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OFFICE OF NUCLEAR REGULATORY RESEARCH

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(For Trial Use)

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GUIDELINES FOR CATEGORIZING STRUCTURES, SYSTEMS, AND COMPONENTS IN NUCLEAR POWER PLANTS ACCORDING TO THEIR SAFETY SIGNIFICANCE

A. INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) has promulgated regulations to permit power reactor licensees and license applicants to implement an alternative regulatory framework with respect to "special treatment," where special treatment refers to those requirements that provide increased assurance beyond normal industrial practices that structures, systems, and components (SSCs) perform their design-basis functions. Under this framework, licensees using a risk-informed process for categorizing SSCs according to their safety significance can remove SSCs of low safety significance from the scope of certain identified special treatment requirements.

The genesis of this framework stems from 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.[1] In that Commission paper, the NRC staff recommended developing risk-informed approaches to the application of special treatment requirements to reduce unnecessary regulatory burden related to SSCs of low safety significance by removing such SSCs from the scope of special treatment requirements. The Commission subsequently approved the NRC staff's rulemaking plan and issuance of an Advanced Notice of Proposed Rulemaking (ANPR) as outlined in SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999.

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[1] Commission papers cited in this trial regulatory guide are available through the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/commission/secys/, and the related *Federal Register* notices are available through the Federal Register Web site sponsored by the Government Printing Office (GPO) at http://www.gpoaccess.gov/fr/index.html.

The U.S. Nuclear Regulatory Commission (NRC) issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff need in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. The NRC staff encourages and welcomes comments and suggestions in connection with improvements to published regulatory guides, as well as items for inclusion in regulatory guides that are currently being developed. The NRC staff will revise existing guides, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Regulatory guides are issued in 10 broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

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The Commission published the ANPR in the *Federal Register* (65 FR 11488) on March 3, 2000, and subsequently published a proposed rule for public comment (68 FR 26511) on May 16, 2003. Then, on November 22, 2004, the Commission adopted a new section, referred to as §50.69, within Title 10, Part 50, of the *Code of Federal Regulations*, on risk-informed categorization and treatment of SSCs for nuclear power plants (69 FR 68008).

This trial regulatory guide describes a method that the NRC staff considers acceptable for use in complying with the Commission's requirements in §50.69 with respect to the categorization of SSCs that are considered in risk-informing special treatment requirements. This categorization method uses the process that the Nuclear Energy Institute (NEI) described in Revision 0 of its guidance document NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," dated July 2005.[2] Specifically, this process determines the safety significance of SSCs and categorizes them into one of four risk-informed safety class (RISC) categories. As such, this regulatory guide is intended to provide guidance for use in developing and assessing evaluation models for accident and transient analyses. An additional benefit is that evaluation models that are developed using these guidelines will provide a more reliable framework for risk-informed regulation and a basis for estimating the uncertainty in understanding transient and accident behavior.

The NRC issued a draft of this guide, Draft Regulatory Guide DG-1121, for public review and comment as part of the §50.69 rulemaking package in May 2003. The staff subsequently received and addressed public comments in developing the current trial regulatory guide. However, a few issues of technical interpretation and implementation still remain, with respect to specific aspects of the guidance. Because the staff believes these issues will be best resolved by testing the guide against actual applications, the NRC decided to issue this guide for trial use. This trial regulatory guide does not establish any final staff positions, and may be revised in response to experience with its use. As such, this trial guide does not establish a staff position for purposes of the Backfit Rule, 10 CFR 50.109, and any changes to this trial guide prior to staff adoption in final form will not be considered to be backfits as defined in 10 CFR 50.109(a)(1). This will ensure that the lessons learned from regulatory review of pilot and follow-on applications are adequately addressed in the final regulatory guide, and that the guidance is sufficient to enhance regulatory stability in the review, approval, and implementation of probabilistic risk assessments (PRAs) and their results in the risk-informed categorization process required by §50.69.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required.

This regulatory guide contains information collections that are covered by the requirements of 10 CFR Part 50 which the Office of Management and Budget (OMB) approved under OMB control number 3150-0011. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

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[2] NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," is available through the NRC's public Web site at http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?ID=052910091:&LogonId=2b2cbc48fd7897510347535dd7c30495, and through the NRC's Agencywide Documents Access and Management System (ADAMS), http://www.nrc.gov/reading-rm/adams/web-based.html, under Accession #ML052910035.

