THIS THIRD ITERATION OF PRELIMINARY RULE LANGUAGE IS BEING RELEASED TO SUPPORT INTERACTIONS WITH STAKEHOLDERS AND THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS). THIS LANGUAGE HAS BEEN SUBJECT TO ONLY LIMITED NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS ITERATION OF PRELIMINARY RULE LANGUAGE AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE PART 53 RULEMAKING ACTIVITIES.

AN IMPORTANT NOTE FOR THIS ITERATION IS THAT THE STAFF IS ACTIVELY ASSESSING VARIOUS ALTERNATIVE DESIGN/LICENSING APPROACHES TO ADDRESS COMMENTS THAT THE RULEMAKING SHOULD SUPPORT METHODOLOGIES THAT ARE LESS RELIANT ON PROBABILISTIC RISK ASSESSMENTS (PRA). THE DEVELOPMENT OF RECENT SUBPARTS (E.G., SUBPARTS H & I) PRIMARILY REFLECTS A RISK-INFORMED, PRA-CENTERED APPROACH. THE STAFF IS DEVELOPING ALTERNATIVE APPROACHES AND RELATED PRELIMINARY RULE SECTIONS FOR A FUTURE ITERATION THAT CAN BE CONSIDERED BY AND DISCUSSED WITH STAKEHOLDERS, NRC MANAGEMENT, AND THE COMMISSION.

THE STAFF IS CONTINUING TO REVIEW ALL OF THE COMMENTS AND SUGGESTIONS RECEIVED TO DATE BUT IS ISSUING THIS THIRD ITERATION TO SUPPORT ONGOING DISCUSSIONS RELATED TO KEY CONCEPTS.

August 2021 - Part 53 Subparts B and C Preliminary Rule Language Introduction

The NRC staff is releasing additional preliminary rule language related to the ongoing “Risk-informed, Technology-Inclusive Regulatory Framework for Advanced Reactors Rulemaking,” which is commonly referred to as the Part 53 rulemaking (Docket ID NRC-2019-0062). In this release, the staff provides below a third iteration of preliminary proposed rule language related to:

- Subpart B, “Technology-Inclusive Safety Requirements,” and
- Subpart C, “Design and Analysis Requirements.”

In separate tables, the first iteration of preliminary proposed rule language related to:

- Portions of Subpart H, “Licenses, Certifications, and Approvals,” and
- Subpart I, “Maintaining and Revising Licensing Basis Information.”

The changes in this iteration of Subparts B and C involve revising the terminology used for the safety criteria to eliminate the previously used “tiers” in the titles and reorganizing the sections such that normal operations are addressed separately from unplanned events. These changes are described below in the Subparts B and C discussion table (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21202A162). These changes also result in a number of conforming changes throughout Subparts B and C. These requirements are supported by the guidance in Regulatory Guide 1.233, “Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of

Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors" (ADAMS Accession No. ML20091L698), and additional guidance that is being prepared as part of utility-led, Department of Energy (DOE) cost-shared initiatives. This iteration of Subparts B and C continue to assume that probabilistic risk assessments are used to systematically assess a wide range of possible plant events and those tools are thereby available to assess and address plant risks against related performance measures. This assumption also affects the later subparts being released, including the preliminary proposed rule language and associated discussion tables for portions of Subparts H (ADAMS Accession No. ML21202A178) and I (ADAMS Accession No. ML21202A175), which use risk-related performance measures within specific requirements (e.g., preliminary Subpart I, § 53.1322, "Evaluating changes to facility as described in final safety analysis reports").

