[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 21, 26, 50, 51, 52, 55, 70, and 73

[NRC-2009-0196]

RIN 3150-AI66

Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations related to the licensing of new nuclear power reactors to ensure consistency in new reactor licensing reviews, promote a more effective and efficient new reactor licensing process, reduce the need for exemptions from existing regulations and license amendment requests, address other new reactor licensing issues deemed relevant by the NRC, and support the principles of good regulation, specifically openness, clarity, and reliability. Concurrently, the NRC is issuing for public comment several draft regulatory guides and draft standard review plans. The NRC plans to hold a public meeting to promote full understanding of the proposed rule and facilitate public comments.

DATES: Submit comments by **[INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject); however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- **Federal rulemaking website:** Go to https://www.regulations.gov and search for Docket ID **NRC-2009-0196**. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: James G. O'Driscoll, Office of Nuclear Material Safety and Safeguards; telephone: 301-415-1325; email:

James.ODriscoll@nrc.gov; or Omid Tabatabai, Office of Nuclear Reactor Regulation; telephone: 301-415-6616; email: omid.tabatabai@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for nuclear power plant application reviews. The Commission directed the NRC staff to proceed with a rulemaking on the alignment of licensing requirements in parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Production and Utilization Facilities" and "Licenses, Certifications, and Approvals for Nuclear Power Plants," respectively. The Commission also directed the NRC staff to pursue rulemaking to incorporate lessons learned from recent new power reactor licensing reviews. The NRC is conducting the alignment and lessons learned rulemakings as a single, coordinated effort.

The NRC's goals in amending these regulations are to ensure consistency in new reactor licensing reviews, promote an efficient new reactor licensing process, reduce the need for exemptions from existing regulations and license amendment requests, address other new reactor licensing issues deemed relevant by the NRC, and support the principles of good regulation, including openness, clarity, and reliability.

The NRC has identified corrections, clarifications, and new requirements to evaluate in the rulemaking. These items have been identified primarily because of part 52 licensing reviews since the NRC amended part 52 in 2007. Nevertheless, the current regulatory frameworks for new reactor licensing, whether under part 50 or part 52,

continue to ensure adequate protection of public health and safety and the common defense and security.

B. Major Provisions

Major provisions of this proposed rule include changes in the following areas:

- *Severe accident requirements.* This proposed rule would require applicants for light-water power reactor licenses under part 50 to provide descriptions and analyses of severe accident design features. Modifications to these plants also would be assessed for their potential to increase the frequency or severity of ex-vessel severe accidents (i.e., severe accidents in which material from a damaged core escapes the reactor pressure vessel). This change supports implementation of the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985, for part 50 applicants (Severe Accident Policy Statement).

- *Probabilistic risk assessment requirements.* This proposed rule would extend the current probabilistic risk assessment requirements in part 52 to apply to part 50 power reactor license applicants. The proposed rule also would expand the applicability of § 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," to allow design certification applicants, power reactor construction permit holders, and combined license holders to risk-inform the categorization of structures, systems, and components. Finally, the proposed rule would simplify the schedule for upgrading the probabilistic risk assessment.

- *Three Mile Island requirements.* This proposed rule would require part 50 applicants to provide information related to addressing lessons learned from the Three Mile Island accident in a similar manner and with similar exceptions as that currently required for part 52 applicants. The proposed rule also would revise these requirements to make them consistent with other existing regulations and guidance. This change would promote the objective of aligning requirements in parts 50 and 52 and ensure that applicants under 10 CFR part 50 address Three Mile Island requirements necessary or desirable to protect public health and safety.

- *Fire protection requirements.* This proposed rule would clarify the part 50 requirements on the submittal of information related to fire protection design features and fire protection plans to be consistent with those currently required for part 52 applicants. This would promote the objective of aligning requirements in part 50 and part 52.