B. DISCUSSION

This trial regulatory guide provides interim guidance for complying with the NRC's requirements in 10 CFR 50.69, by using the process described in Revision 0 of NEI 00-04 to determine the safety significance of SSCs and place them into the appropriate RISC categories. The safety significance of SSCs is determined using an integrated decision-making process, which incorporates both risk and traditional engineering insights. The safety functions of SSCs include both the design-basis functions (derived from the safety-related definition) and functions credited for severe accidents. Treatment requirements are then commensurately applied for the categorized SSCs to maintain their functionality.

Figure 1 provides a conceptual understanding of the new risk-informed SSC categorization scheme. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new safety-significance categorization. In the traditional deterministic approach, SSCs were generally categorized as either "safety-related" (as defined in 10 CFR 50.2) or "nonsafety-related." This division is shown by the vertical line in the figure. Risk insights, including consideration of severe accidents, can be used to identify SSCs as being either safety-significant[3] or low-safety-significant (LSS) (as shown by the horizontal line in the figure). This results in SSCs being grouped into one of four categories, as represented by the four boxes in Figure 1.

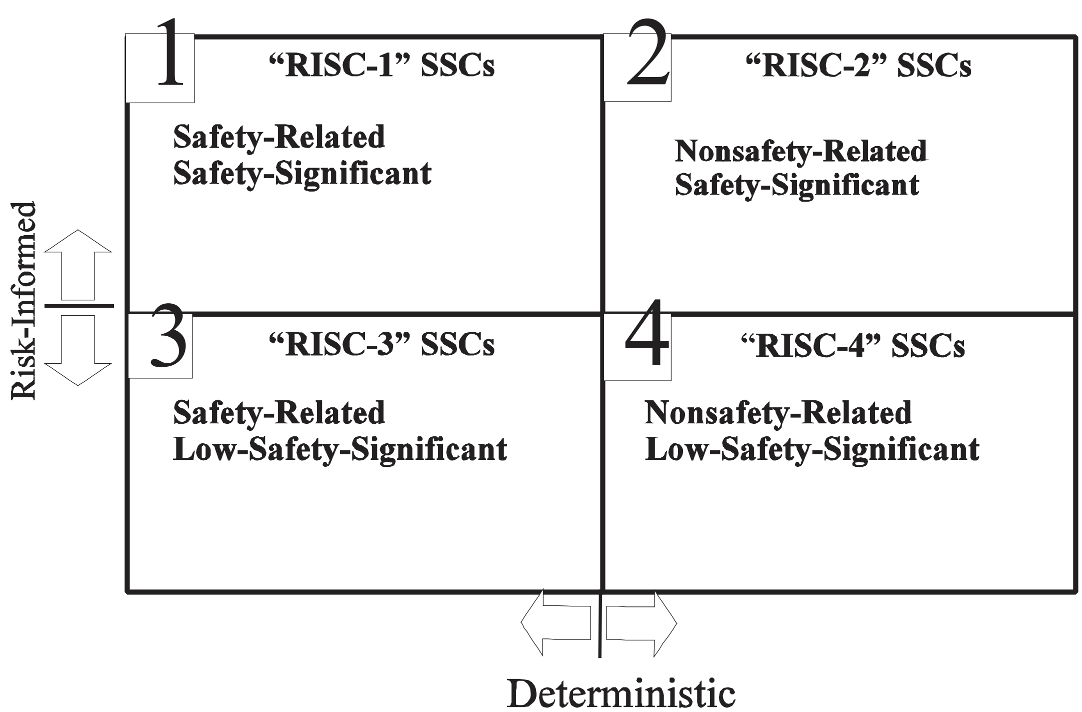

Figure 1. §50.69 RISC Categories

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[3] NEI 00-04 uses the term "high-safety-significant (HSS)" to refer to SSCs that perform safety-significant functions. The NRC understands HSS to have the same meaning as "safety-significant" (i.e., SSCs that are categorized as RISC-1 or RISC-2), as used in §50.69.

RISC-1 SSCs are safety-related SSCs that the risk-informed categorization process determines to be significant contributors to plant safety. Licensees must continue to ensure that RISC-1 SSCs perform their safety-significant functions consistent with the categorization process, including those safety-significant functions that go beyond the functions defined as safety-related for which credit is taken in the categorization process.