The staff has received requests from some external stakeholders to provide an alternative to the risk-informed, performance-based methodology currently reflected in the Part 53 preliminary proposed rule language and related guidance. One reason for developing such an alternative is to provide a framework that more closely aligns with licensing methodologies used in international standards such as the International Atomic Energy Agency (IAEA) Specific Safety Standard 2/1, "Safety of Nuclear Power Plants: Design." The IAEA standard reflects a more traditional or deterministic approach, like NRC's regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52, "Licenses, Certifications and Approvals for Nuclear Power Plants," including associated design requirements such as using the "single failure criterion" within plant design activities and including measures to mitigate severe plant conditions. The staff is actively working to develop such an alternative approach that would generally increase the use and importance of preestablished design criteria compared to the preliminary proposed Part 53 rule language and allow the use of probabilistic risk assessments in a supporting role for the methodology, rather than a leading role. The staff plans to release preliminary proposed rule language to support additional stakeholder discussions on this alternative design and licensing methodology in September 2021. The preliminary proposed rule language is expected to incorporate some existing NRC requirements and policies, provide technology-inclusive alternatives to existing requirements that were developed primarily for large light-water reactors, and align with some ongoing activities such as the "Emergency Preparedness for Small Modular Reactors and Other New Technologies," rulemaking (Docket ID NRC-2015-0225), as well as possible changes in areas such as siting criteria, and plant security. The staff will have a public meeting to discuss the alternative technology-inclusive framework after releasing the preliminary proposed rule language.

Subpart B, "Technology-Inclusive Safety Requirements"

3rd Iteration (Redline/Strikeout) of Preliminary Rule Language	Discussion
§ 53.200 Safety Objectives. Each ~~advanced~~commercial nuclear plant must be designed, constructed, operated, and decommissioned to limit the possibility of an immediate threat to the public health and safety. In addition, each ~~advanced~~commercial nuclear plant must take such additional measures as may be appropriate when	No changes from the previously released preliminary language in this section, other than a conforming change related to referring to "commercial nuclear plant" licensed under this part versus "advanced nuclear plant." Key documents related to the Part 53 rulemaking, including preliminary proposed rule language and

considering potential risks to public health and safety. These safety objectives shall be carried out by meeting the safety criteria identified in this subpart.	stakeholder comments, can be found at Regulations.gov under Docket ID NRC-2019-0062. Previous iterations related to Subparts B and C can also be found in NRC's ADAMS under accession numbers ML20311A004, ML20337A422 and ML21083A031. As described in the release of the second iteration language, the safety objectives do not refer to the Atomic Energy Act (AEA) Sections 182 and 161 authorities as the safety objectives for part 53. Instead, the use of "adequate protection" is expected to be used in its traditional role as an NRC regulatory finding, which is presumed through compliance with NRC regulations including part 53 or other license requirements, as appropriate. While Sections 182 and 161 of the AEA will be cited as enabling legislation within the rule package (e.g., in the *Federal Register Notice*), the staff does not foresee incorporating language from the AEA into the safety objectives or specific criteria in part 53.
§ 53.210 ~~First Tier~~ Safety Criteria for Design Basis Accidents. ~~(a) *Normal operations.*~~ Design features and programmatic controls must be provided for each ~~advanced nuclear plant to ensure the contribution to total effective dose equivalent to individual members of the public from normal plant operation does not exceed the public dose limits provided in Subpart D to 10 CFR part 20.~~ ~~(b) *Unplanned events*. Design features and programmatic controls must be provided for each advanced~~commercial nuclear plant such that analyses of ~~licensing~~design basis ~~events~~accidents in accordance with § 53.240~~, including treatment of uncertainties,~~ demonstrate ~~that events with an upper bound frequency greater than approximately once per 10,000 years meet~~ the following: (~~1~~a) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release would not receive a	To address numerous comments related to the use of "first tier" and "second tier" safety criteria in the previously released preliminary language for this section and § 53.220, the section titles are changed to "Safety Criteria for Design Basis Accidents" and "Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents." This change is intended to better describe the role of the two categories of safety criteria, the relationship between these safety criteria and the different types of LBEs, and the relationship to later sections in Subpart B and C. This change also leads to moving the requirements for normal operations to a separate section (§ 53.260). Relocating the requirements for normal operations from the safety criteria sections will hopefully clarify the requirements for normal operations and how they are addressed in later subparts, which is separate from measures taken to prevent or mitigate licensing basis events (i.e., unplanned events).

radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent; and (~~2~~b) An individual located at any point on the outer boundary of the low population zone who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (250 mSv) total effective dose equivalent.[1] 1. A whole body dose of 25 rem has been stated to correspond numerically to the once in a lifetime accidental or emergency dose for radiation workers which, according to NCRP [National Council on Radiation Protection and Measurements] recommendations at the time could be disregarded in the determination of their radiation exposure status (see NBS Handbook 69 dated June 5, 1959). However, its use is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.	The changes in the section titles and relocation of normal operations to a separate section do not change the technical requirements being proposed within the previously released preliminary rule language.
§ 53.220 ~~Second Tier~~ Safety Criteria~~.~~ ~~(a) *Normal operations.*~~ **for Licensing Basis Events Other than Design** ~~features and programmatic controls must be provided for each advanced nuclear plant to ensure the estimated total effective dose equivalent to individual members of the public from effluents resulting from normal plant operation are as low as is reasonably achievable taking into account the state of technology, the economics of improvements in relation to the state of technology, operating experience, and the benefits to the public health and safety. Design features and programmatic controls must be established such that [to be reworded for consistency with 10 CFR part 20 and 40 CFR part 190].~~**Basis Accidents.** ~~(b) *Unplanned events.*~~ Design features and programmatic controls must be provided to: (~~1~~a) Ensure plant structures, systems and components (SSCs~~,~~), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address	See above discussion for § 53.210. The staff is assessing various alternative design/licensing approaches to address comments that the rulemaking should support methodologies less reliant on PRA and related measures. This iteration of this section reflects the risk informed option being developed and has been used to develop first iterations of other subparts (e.g., Subparts H and I). The staff is developing alternate approaches and related preliminary rule sections for a future iteration that can be considered by and discussed with stakeholders, NRC management, and the Commission.

licensing basis events in accordance with § 53.240 and provide measures for defense-in-depth in accordance with § 53.250; and (~~2~~b) Maintain overall cumulative plant risk from licensing basis events such that the risk to an average individual within the vicinity of the plant receiving a radiation dose with the potential for immediate health effects remains below five in 10 million years, and the risk to such an individual receiving a radiation dose with the potential to cause latent health effects remains below two in one million years.	
§ 53.230 Safety Functions. (a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during routine operation and for licensing basis events over the life of the plant. (b) Additional safety functions supporting the retention of radioactive materials during ~~routine operation and~~ licensing basis events—such as controlling heat generation, heat removal, and chemical interactions--must be defined. (c~~).~~) The primary and additional safety functions are required to meet the ~~first and second tier~~ safety criteria defined in §§ 53.210 and 53.220 and are fulfilled by the design features and programmatic controls specified throughout this part.	Conforming changes to reflect changes to §§ 53.210 and 53.220.
§ 53.240 Licensing Basis Events. Licensing basis events must be identified for each ~~advanced~~commercial nuclear plant and analyzed in accordance with § 53.450 to support assessments of the safety requirements in this subpart. The licensing basis events must address combinations of malfunctions of plant SSCs, human errors, and the effects of external hazards ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the ~~advanced nuclear plant. The evaluation~~commercial nuclear plant. The analysis of licensing basis events must include analysis of one or more design basis	Conforming changes to reflect changes to §§ 53.210 and 53.220. The addition of specific wording for the analysis of design basis accidents relates to the clarification of § 53.210 and alignment of this section with § 53.450(f). The addition does not change the technical requirements from those included within the previously released preliminary rule language.

accidents in accordance with § 53.450(f). The analysis of licensing basis events must be used to confirm the adequacy of design features and programmatic controls needed to satisfy ~~first and second tier~~ safety criteria ~~of this subpart~~defined in §§ 53.210 and 53.220 and to establish related functional requirements for plant SSCs, personnel, and programs.	

§ 53.250 Defense in Depth. Measures must be taken for each ~~advanced~~commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties such that there is high confidence that the safety criteria in this subpart are met over the life of the plant. The uncertainties to be considered include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during routine operation and for licensing basis events, and those related to the reliability and performance of plant SSCs and personnel, and programmatic controls. No single engineered design feature, human action, and or programmatic control, no matter how robust, should be exclusively relied upon to meet the safety criteria of § 53.220 or the safety functions defined in accordance with § 53.230.	No changes (other than conforming changes) from the previously release preliminary language in this section.