- *Operator's licenses requirements.* This proposed rule would amend the requirements in 10 CFR part 55, "Operators' Licenses," for simulation facilities. These facilities are used to administer the operating license test and meet operator experience requirements at plants that are under construction (i.e., cold plants). This proposed rule also would amend part 55 to permit the use of suitable alternatives in lieu of the plant walkthrough portion of the operating test while the facility is under construction; permit a licensee to ask for a waiver for examination and test requirements for multiple unit sites of the same design; and require actions that would ensure that an operator license applicant's knowledge, skills, and abilities are maintained when significant time elapses between when the applicant successfully passes the licensing exam and completes the

remaining requirements to be licensed. These changes would promote a more efficient and effective operator licensing process at cold plants.

- *Physical security requirements.* This proposed rule would change the implementation milestone for the security requirements in § 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," and § 73.56, "Personnel access authorization requirements for nuclear power plants," from before fuel is allowed onsite to initial fuel load into the reactor. Additionally, the proposed rule would amend § 70.22, "Contents of applications," and § 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance," to align the security requirements for special nuclear material of moderate to low strategic significance for facilities licensed under part 50 and part 52. The proposed changes would enhance consistency and establish a level of protection for special nuclear material commensurate with the security risk associated with the material.

- *Fitness-for-duty requirements.* This proposed rule would address lessons learned from the implementation of fitness-for-duty (FFD) programs at nuclear power reactor construction sites. This proposed rule would change the implementation milestone for an FFD program required to implement all requirements of part 26, except subparts I, "Managing Fatigue," and K, "FFD Program for Construction," from establishment of the protected area to before initial fuel load into the reactor. Additionally, this proposed rule would revise requirements that address the escorting of construction workers at the construction site and procedures for Medical Review Officers. Other changes would clarify regulatory language.

- *Emergency planning requirements.* The proposed rule would address lessons learned, align the licensing process within 10 CFR parts 50 and 52, and clarify requirements related to the emergency plan change process, emergency preparedness exercises, and the review of emergency plans.

- *Part 52 licensing process.* This proposed rule would eliminate requirements for renewing design certifications and expiration dates of existing design certifications and standard design approvals. The proposed rule would extend the maximum duration of new and renewed manufacturing licenses from 15 years to 40 years. This proposed rule also would address lessons learned about the approval process for standard designs, the change process for approved designs, and the scope of the design applicants must submit for NRC review. The proposed rule also would address requirements for evaluating the impact on standardization when approving changes or departures.

- *Environmental requirements.* This proposed rule would amend the regulations to clarify that an applicant for a construction permit can incorporate by reference an environmental document prepared by the NRC for a different approval.

- *Other NRC processes.* This proposed rule would address how other regulatory processes apply to the part 52 licensing process. These processes include the hearing process, requirements for submittal of information to the NRC, and the backfitting process.

- *Miscellaneous topics.* This proposed rule would clarify requirements related to the closure of inspections and tests, reporting of defects and noncompliance, reporting of emergency core cooling system analyses, notifications to the NRC of

significant information, the generic issues program, and reporting the completion of power ascension or startup testing.

C. Costs and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative costs and benefits of this proposed rule, as well as qualitative factors to be considered in the NRC's rulemaking decision. The conclusion of the analysis is that the NRC's proposed rule and guidance development is, overall, cost beneficial to the nuclear industry, government, and society as shown in Table 1. The analysis combines the costs and benefits from all the proposed changes to regulations and guidance discussed in this document. The analysis discusses the economic impact to the nuclear industry, government, and society from the rulemaking and associated guidance.

Table 1 – Summary of Benefits (Costs) NPV 7 Percent

Description	Benefit	Cost	Net
Industry	$12,049,000	($4,519,000)	$7,530,000
NRC	$11,762,000	($3,165,000)	$8,597,000
Combined	$23,811,000	($7,684,000)	$16,127,000

The draft regulatory analysis also considers, in a qualitative fashion, regulatory efficiency, public health and safety, and common defense and security. For the regulatory efficiency aspect, this proposed rule would enable the NRC to better maintain and administer the new reactor licensing process and ensure that the requirements for the licensing of new reactors are clear and appropriate.

Based on these quantitative and qualitative factors, the draft regulatory analysis concludes that the proposed rule should be adopted. For more information, the draft regulatory analysis is available as indicated in the "Availability of Documents" section of this document.