RISC-2 SSCs are those that are defined as nonsafety-related, although the risk-informed categorization process determines that they are significant contributors to plant safety on an individual basis. The NRC staff recognizes that some RISC-2 SSCs may not have existing special treatment requirements. As a result, the focus for RISC-2 SSCs is on the safety-significant functions for which credit is taken in the categorization process.

RISC-3 SSCs are those that are defined as safety-related, although the risk-informed categorization process determines that they are not significant contributors to plant safety. Special treatment requirements are removed for RISC-3 SSCs and replaced with high-level requirements. These high-level requirements are intended to provide sufficient regulatory treatment, such that these SSCs are still expected to perform their safety-related functions under design-basis conditions, albeit at a reduced level of assurance compared to the current special treatment requirements. However, 10 CFR 50.69 does not allow these RISC-3 SSCs to lose their functional capability or be removed from the facility.

Finally, RISC-4 SSCs are those that are defined as nonsafety-related, and that the risk-informed categorization process determines are not significant contributors to plant safety. Section 50.69 does not impose alternative treatment requirements for these RISC-4 SSCs. However, as with the RISC-3 SSCs, changes to the design bases of RISC-4 SSCs must be made in accordance with current applicable design change control requirements(if any), such as those set forth in 10 CFR 50.59.

The regulatory positions set forth in Section C of this trial regulatory guide contain specific instructions and cautions regarding the use of the categorization process.

C. REGULATORY POSITION

This trial regulatory guide provides interim guidance for trial use of the process and criteria for determining the safety significance of SSCs using the categorization process described in Revision 0 of NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," dated July 2005.

1. Other Documents Referenced in Revision 0 of NEI 00-04

Revision 0 of NEI 00-04 references numerous other documents, but the NRC's endorsement of Revision 0 of NEI 00-04 does not constitute an endorsement of those other referenced documents.

2. Use of Examples in Revision 0 of NEI 00-04

Revision 0 of NEI 00-04 includes examples to supplement the guidance. While these examples are appropriate to illustrate and reinforce the guidance, the NRC's endorsement of Revision 0 of NEI 00-04 does not constitute a determination that the examples are applicable for all licensees. A licensee or applicant must ensure that a given example is applicable to its particular circumstances before implementing the guidance as described in that example.

3. Use of Methods Other Than Revision 0 of NEI 00-04

To meet the requirements of §50.69 for categorization of SSCs, licensees may use methods other than those set forth in Revision 0 of NEI 00-04. The NRC staff will determine the acceptability of such other methods by evaluating them against the requirements of §50.69.

4. Limitations of Types of Analyses Used in Implementing Revision 0 of NEI 00-04

In its Final Policy Statement on Use of PRA Methods in Nuclear Regulatory Activities, SP-95-146, dated August 16, 1995, the Commission determined that the use of PRA technology should be increased in all regulatory matters, to the extent supported by state-of-the-art PRA methods and data.[4] Implementation of risk-informed regulation is possible because the development and use of a quantitative PRA requires a systematic and integrated evaluation. Development of a technically defensible quantitative PRA also requires sufficient and structured documentation to allow investigations of all aspects of the evaluation. To meet the requirements of §50.69 for categorization of SSCs, licensees must use risk evaluations and insights that cover the full spectrum of potential events (i.e., internal and external initiating events) and the range of plant operating modes (i.e., full-power, low-power, and shutdown operations). The NRC staff believes that current state-of-the-art PRA methods are available to quantitatively address the full spectrum of potential events and the full range of plant operating modes for this type of application. However, Revision 0 of NEI 00-04 allows the use of non-PRA-type evaluations (e.g., fire-induced vulnerability evaluation (FIVE), seismic margins analysis (SMA), and NEI guidance in NUMARC 91-06, "Guidelines for Industry Actions to Assess Shutdown Management,"[5] to address shutdown operations), when PRAs have not been performed. Such non-PRA-type evaluations will result in more conservative categorization, in that special treatment requirements will not be allowed to be relaxed for SSCs that are relied upon in such evaluations. It should be recognized that the degree of relief that the NRC will accept under §50.69 (i.e., SSCs subject to relaxation of special treatment requirements) will be commensurate with the assurance provided by the evaluation.

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4 The Commission's Final Policy Statement on Use of PRA Methods in Nuclear Regulatory Activities, SP-95-146, announced in the Federal Register (60 FR 42622) on August 16, 1995, is available through the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/commission/policy/60fr42622.pdf.