§ 53.260 Normal Operations (a) *Maximum public dose*. Licensees under this part must ensure that the contribution to total effective dose equivalent to individual members of the public from normal plant operation does not exceed the public dose limits provided in Subpart D to 10 CFR part 20. (b) *As low as reasonably achievable*. Design features and programmatic controls must be established such that the estimated total effective dose equivalent to individual members of the public from effluents resulting from normal plant operation are as low as is reasonably achievable in accordance with 10 CFR part 20 [consider also possible updates for consistency with requirements in 10 CFR 50.34a, Appendix I to part 50, and 40 CFR part 190].	The addition of this section results from the removal of normal operations from §§ 53.210 and 53.220. The reorganization of the preliminary rule language does not change the technical requirements from those included in the previously released preliminary rule language. The staff continues to seek suggestions on how an integrated framework can be best incorporated into the individual subparts for lifecycle stages, such as establishing requirements for design, analysis, and operations. For example, staff is considering how to best address in part 53 the corresponding requirements in parts 50 and 52 for applications for a construction permit, standard design approval, a design certification, or a manufacturing license to identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable (see 10 CFR 50.34a[1]). Various sections of Parts 50 and 52, Appendix I to Part 50, and Part 190 to Title 40 (Protection of Environment) currently require plant designs to contribute to keeping public doses from routine effluents low (below performance objectives on the order of millirems). The requirement in § 53.260(b) serves to accomplish the same purpose. 1. 10 CFR 50.34a, paragraph(e) states: (e) Each application for a design approval, a design certification, or a manufacturing license under part 52 of this chapter shall include: (1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and (2) The information required in paragraph (b)(2) of this section The referenced paragraph (a) states: (a) An application for a construction permit shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including expected operational

	occurrences. In the case of an application filed on or after January 2, 1971, the application shall also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as is reasonably achievable. The term "as low as is reasonably achievable" as used in this part means as low as is reasonably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other societal and socioeconomic considerations, and in relation to the use of atomic energy in the public interest. The guides set out in appendix I to this part provide numerical guidance on design objectives for light-water-cooled nuclear power reactors to meet the requirements that radioactive material in effluents released to unrestricted areas be kept as low as is reasonably achievable. These numerical guides for design objectives and limiting conditions for operation are not to be construed as radiation protection standards. As discussed in the release of the second iteration language, this issue is related to and also addressed in the NRC Advanced Reactor Content of Application Project (ARCAP). Specifically, draft guidance for ARCAP Chapter 9 (ML20262H264) includes the following: *… in lieu of providing detailed system descriptions and analysis of estimated effluent releases as required by 10 CFR 50.34, 50.34a, 52.47, and 52.79, an application may demonstrate compliance with the applicable regulations by describing a radiation protection program and an effluent release monitoring program that will ensure that effluent release limits will be met during normal operations for the life of the plant. Information related to physical systems can be limited to general descriptions of layout and technologies used to limit the release of the various inventories of radioactive materials within the plant.*
§ 53.~~260~~270 Protection of Plant Workers. ~~(a) Design features and programmatic controls must exist for each advanced nuclear plant to~~(a) *Maximum occupational dose.* Licensees under this part must ensure that radiological dose to plant workers does not exceed the occupational dose limits provided in subpart C to 10 CFR part 20. ~~(b)~~(b) *As low as reasonably achievable.* As required by Subpart B to 10 CFR part 20, design features and programmatic	This section is renumbered and includes conforming changes to reflect the proposed revisions in previous sections. Section 53.270(a) is revised to require “licensees under this part” to ensure that the dose to plant workers does not exceed limits in 10 CFR Part 20. The change clarifies that while design features may contribute to limiting the dose to plant workers, ultimately

controls must, to the extent practical, be based upon sound radiation protection principles to achieve occupational doses that are as low as is reasonably achievable.	the licensee is responsible for limiting occupational exposures taking into account both design features and programmatic controls. The staff continues to seek suggestions on how an integrated framework can be best incorporated into the subparts for lifecycle stages such as establishing requirements for design, analysis, and operations.