TABLE OF CONTENTS:

I. Obtaining Information and Submitting Comments
  A. Obtaining Information
  B. Submitting Comments
II. Background
III. Discussion
  A. Applying the Severe Accident Policy Statement to New Part 50 License Applications
  B. Probabilistic Risk Assessment Requirements
  C. Three Mile Island Requirements
  D. Description of Fire Protection Design Features and Fire Protection Plans
  E. Operator Licensing
  F. Physical Security and Fitness-for-Duty Requirements
  G. Emergency Planning
  H. The Part 52 Licensing Process
  I. Environmental
  J. Applicability of Other Processes to the Part 52 Licensing Process
  K. Miscellaneous Topics
IV. Specific Requests for Comments
V. Section-by-Section Analysis
VI. Regulatory Flexibility Certification
VII. Regulatory Analysis
VIII. Backfitting and Issue Finality
  A. Current and Future Applicants
  B. Existing Design Certifications
  C. Existing Licenses
  D. Draft Regulatory Guidance
IX. Cumulative Effects of Regulation
X. Plain Writing
XI. National Environmental Policy Act
XII. Paperwork Reduction Act Statement
XIII. Criminal Penalties
XIV. Voluntary Consensus Standards
XV. Availability of Guidance
XVI. Public Meeting
XVII. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2009-0196 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to https://www.regulations.gov and search for Docket ID NRC-2009-0196.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. To make an appointment to visit the PDR, please

send an email to pdr.resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (https://www.regulations.gov). Please include Docket ID NRC-2009-0196 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

The regulatory framework for new reactor licensing has evolved over the years, as have several Commission policies and directions related to new reactors. This section describes this evolution and lessons learned from new reactor licensing actions and the changes they may warrant to improve the efficiency of the licensing process.

A. Licensing of Nuclear Installations

Initially, all nuclear power plants were licensed by the NRC under a two-step process described in part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), “Domestic Licensing of Production and Utilization Facilities.” This process requires both a construction permit (CP) and an operating license (OL). To improve regulatory efficiency and add greater predictability to the process, in 1989 the NRC established alternative licensing processes in part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” that include the issuance of a single combined license (COL). The COL process combines a construction permit and an operating license with conditions for plant operation.

Part 52 includes other licensing options. An early site permit (ESP) allows an applicant to obtain NRC approval for a reactor site without specifying the design of the reactor(s) that could be built at that site. A standard plant design can be referenced in a license application. The design can be either approved by the NRC staff (a standard design approval (SDA)) or certified by the Commission in a rulemaking (design certification (DC)). An application for an SDA may request approval of a major portion of a facility, but a request to certify a standard design must describe an essentially complete design. Part 52 also includes a process to grant a license to manufacture a nuclear power plant. Such a plant would be fabricated at one location but sited and operated elsewhere.

Under either the part 50 or part 52 process, NRC approval is necessary before a nuclear power plant can be built and operated. The NRC maintains oversight of the construction and operation of a facility throughout its lifetime to ensure compliance with the agency’s regulations for the protection of public health and safety, the common defense and security, and the environment.

Additional details about both licensing processes, beyond those given in the following sections, can be found in the "Nuclear Power Plant Licensing Process" backgrounder dated July 2020.

B. Part 50 Process

As of 2021, all nuclear power plants operating in the United States were licensed under the process described in part 50. The NRC and its predecessor, the Atomic Energy Commission, approved construction of these plants between 1964 and 1978, and the NRC granted the most recent OL under part 50 in 2015.

Under the part 50 process, a prospective nuclear power plant licensee applies first for a construction permit. The requirements in § 50.34(a), "Preliminary safety analysis report [PSAR]," outline the information an applicant must submit in a preliminary safety analysis report. The PSAR incorporates by reference or contains preliminary design information and criteria for the proposed reactor and comprehensive data about the proposed site. It also discusses various hypothetical accident situations and the safety features of the plant that would prevent accidents or lessen their effects. In addition, the application must contain a comprehensive assessment of the environmental impact of the proposed plant.