5 Copies of NUMARC 91-06, "Guidelines for Industry Actions to Assess Shutdown Management," dated December 1991, may be obtained from the Nuclear Energy Institute, Attention: Ms. Tonya Cameron, 1776 I Street, NW, Suite 400, Washington, DC 20006-3708 (phone: 202-739-8148).

5. Technical Adequacy Attributes of Analyses Implementing Revision 0 of NEI 00-04

The peer review process described in NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guidance,"[6] as amended to incorporate NRC comments provided in the NRC's letter to NEI, dated April 2, 2002,[7] and as endorsed in Regulatory Guide (RG) 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessments," provides a mechanism for licensees to determine if their internal events PRA meets the attributes required for this application.[8] An alternative to NEI 00-02 is the American Society for Mechanical Engineers (ASME) Standard ASME RA-S-2002, "Standard for Probabilistic Risk Assessments for Nuclear Power Plant Applications,"[9] as amended to incorporate NRC comments and as endorsed in RG 1.200. Both NEI 00-02 and the ASME Standard are endorsed for trial use by the NRC in RG 1.200, with appropriate clarifications and exceptions. However, these documents currently cover only internal events at full power. There is not currently a similarly endorsed standard for the external events PRA and non-PRA-type analyses (e.g., FIVE, SMA, NUMARC 91-06), and only limited guidance is provided in Section 3.3 of Revision 0 of NEI 00-04 for determining the technical adequacy attributes required for these types of analyses for this specific application. Industry standards have been or are being prepared for external events (e.g., seismic, high winds, and other external events), fire, and low-power and shutdown PRAs. Therefore, the NRC staff expects that the licensee or applicant to document the bases for why the method employed is adequate to perform the analysis required to support the categorization of SSCs. The licensee or applicant will provide the bases supporting the technical adequacy of the external events, other operating modes, and non-PRA-type analyses for each plant-specific request to implement §50.69. As standards are developed by the industry and endorsed by the NRC via revisions to RG 1.200 for external events, fires, and low-power and shutdown operations, the NRC expects the licensee or applicant to consider using those standards to demonstrate the technical adequacy of the PRAs addressing those events and operating modes and to document the bases for not using those standards.

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6 Copies of NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guidance," Rev. A3, dated March 20, 2000, may be obtained from the Nuclear Energy Institute, Attention: Mr. Biff Bradley, 1776 I Street, NW, Suite 400, Washington, DC 20006-3708 (phone: 202-739-8083).

7 The letter from Cynthia A. Carpenter (NRC) to Anthony R. Pietrangelo (NEI), dated April 2, 2002, concerns NRC staff review guidance for PRA results used to support Option 2 based upon NEI 00-04, supported by NEI 00-02. This letter is available electronically through the NRC's public Web site at http://adamswebsearch2.nrc.gov/idmws/doccontent.dll?ID=004066065:&LogonId=b1d7d050903b9714e6861221ea531aab, and through the NRC's Agencywide Documents Access and Management System (ADAMS), http://www.nrc.gov/reading-rm/adams/web-based.html, under Accession #ML020930632.

8 Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to DISTRIBUTION@nrc.gov. Active guides may also be purchased from the National Technical Information Service (NTIS)on a standing order basis. Details on this service may be obtained by contacting NTIS at 5285 Port Royal Road, Springfield, Virginia 22161, online at http://www.ntis.gov, or by telephone at (703) 487-4650. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland; the PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by email to PDR@nrc.gov. Copies of certain guides and many other NRC documents are available electronically through the Public Electronic Reading Room on the NRC's public Web site, http://www.nrc.gov, and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html.

9 ASME RA-S-2002, "Standard for Probabilistic Risk Assessments for Nuclear Power Plant Applications," is available through the Web-based product catalog sponsored by the American Society for Mechanical Engineers at http://catalog.asme.org/Codes/PrintBook/RAS_2002_Probabilistic_Risk.cfm?CATEGORY=CS&StartRow=101.