Subpart C, Design and Analysis Requirements	
3rd Iteration (Redline/Strikeout) of Preliminary Rule Language	**Discussion**
§ 53.400 Design Features for Licensing Basis Events. Design features must be provided for each ~~advanced~~commercial nuclear plant such that, when combined with associated programmatic controls and human actions, the plant will satisfy the ~~first and second tier~~ safety criteria defined in §§ 53.210 and 53.220. Design features must ensure that the safety functions identified in § 53.230, of limiting the release of radioactive materials from the facility, ~~is maintained~~are fulfilled during ~~routine operations and~~ licensing basis events ~~by controlling the release of radioactive materials and by supporting other safety functions~~.	Conforming changes to reflect changes to §§ 53.210 and 53.220 and to better align design features under § 53.400 to those needed to prevent or mitigate licensing basis events (i.e., unplanned events).
§ 53.410 Functional Design Criteria for ~~First Tier Safety Criteria~~Design Basis Accidents. ~~(a) *Normal operations*. Functional design criteria must be defined for each design feature required by § 53.400 to demonstrate compliance with the first tier safety criteria defined in § 53.210(a). Corresponding programmatic controls, including monitoring programs, must be established to confirm that the established functional design criteria and the first tier safety criteria required in § 53.210(a) are not exceeded during normal operations.~~ ~~(b) *Unplanned events*.~~ Functional design criteria must be defined for each design feature required by § 53.400 relied upon to demonstrate compliance with the ~~first tier~~ safety criteria defined in § 53.210~~(b).~~. Corresponding programmatic controls and interfaces must be established in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the established functional design criteria and the ~~first tier~~ safety criteria required in § 53.210~~(b),~~, and to maintain consistency with analyses required by § 53.450.	Conforming changes to reflect changes to § 53.210 (Safety Criteria for Design Basis Accidents), which include relocating requirements for normal operations and emphasizing the tie to design basis accidents.

§ 53.420 Functional Design Criteria for ~~Second Tier Safety Criteria~~Licensing Basis Events Other than Design Basis Accidents. ~~(a) *Normal operations.*~~ Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with the ~~second tier safety criteria in § 53.220(a). Corresponding programmatic controls, including monitoring programs, must be established to confirm that the established functional design criteria and the safety criteria and performance objectives in § 53.220(a) are not exceeded during normal operations.~~ ~~(b) *Unplanned events*. Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with the second tier safety criteria in § 53.220(b) considering~~ safety criteria in § 53.220 considering licensing basis events ranging from anticipated operational occurrences to very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the ~~advanced~~commercial nuclear plant. Corresponding programmatic controls and interfaces must be established in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to meet the ~~second tier~~ safety criteria in § 53.220~~(b)~~ and to maintain consistency with analyses required by § 53.450.	Conforming changes to reflect changes to § 53.220 (Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents), which include relocating requirements for normal operations and emphasizing the tie to licensing basis events such as anticipated operational occurrences, unlikely event sequences, and highly unlikely event sequences.
§ 53.~~430~~425 Design Features and Functional Design Criteria for ~~Protection of Plant Workers.~~Normal Operations Design features must be provided for each ~~advanced~~commercial nuclear plant such that, when combined with associated programmatic controls and human actions, there is reasonable assurance the requirements for limiting the ~~protection of plant workers~~public dose from normal operations in § 53.260 will be met. Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.260. Corresponding programmatic controls, including monitoring programs, must be established to confirm that the	The addition of this section results from the removal of normal operations from §§ 53.210 and 53.220 and the movement of normal operations in Subpart B to § 53.260. This section, as well as the following section for protection of plant workers, present a challenge in terms of implementing a performance-based approach that recognizes the roles of both design features and programmatic controls in reaching desired objectives. The staff continues to seek suggestions on how an

