device design is avoided;

(3) System redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (*e.g.*, no risk outliers);

(4) Defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed;

(5) The independence of barriers is not degraded; and

(6) defenses against human errors are preserved.

II. Rule Initiation

In addition to RG 1.174, the NRC also issued other regulatory guides on risk-informed approaches for specific types of applications. These included RG 1.175, Risk-informed Inservice Testing, RG 1.176, Graded Quality Assurance, RG 1.177, Risk-informed Technical Specifications, and RG 1.178, Risk-informed Inservice Inspection. In this respect, the Commission has been successful in developing and implementing a regulatory means for considering risk insights into the current regulatory framework. One such risk-informed application, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company (STPNOC) requested that the NRC approve a revised Operations Quality Assurance Program (OQAP) that incorporated the methodology for grading quality assurance (QA) based on PRA insights. The STP graded QA proposal was 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 10 CFR Part 50 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. Subsequent to NRC's approval, STPNOC identified implementation difficulties associated with the graded QA program. Despite the reduced QA requirement applied for a large number of SSCs in which the licensee judged to be of low safety significance, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, or seismic

continue to impose substantial burdens. As a result, the replacement of such a low safety significant component needs to satisfy other special requirements during a procurement process. These requirements prevented STPNOC 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 graded QA), STPNOC submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including 10 CFR 50 Appendix B) for SSCs categorized as low safety significant or as non-risk significant. STPNOC's exemption was ultimately approved by the staff in August 2001 (further discussed in Section IV.4).

The experience with graded QA was a principal factor in the NRC's determination that rule changes would be necessary to proceed with some activities to risk-inform requirements. The Commission also believes that the development of PRA technology and decision-making tools for using risk information together with deterministic information supported rulemaking activities to allow the NRC to refocus certain regulatory requirements using this type of information.

Under Option 2 of 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 recommended that risk-informed approaches to the application of special treatment requirements be developed as one application of risk-informed regulatory changes. Option 2 (also referred to as RIP50 Option 2) addresses the implementation of changes to the scope of SSCs needing special treatment while still providing assurance that the SSCs will perform their design functions. Changes to the requirements pertaining to the design of the plant or the design basis accidents are not included in Option 2. These technical risk-informed changes are addressed under Option 3 of SECY-98-300. The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999.

The stated purpose of the "Option 2" rulemaking was 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. As part of this process, those SSCs found to be of risk-significance would be brought under a greater degree of regulatory control through the requirements being added to the rule designed to maintain consistency between actual performance and the performance considered in the assessment process that determines their significance. As a result, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance.

The Commission directed the staff to evaluate strategies to make the scope of the nuclear power reactor regulations that impose special treatment risk-informed. SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999, was sent to the Commission to obtain approval for a rulemaking plan and issuance of an Advance Notice of Proposed Rulemaking (ANPR). By SRM dated January 31, 2000, the Commission approved publication of the ANPR and approved the rulemaking plan. The ANPR was published in the **Federal Register** on March 3, 2000 (65 FR 11488) for a 75-day comment period, which ended on May 17, 2000. In the rulemaking plan, the NRC proposed to create a new section within part 50, referred to as § 50.69, to contain these alternative requirements.

The Commission received more than 200 comments in response to the ANPR. The staff sent the Commission SECY-00-194 "Risk-Informing Special Treatment Requirements," dated September 7, 2000, which provided the staff's preliminary views on the ANPR comments and additional thoughts on the preliminary regulatory framework for implementing a rule to revise the scope of special treatment requirements for SSCs. The comments from the ANPR are further discussed in Section IV.1.0 below.

The concept developed for this proposed rule, discussed at length in the ANPR, was to apply treatment requirements based upon the safety-significance of SSCs, determined through consideration of both risk insights and deterministic information. Thus, the risk-informed approach discussed in this proposed rule for establishing an alternative scope of SSCs subject to special treatment requirements uses both risk and traditional deterministic methods in a blended "risk-informed" approach. The Commission finds the risk-informed