6. Uncertainty Considerations in Revision 0 of NEI 00-04

The NRC staff notes that Revision 0 of NEI 00-04 does not explicitly address modeling or data uncertainties. However, the sensitivity studies performed to support SSC categorization are intended to address some of the major sources of uncertainty (i.e., human error probabilities, common-cause failure probabilities, and those items identified in assessing the technical adequacy of the PRA). When assessing the potential increase in core damage frequency (CDF) and large early release frequency (LERF) as a result of implementing §50.69, the licensee or applicant should address uncertainties consistent with Section 2.2.5 of Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."[10]

7. Common Cause Failure and Degradation Mechanism Considerations in Revision 0 of NEI 00-04

The NRC staff notes that mechanisms that could lead to large increases in CDF and LERF, which could potentially invalidate the categorization process, are extensive, across system common-cause failures (CCFs) and unmitigated degradation. However, for such extensive impacts to occur, the mechanisms that lead to failure, in the absence of treatment, would have to be sufficiently rapidly developing or not self-revealing, such that there would be few opportunities for early detection and corrective action. Those aspects of treatment that are necessary to prevent SSC degradation or failure from known mechanisms, to the extent that the results of the risk sensitivity study would be invalidated, should be identified by the licensee or applicant, and such aspects of treatment should be retained. This requires an understanding of the degradation mechanisms and the elements of treatment that are sufficient to prevent the degradation.

As an example of how this might be implemented, the known existence of certain degradation mechanisms affecting pressure boundary SSC integrity would support retaining the current requirements regarding inspections or examinations or use of the risk-informed ASME Code Cases, as accepted by the NRC's regulatory process. As another example, changing levels of treatment on several similar SSCs that might be sensitive to potential CCF would require consideration of whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective to sufficiently minimize CCF potential, such that the categorization process (including the risk sensitivity study) remains valid.

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10 Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to DISTRIBUTION@nrc.gov. Active guides may also be purchased from the National Technical Information Service (NTIS)on a standing order basis. Details on this service may be obtained by contacting NTIS at 5285 Port Royal Road, Springfield, Virginia 22161, online at http://www.ntis.gov, or by telephone at (703) 487-4650. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland; the PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by email to PDR@nrc.gov. Copies of certain guides and many other NRC documents are available electronically through the Public Electronic Reading Room on the NRC's public Web site, http://www.nrc.gov, and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html.

8. Importance of, and Interrelationships within, the Processes Described in Revision 0 of NEI 00-04

The NRC staff notes that the implementation of all processes described in NEI 00-04 (i.e., Sections 2 through 12) is integral to providing reasonable confidence in the evaluations required by §50.69(c)(1)(iv). All aspects of the guidance are important and interrelated. Sections 2 through 7 and Section 10 of NEI 00-04 describe the processes used to determine the set of SSCs, for which unreliability is adjusted in the risk sensitivity study described in Section 8, which is used to confirm that the categorization process results in acceptably small increases to CDF and LERF. Section 9 describes the integrated decisionmaking panel (IDP) function of reviewing and ensuring that the system functions and operating experience have been appropriately considered in the process. Finally, Sections 11 and 12 describe the processes that provide reasonable confidence that the validity of the categorization process (including the risk sensitivity study) is maintained. Thus, all aspects of NEI 00-04 must be followed to achieve reasonable confidence in the evaluations required by §50.69(c)(1)(iv).

9. NRC Endorsement of Revision 0 of NEI 00-04; Specific Limitations and Conditions

Revision 0 of NEI 00-04 provides an approach that the NRC staff considers acceptable for use in meeting the categorization requirements set forth in §50.69, subject to the above regulatory positions and the following specific clarifications.

Section 1.2

The second paragraph of Section 1.2 discusses a third set of equipment referred to as "important-to-safety" and its relation to safety-related and nonsafety-related equipment. This usage is incorrect. The NRC staff's general endorsement of NEI 00-04 does not constitute an endorsement of this usage of the term "important-to-safety." Although incorrect, in the context of this guidance, the NRC staff interprets this term to refer to nonsafety-related SSCs that have been determined to be important. These nonsafety-related SSCs will be categorized as either RISC-2 or RISC-4, as determined by their safety significance, in accordance with the §50.69 categorization process.

The fourth paragraph of Section 1.2 states that the integrated decision-making process "…blends risk insights, new technical information and operational feedback…." The NRC staff interprets this phrase, and similar phrases (e.g., the third guiding principle in Section 1.3), as meaning that the integrated decision-making process must systematically consider the quantitative and qualitative information available regarding the various modes of plant operation and initiating events, including PRA, quantitative risk results and insights (e.g., CDF, LERF, and importance measures); deterministic, traditional engineering factors and insights (e.g., defense-in-depth, safety margins, and containment integrity), and any other pertinent information (e.g., industry and plant-specific operational and performance experience, feedback, and corrective actions program) in the categorization of SSCs.