~~worker protection~~public dose criteria in § 53.260(a) are not exceeded. In addition, functional design criteria must be defined for each design feature to ensure that plant SSCs and associated programmatic controls, including monitoring programs, achieve ~~occupational~~public doses as low as is reasonably achievable as required by § 53.260(b).	integrated framework can be best incorporated into the subparts for lifecycle stages such as design and analysis.
§ 53.430 Design Features and Functional Design Criteria for Protection of Plant Workers. Design features must be provided for each commercial nuclear plant such that, when combined with associated programmatic controls and human actions, there is reasonable assurance the requirements for the protection of plant workers in § 53.270 will be met. Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.270. Corresponding programmatic controls, including monitoring programs, must be established to confirm that the worker protection criteria in § 53.260(a) are not exceeded. In addition, functional design criteria must be defined for each design feature to ensure that plant SSCs and associated programmatic controls, including monitoring programs, achieve occupational doses as low as is reasonably achievable as required by § 53.270(b).	Conforming changes to reflect renumbering of § 53.270. This section, as well as the preceding section for normal operations, present a challenge in terms of implementing a performance-based approach that recognizes the roles of both design features and programmatic controls in reaching desired objectives. The staff continues to seek suggestions on how an integrated framework can be best incorporated into the subparts for lifecycle stages such as design and analysis.
§ 53.440 Design Requirements. (a) The design features required to meet the ~~first and second tier~~ safety criteria defined in §§ 53.210 and 53.220 ~~shall~~must be designed using generally accepted consensus codes and standards wherever applicable. (b) The materials used for safety related and non-safety related but safety significant SSCs [as will be defined in subpart A] must be qualified for their service conditions over the plant lifetime. (c) Possible degradation mechanisms related to aging, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect the performance of safety related and non-safety related but safety	Conforming changes to reflect changes to §§ 53.210 and 53.220. The addition of this paragraph (c) results from the need for designers to evaluate and consider, in both the design and integrity assessment programs, possible degradation mechanisms such as aging, fatigue, and chemical interactions.

significant SSCs must be evaluated and used to inform the design and the development of integrity assessment programs under § 53.850. ~~(c~~(d) Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features. (~~d~~e) Design features must be demonstrated capable of fulfilling functional design criteria considering interdependent effects ~~-~~through analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof for the range of conditions under which the analysis required in § 53.450 assumes these features will function throughout the plant's lifetime.	This is similar to the Design Reliability Assurance Program for passive LWRs established under the Part 52 design certification process. As in other areas, the staff is seeking input on the appropriate balancing of requirements to be fulfilled at the design stage and the consideration of performance-based approaches that assess both design and monitoring requirements.
(f)(1) Safety-related (SR) and non-safety-related but safety significant (NSRSS) structures, systems, and components must be designed and located to minimize, consistent with other safety requirements in this Part, the probability and effect of fires and explosions. (2) Noncombustible and fire-resistant materials shall be used wherever practical throughout the facility, particularly in locations with SR and NSRSS structures, systems, and components. (3) Fire detection and fire suppression systems of appropriate capacity and capability shall be provided and designed to minimize the adverse effects of fires on SR and NSRSS structures, systems, and components. (4) Fire suppression systems shall be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS structures, systems, and components to perform their safety function to meet § 53.230.	Paragraph (f) was added to provide additional discussion for fire protection.
(g) The reactor system and waste stores for each commercial nuclear plant must be capable of achieving and maintaining a subcritical condition during normal operations and following any licensing basis event identified in accordance with § 53.240.	Paragraphs (g) & (h) add requirements for longer term (e.g., after achieving a safe stable end state in the LBE analysis) capabilities to ensure reactor and waste stores can achieve and maintain subcritical conditions and cooling.

(h) Each commercial nuclear plant must have a capability to provide long-term cooling of the reactor fuel and waste stores following normal operations or any licensing basis event identified in accordance with § 53.240. (i) The design of each commercial nuclear plant must consider in the design, analysis, and development of programmatic controls the number of reactor units, waste stores, and other significant inventories of radioactive materials and the associated operating configurations, common systems, system interfaces, and system interactions.	Paragraph (i) is added to reinforce that the design and analyses activities under Part 53 are based on the concept of a "nuclear plant" and need to consider the number of units and radioactive sources and possible interactions between them.
§ 53.450 Analysis Requirements. (a) *Requirement to have a probabilistic risk assessment.* A probabilistic risk assessment (PRA) of each ~~advanced~~commercial nuclear plant [reminder – plant definition to include multi-module and multi-source] must be performed to identify potential failures, ~~degradation mechanisms,~~ susceptibility to internal and external hazards, and other contributing factors to ~~unplanned events~~event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that each ~~advanced~~commercial nuclear plant meets the ~~second tier~~ safety criteria of § 53.220~~(b).~~. (b) *Specific uses of analyses*. The PRA, other generally accepted risk-informed ~~approach~~approaches for systematically evaluating engineered systems, or combination thereof must be used: (1) In determining the licensing basis events, as described in § 53.240, which must be considered in the design to determine compliance with the safety criteria in Subpart B of this part. (2) For classifying SSCs and human actions according to their safety significance in accordance with § 53.460 and for identifying the environmental conditions under which the SSCs and operating staff must perform their safety functions. (3) In evaluating the adequacy of defense-in-depth measures required in accordance with § 53.250.	Paragraph (a): Conforming changes to reflect changes to § 53.220 (Safety Criteria for Licensing Basis Events Other Than Design Basis Accidents) and to remove "degradation mechanisms," which are better addressed through the design and programmatic requirements defined elsewhere in Part 53. The staff is investigating the best approach to address comments and suggestions to enable a more traditional or deterministic approach within the technology-inclusive regulatory framework. Such requests for a more deterministic approach would generally be seen as corresponding to the second element in the preliminary language "other generally accepted risk-informed approaches for systematically evaluating engineered systems." As mentioned in the general discussion at the beginning of this discussion table, an example of such an approach is the methodology described in IAEA SSR 2/1. In developing Subparts H and I and some specific sections within Subparts B and C, the staff is assuming a risk-informed approach that corresponds to the first element in paragraph (b),