After reviewing the application, if the NRC determines that the application satisfies NRC siting regulations and applicable design requirements, then the NRC issues its safety evaluation report (SER). The NRC also conducts an environmental review and issues a final environmental impact statement (EIS). Section 189a.(1)(A) of the Atomic Energy Act of 1954, as amended (AEA), requires that a public hearing be held before a CP is issued for a nuclear power plant. The public hearing is conducted by the Commission or a three-member Atomic Safety and Licensing Board.

If the NRC grants the application and issues the CP, then the holder of the CP may apply for an operating license. An operating license application includes a final safety analysis report (FSAR), whose content is specified by § 50.34(b), "Final safety analysis report," and describes the bulk of the facility's licensing basis. The NRC reviews the FSAR to develop the agency's final SER. The NRC also conducts an environmental review and issues a supplemental EIS. Before issuing either a CP or an OL, the NRC provides interested persons an opportunity for hearing if they establish standing and submit an admissible contention as required by § 2.309, "Hearing requests, petitions to intervene, requirements for standing, and contentions." At the end of successful construction, if the NRC determines that the applicant satisfies the applicable requirements, then the NRC issues the OL, which is valid for a period of no more than 40 years.

C. Part 52 Process

1. Background

By the late 1980s, the NRC observed that the part 50 licensing process had certain disadvantages. The part 50 process requires the NRC to perform a unique, complete review of all aspects of the reactor's design, construction, and operation for each application. The resulting considerable variation in the design, construction, operation, and maintenance of nuclear plants led to an operating reactor population of great variability and diversity, even among reactors from the same vendor. While giving freedom to innovation during the early years of the industry, when innovation was most needed, the NRC realized that the "one-of-a-kind" licensing approach may have hindered the growth of significant economies of scale that could have benefitted safety and the efficiency and predictability of regulation.

To address this, during the 1970s and 1980s, the Commission added provisions to part 50 and part 2, “Agency Rules of Practice and Procedure,” to allow for limited degrees of standardization, and for as many years, the Commission proposed legislation to Congress on the subject. Members of Congress frequently asked the Commission whether legislation on the subject was necessary, and in doing the analysis to reply to these questions, the Commission eventually concluded that much of what it sought could be accomplished within its current statutory authority. Thus, the Commission embarked on a standardization rulemaking.

The Commission announced its intent to pursue a standardization rulemaking in its policy statement on “Nuclear Power Plant Standardization” (September 15, 1987). The policy statement set forth the principles that would guide the rulemaking. These principles were intended to encourage the use of standardized designs and the resolution of technical issues before plant construction begins. In 1988, the Commission issued the proposed rule on ESPs, DCs, and COLs (August 23, 1988), which first introduced part 52. In 1989, the Commission published the part 52 final rule (April 18, 1989), providing for issuance of ESPs, DCs, and COLs for nuclear power reactors.

The NRC expected the final rule would encourage the standardization of reactor designs and result in greater accumulation of construction and operating experience with a given design, easier transfer of that experience from one reactor to another, and easier maintenance by qualified vendor support, all of which should advance safe and reliable operation. Moreover, the NRC expected that a licensing process that encouraged early identification and resolution of safety issues, standardization, and other means of achieving early resolution of licensing issues would allow public participants in the licensing process an earlier entry into that process, greatly reduce the number and importance of safety issues that are decided late in the process, and permit a timely, yet

thorough, NRC review whenever an application incorporates a certified standardized design. Thus, early resolution of issues would lead to a simpler and more predictable licensing process.

2. 2007 Revision to Part 52

Based on lessons learned during the early DC reviews and discussions with nuclear industry representatives about the part 52 licensing processes, the NRC staff submitted SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998, proposing to enhance part 52. In a January 14, 1999, staff requirements memorandum (SRM), the Commission approved the rulemaking plan. On July 3, 2003, the NRC published a proposed rule. On March 13, 2006, the NRC issued a revised proposed rule that superseded the 2003 proposed rule and would rewrite part 52, make changes throughout the Commission's regulations to ensure that all licensing processes in part 52 were addressed, and clarify the applicability of various requirements to each of the processes in part 52. The final rule was issued on August 28, 2007.