Section 1.3

The second guiding principle in Section 1.3 states that deterministic or qualitative information should be used if no PRA information exists related to a particular hazard or operating mode. This principle is not to be interpreted to mean that deterministic or qualitative information should be used ***only*** when no PRA information exists. The NRC staff believes that the integrated decision-making process must systematically consider the quantitative and qualitative information available regarding the various modes of operation and initiating events, including PRA, quantitative risk results and insights; deterministic, traditional engineering factors and insights, and any other pertinent information in the categorization of SSCs.

Section 4.0

In Section 4.0 and Section 5.1, NEI 00-04 references ASME Code Case N-660, "Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities," as an approach for addressing the pressure-retaining function or passive function of active components.[11] The version of ASME Code Case N-660 that is acceptable to the NRC staff for use in this application is the version identified in RG 1.147, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," subject to any conditions or limitations specified therein.

Section 5.1

In the discussion of the internal events assessment, NEI 00-04 states that the safety-significant attributes are identified by the component failure mode that contributes significantly to the importance of the SSC. It should be recognized that multiple component failure modes may contribute significantly to the importance of an SSC, especially if no individual failure mode alone exceeds the screening criteria, but a number of failure modes collectively could exceed those criteria. In such cases, the guidance should not be inferred to limit the identification of safety-significant attributes based on the single highest contributing failure mode, but should include all significantly contributing failure modes.

Section 6.2

In Section 6.2, the NEI 00-04 guidance contains criteria for confirming that an SSC is LSS (or recategorizing it as safety-significant) based on defense-in-depth considerations, which include criteria related to containment bypass, containment isolation, early hydrogen burns, and long-term containment integrity. The containment isolation criteria listed in this section of NEI 00-04 are applicable to containment penetrations. The NRC staff interprets "containment penetration" as including electrical penetrations, air locks, equipment hatches, and piping penetrations (including containment isolation valves). Further, the staff notes that the containment isolation criteria in this section of NEI 00-04 are separate and distinct from those set forth in §50.69(b)(1)(x). The criteria in §50.69(b)(1)(x) are to be used in determining which containment penetrations and valves may be exempted from the Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR Part 50. The provision in §50.69(b)(1)(x) does not apply to whether containment isolation valves or penetrations can be categorized as RISC-3 SSCs, with the consequent elimination of other special treatment requirements such as design control, procurement control, quality assurance, ASME Code inservice testing, maintenance, procedures, documentation, and recordkeeping.

Section 8

The NRC staff agrees with the NEI 00-04 guidance that the risk sensitivity study is used to confirm that the categorization process results in acceptably small increases to CDF and LERF, and that the entire risk evaluation process (i.e., Sections 2 through 7 of NEI 00-04) is integral to performance of this risk sensitivity study. The NRC staff also notes that the subsequent sections of NEI 00-04 (Sections 9 through 12), especially Sections 11 and 12, are also integral to the performance of this risk sensitivity study in that they provide reasonable confidence that the validity of the categorization process (including the risk sensitivity study) is maintained.

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[11] Code Cases associated with the ASME Boiler and Pressure Vessel Code are available through the Web-based ASME Digital Store sponsored by the American Society for Mechanical Engineers at http://store.asme.org/category.asp?catalog%5Fname=Codes+and+Standards&category%5Fname=Boilers+and+Pressure+Vessels&Page=1.

Section 8 (and Section 8.1, in particular) of NEI 00-04 contains a number of statements that could mislead licensees and applicants to not fully perform the risk sensitivity studies, implement the necessary performance monitoring programs, or fully consider CCF potential. Licensees and applicants who implement §50.69 should ensure that their programs can achieve the statements made in this section of NEI 00-04. The NRC staff offers the following responses to statements in this section of NEI 00-04:

(1) NEI 00-04 states that the failure rates for equipment used in the PRA include the quantifiable impacts from known degradation mechanisms, as well as other mechanisms. This implies that the failure rates used in the PRA for most safety-related SSCs will remain valid with the elimination of special treatment requirements. NEI 00-04 also states that subsequent performance monitoring and PRA updates will continue to capture this data and provide timely insights into the need to account for any important new degradation mechanisms. The NRC staff notes that these statements cannot be confirmed or validated at this time without documented experiential data from a plant operating without special treatment requirements on the subject SSCs. Licensees and applicants should ensure that their programs can achieve the stated expectations.