(4) To identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment. (5) To identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events, such as earthquakes, identified in accordance with Subpart D of this part. (c) *Maintenance and upgrade of analyses*. The PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof must be maintained and upgraded in conformance with generally accepted methods, standards, and practices. (d) *Qualification of analytical codes*. The analytical codes used in modeling plant behavior in analyses of licensing basis events (e.g. thermodynamics, reactor physics, fuel performance, mechanistic source term) must be qualified for the range of conditions for which they are to be used.	which includes reliance on a PRA to support the various design and licensing activities listed in the paragraph. The staff is developing alternate approaches and related preliminary rule sections for the second element in paragraph(b) for approaches less reliant on a PRA. A future iteration will address this alternative more directly and will be used to support discussions with stakeholders, NRC management, and the Commission
(e) *Analyses of licensing basis events*. Analyses must be performed for licensing basis events ~~ranging from~~including anticipated operational occurrences ~~to~~, unlikely event sequences, and very unlikely event sequences with estimated frequencies well below the frequency of events expected to occur in the life of the ~~advanced~~commercial nuclear plant. The licensing basis events must be identified using insights from a PRA, other generally accepted risk-informed ~~approach~~approaches for systematically evaluating engineered systems, or combination thereof to ~~systematically~~ identify and analyze equipment failures and human errors. The analyses must address event sequences from initiation to a defined end state and demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy evaluation criteria defined for licensing basis events, to satisfy the ~~second tier~~ safety criteria of	Paragraph (e) is revised to include requirements to define evaluation criteria for specific event categories and a means to identify event sequences deemed significant for controlling risks posed to public health and safety. These requirements are added to support the evaluation of events, which need criteria beyond the aggregate or cumulative risk measures in § 53.220 and to support a proposed requirement for assessing plant changes in Subpart I. Examples of evaluation criteria for event categories and risk-significant licensing basis events is provided in NEI 18-04.

§ 53.220~~(b)~~, and provide defense in depth as required by § 53.250. The methodology used to identify, categorize, and analyze licensing basis events must include a means to identify event sequences deemed significant for controlling the risks posed to public health and safety.	
(f) *Analysis of design basis accidents*. The analysis of licensing basis events required by §§§ 53.240 and~~ §~~ 53.450(e) must include analysis~~ of a set~~ of design basis accidents that address possible challenges to the safety functions identified in accordance with § 53.230. Design basis accidents must be selected from those ~~unanticipated~~unlikely event sequences ~~with an upper bound~~within a frequency range of at least less than one hundred years and greater than one in 10,000 years as identified using insights from a PRA, other generally accepted risk-informed ~~approach~~approaches for systematically evaluating engineered systems, or combination thereof to ~~systematically~~ identify and analyze events considering equipment failures~~ and~~, human errors, and uncertainties. The events selected as design basis accidents should be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210~~(b).~~. The design-basis accidents selected must be analyzed using deterministic methods that address event sequences from initiation to a safe stable end state and assume only the safety-related SSCs identified in § 53.460 and human actions addressed by § 53.8xx (reference to concept of operations sections of Subpart F) are available to perform the safety functions identified in accordance with § 53.230. The analysis must conservatively demonstrate compliance with the safety criteria in § 53.210~~(b).~~.	Paragraph (f) is revised to clarify the selection of design basis accidents.
(g) *Other required analyses*. If not addressed within the PRA, other generally accepted risk-informed approach for systematically evaluating engineered systems, or combination thereof under paragraph (b), analyses must be performed to assess: (1) fire protection measures ~~provided~~ to ~~protect against, detect and suppress fires~~demonstrate reasonable assurance that	Paragraph (g) updated for fire protection analysis.