(2) NEI 00-04 states that CCFs are treated in the base PRA, cites examples from the ASME Internal Events at Power PRA Standard, and then states that the evaluation of CCF will be equivalent to Capability Category II of the ASME standard. The NRC staff notes that although the cited standard does address CCFs, inter-system CCFs are only addressed for PRAs that achieve Capability Category III in this area of analysis. Licensees and applicants should ensure that their programs can mitigate the potential for inter-system CCFs.

(3) NEI 00-04 states that operating experience has shown that CCFs occur within systems. Contrary to this statement, the NRC staff notes many instances of operating experience with motor-operated valve performance that have involved inter-system common-cause concerns. Licensees and applicants should ensure that their programs can mitigate the potential for inter-system CCFs.

(4) NEI 00-04 states that the integrated risk sensitivity study conservatively increases the failure rate of all RISC-3 SSCs simultaneously to ensure that potential increases in delta CDF and delta LERF attributable to changes in treatment are small. However, the NRC staff notes that the increase in failure rate used in the risk sensitivity study may not be more conservative than other approaches (e.g., increasing the failure rate of a selected group of SSCs by a greater factor or assuming failure of this group of SSCs) and is only conservative if the licensee's or applicant's programs achieve the stated expectations.

(5) NEI 00-04 states that performance monitoring will ensure that potential increases in failure rates will be detected and addressed before reaching the rate assumed in the risk sensitivity study. Licensees and applicants should ensure that their performance monitoring programs will detect and address potential increases in failure rates before reaching the rate assumed in the risk sensitivity study.

(6) NEI 00-04 states that individual SSCs could see variations in performance, but that it is exceedingly unlikely that a large group of SSCs would all simultaneously experience unfavorable performance shifts. However, the NRC staff notes that a very large degradation in performance or failure of a selected group of RISC-3 SSCs could impact overall plant risk. Licensees and applicants should ensure that their programs can achieve the stated expectation.

(7) NEI 00-04 states that a guiding principle of the categorization process is that changes in treatment should not significantly degrade the performance of RISC-3 SSCs. However, this statement is not reflected as a guiding principle in Section 1.3. Licensees and applicants should ensure that their programs can achieve the stated expectation.

(8) NEI 00-04 states that utility corrective action programs would see a substantial rise in failure events, and would take corrective actions long before the entire population experienced degradation. The NRC staff notes that a utility's corrective action program alone, without a well-structured performance monitoring program, may not detect and correct RISC-3 degradation in a timely manner. Licensees and applicants should ensure that their programs can achieve the stated expectations.

Section 8 of NEI 00-04 provides high-level guidance, with some examples, for use in performing the risk sensitivity study. However, the example for implementation is overly simplistic and technically unacceptable. An acceptable process would need to include a focused cause analysis whenever a RISC-3 SSC failed, in order to determine whether its failure was attributable to the reduction in treatment and/or an indication of a potential CCF or new degradation mechanism. If there is indication that one of these factors is the cause of the failure, the licensee or applicant should have a process to immediately expand inspection or testing to similar SSCs to verify their functionality and to make any necessary adjustments in the treatment and/or categorization processes. Likewise, if the expected number of failures of a group of RISC-3 SSCs is exceeded over the evaluation interval, based on plant experience and reliability values used in the PRA, the licensee or applicant should implement a similar process to determine the cause of the higher-than-expected failure rates and should initiate corrective action in the treatment and/or categorization processes.

Mechanisms that could lead to large increases in CDF and LERF, which could potentially invalidate the categorization process, include extensive cross-system CCFs and unmitigated degradation. However, for such extensive impacts to occur, the mechanisms that lead to failure, in the absence of treatment, would have to be sufficiently rapidly developing or not self-revealing, such that there would be few opportunities for early detection and corrective action. Therefore, the factor used in adjusting the unreliability of RISC-3 SSCs in the risk sensitivity study should be set at a level such that an actual increase in unreliability of a RISC-3 SSC would be detected and corrected through the licensee's or applicant's monitoring, detection, corrective action, and feedback processes. The NRC staff expects that licensees and applicants who request to implement §50.69 will specifically describe how their implementation programs address and control the potential for and effects of common-cause interaction susceptibility, especially cross-system common-cause interaction, and the potential for and impacts of known degradation mechanisms, to provide reasonable confidence that the validity of the categorization process (including the risk sensitivity study) is maintained.