~~could impact the ability of~~no fire or explosion in any plant area can: (i) prevent equipment ~~to perform~~from performing its safety function ~~and~~to meet § 53.230, or (ii) challenge the safety criteria ~~contained~~ in §§ 53.210 and 53.220. (2) measures provided to protect against aircraft impacts as required by 10 CFR 50.150, and (3) measures to mitigate specific beyond design basis events as required by 10 CFR 50.155.	
§ 53.460 Safety Categorization and Special Treatment. (a) SSCs and human actions must be classified according to their safety significance. The categories must include "Safety Related" (SR), "Non-Safety Related but Safety Significant" (NSRSS), and "Non-Safety Significant" (NSS), as defined in subpart A of this part. (b) For SR and NSRSS SSCs and human actions, the conditions under which they must perform their safety function in § 53.230 must be identified. Special Treatment (e.g., functional design criteria and programmatic controls) must be established in accordance with this and other Subparts to provide appropriate confidence that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210~~(b)~~ and 53.220~~(b).~~. (c) Human actions to prevent or mitigate licensing basis events must be capable of being reliably performed under the postulated environmental conditions present and be addressed by programs established in accordance with Subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to provide reasonable assurance of meeting the safety criteria in §§ 53.210~~(b)~~ and 53.220~~(b).~~.	No changes (other than conforming changes) from the previously release preliminary language in this section.

§ 53.470 Application of Analytical Safety Margins to Operational Flexibilities. Where an applicant or licensee so chooses, ~~design~~alternative criteria more restrictive than those defined in ~~§~~ §§ 53.220~~(b~~ and 53.450(e) may be adopted to support operational flexibilities (e.g., emergency planning requirements under Subpart F of this part). In such cases, applicants and licensees must ensure that the functional design criteria of §~~-~~ 53.420~~(b),~~, the analysis requirements of § 53.450~~,~~(e), and identification of special treatment of SSCs and human actions under § 53.460 reflect and support the use of alternative ~~design~~ criteria to obtain additional analytical safety margins. Licensees must ensure that measures taken to provide the analytical margins supporting operational flexibilities are incorporated into design features and programmatic controls and are maintained within programs required in other Subparts.	Conforming changes to reflect changes to §§ 53.210 and 53.450.
§ 53.480 Design Control Quality Assurance. (a) Measures must be established to assure that the design criteria, analysis, categorization and special treatment of SSCs as required by § 53.460 are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes needed to meet the safety criteria identified per §§ 53.210 and 53.220 in accordance with Subpart E of this part. The QA program must conform with generally accepted consensus codes and standards. (b) Measures must be established for the identification and control of design interfaces in accordance with § 53.490. (c) The design control measures must provide for verifying or checking the adequacy of design in a manner commensurate with its safety significance, such as by the	No changes from the previously release preliminary language in this section.

performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process must be performed in accordance with appropriate quality standards. Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another qualified organization.	
§ 53.490 Design and Analyses Interfaces. Measures must be established for the identification and control of interfaces between (a) the plant design and supporting analyses required by this Subpart and (b) the activities addressed by other Subparts over the life of each ~~advanced~~commercial nuclear plant. These measures must include procedures for the review, approval, release, distribution, and revision of documents involving design interfaces such that design decisions are made in an integrated fashion considering all aspects of the facility impacted by the design or operational change prior to its implementation. Changes to design features and related programmatic controls over the lifetime of an ~~advanced~~commercial nuclear plant must be considered along with the state of technology, the economics of improvements in relation to the state of technology, operating experience, and benefits to the public health and safety, and other factors included in the assessments performed under the facility safety program required by § 53.800.	No changes (other than conforming changes) from the previously release preliminary language in this section.