Section 9.2

Section 9.2 of NEI 00-04 limits the IDP review of risk information to active functions and SSCs. The NRC staff believes that this limitation in review scope is attributable to the reliance of NEI 00-04 on ASME Code Case N-660 to address passive functions, which is performed by an expert panel. The expert panel used in performing ASME Code Case N-660 may be the same panel as the IDP used in the §50.69 categorization process; however, it is not required to be the same panel. As such, the IDP review of risk information should address both active and passive functions and SSCs.

Section 11.1

In addressing regulatory commitments associated with special treatment requirements listed in §50.69(b)(1) for RISC-3 SSCs, Revision 0 of NEI 00-04 specifies that licensees and applicants should ensure that any design-basis commitments for RISC-3 SSCs continue to be maintained. The NRC staff interprets this guidance as applying to any commitments related to the design-basis functionality of RISC-3 SSCs.

Section 11.2

The requirements set forth in §50.69 do not establish a specific change control process to govern changes to the NRC-approved categorization process. As part of its §50.69 approval of a license amendment submittal, the NRC staff intends to impose a license condition that will govern changes to the categorization process. If a licensee or applicant wishes to change its categorization process, and the change is outside the bounds of the NRC's license condition, the licensee or applicant will need to seek NRC approval of the revised categorization process.

Section 12

The guidance in Section 12 of NEI 00-04 refers to the need to update the risk information and categorization process if the categorization results are "…more than minimally affected." The NRC staff interprets this phrase as applying to the entire risk evaluation process (i.e., Sections 2 through 8 of NEI 00-04) such that they would indicate a change in categorization of an SSC. The NRC staff also recognizes that the licensee or applicant may change the categorization and/or treatment aspects of SSCs so that there is reasonable confidence that the cumulative risk increase from implementing §50.69 is maintained acceptably small.

Section 12.4

The guidance in Section 12.4 of NEI 00-04 defines CCF as "…the simultaneous failure of more than one SSC to perform its function, due to the same cause…," and Appendix B to NEI 00-04 provides a similar definition. These definitions are derived from, and are appropriate for use in, PRAs. However, in the context of corrective action, these definitions may mislead licensees and applicants to not fully consider the implications of observed failures of SSCs. The NRC staff notes that SSCs can fail from a common cause at different times, depending on the degradation rate, actuation timing, operational and performance monitoring factors, and so forth. The licensee's or applicant's corrective action program associated with the implementation of §50.69 should address the potential for SSC failures at different times resulting from a common cause.

Section 12.4 of NEI 00-04 also states that component group failure data are reviewed to detect the occurrence of potential inter-system CCFs, and failures of RISC-3 SSCs are reviewed to determine the extent of the condition (i.e., whether this failure is indicative of a potential CCF). However, NEI 00-04 later states that failures of a group of SSCs that exceed a factor of two increase over the expected number of failures would reflect a potentially adverse trend requiring further assessment. For significant conditions adverse to quality, §50.69(d)(2)(ii) requires that measures be taken to provide reasonable confidence that the cause of the condition is determined and corrective action is taken to preclude repetition. To meet the requirement of §50.69(d)(2)(ii), each failure of a RISC-3 SSC must be assessed to determine whether a common-cause concern (inter-system or intra-system) exists.

In addition, Section 12.4 of NEI 00-04 states that failures of RISC-3 SSCs will be documented and tracked, and the corrective action reviews will consider previous component performance history. The NRC staff notes that although §50.69 does not require documentation or recordkeeping for RISC-3 SSCs, an effective corrective action process should include such documentation and recordkeeping. Licensees or applicants who implement §50.69 should incorporate these features into their corrective action processes.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this trial regulatory guide. No backfitting is intended or approved in connection with the issuance of this guide.

Except in those cases in which an applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in this guide will be used in evaluating licensee compliance with the requirements of §50.69 for the categorization of SSCs, as presented in (1) submittals in connection with applications for construction permits, standard plant design certifications, operating licenses, early site permits, and combined licenses; and (2) submittals from operating reactor licensees who voluntarily propose to initiate system modifications if there is a clear nexus between the proposed modifications and the subject for which guidance is provided herein.

REGULATORY ANALYSIS

The NRC staff did not prepare a separate regulatory analysis for this trial regulatory guide. The regulatory analysis that was prepared for the rulemaking is still applicable, as is its value/impact statement. The regulatory analysis is available in the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession #ML022630028.