3. Part 52 Regulatory Framework

One of the basic principles underlying part 52 is to promote the early resolution of technical, regulatory, and licensing issues. ESPs, SDAs, DCs, and manufacturing licenses (MLs) are licensing and regulatory processes that provide varying degrees of issue finality for siting and design issues. Issue finality in part 52 means that a part 52 approval, such as a DC, cannot be changed by the NRC unless certain criteria are met. These processes provide COL, CP, and OL applicants with greater regulatory certainty and predictability than using only the part 50 licensing process.

The NRC approves and certifies power reactor designs under part 52 through a rulemaking, independent of a specific site. A DC application must contain sufficient design information to enable the Commission to reach a conclusion that the applicant

has satisfied all applicable regulations associated with the design. In general terms, a design certification application should supply an essentially complete nuclear plant design, except for some site-specific design features. The DC application presents the design basis, the limits on operation, and a safety analysis of the structures, systems, and components of the facility. The scope and contents of a DC application are equivalent to the level of detail found in a final safety analysis report for the design of a power plant licensed under part 50. An application for a DC also must contain proposed inspections, tests, analyses, and acceptance criteria (ITAAC) for the standard design. The application must demonstrate how the applicant complies with the relevant Commission regulations.

The NRC prepares a safety evaluation report that documents its review of the standard design application and the basis for its finding that the design meets applicable regulations. If the NRC determines that the application meets the relevant standards and requirements of the AEA and the NRC's regulations, then the NRC publishes a final rule certifying the design as an appendix to the part 52 regulations. A DC is valid for 15 years and can be renewed for an additional 10 to 15 years. Design certifications provide a significant degree of regulatory issue finality to an applicant that references a design certification rule in a license application.

Site suitability issues, which may be independent of a specific nuclear power plant design, can be resolved through the issuance of an ESP. An ESP application must address the safety and environmental characteristics of the proposed reactor site and evaluate significant impediments to developing an acceptable emergency plan. An ESP application may also propose complete and integrated emergency plans for NRC review and approval. After reviewing the application, the NRC documents its findings related to site safety and emergency planning (if applicable) in a safety evaluation report and its

findings related to environmental impacts in an environmental impact statement. The process for reviewing and approving an ESP includes an opportunity for the public to challenge the application or the environmental impact statement in a contested hearing. A petitioner must submit a hearing request that demonstrates standing and includes at least one admissible contention. Before issuing an ESP, the NRC also conducts an uncontested hearing for the ESP. This hearing occurs even if the NRC does not receive a petition from the public requesting a hearing. The ESP is initially valid for no less than 10 years and no more than 20 years and can be renewed for 10 to 20 years. Once an ESP is issued, an applicant can reference it in one or more applications for permission to construct and operate nuclear power plants, and issues resolved in the ESP proceeding are governed by the issue finality provisions applicable to ESPs.

An ML application enables an entity to apply for Commission approval of a final reactor design and authority to manufacture the reactor at a site other than the site where the nuclear power plant will be installed and operated. Unlike a DC, an ML provides the NRC’s pre-approval of the procurement, manufacturing, and quality assurance processes of a specific reactor design. Issues resolved in an ML proceeding are governed by the issue finality provisions applicable to MLs.

Standard designs can also be approved by the NRC staff in an SDA. These approvals do not include ITAAC and are not Commission certifications. When an SDA is referenced in a subsequent license application, the issues addressed in an SDA are subject to change by the Atomic Safety and Licensing Board or Commission through the hearing process and thus do not have the same level of issue finality as DCs, MLs, and ESPs.

Under the part 52 regulatory framework, a prospective nuclear power plant operator applies for a COL that authorizes both plant construction and (after certain

criteria are met) operation. The application may reference a DC, an SDA, an ML, or an ESP to take advantage of reviews previously completed by the Commission or NRC staff. The NRC includes in the combined license the acceptance criteria that the NRC will use to evaluate, after construction, whether the plant has been built as specified in the COL application. The process for reviewing and approving a COL includes an opportunity for the public to challenge the application or the environmental impact statement in a contested hearing. A petitioner must submit a hearing request that demonstrates standing and includes at least one admissible contention. The AEA also requires the NRC to conduct a public hearing before a COL is issued. There is also an opportunity for a hearing after a COL is issued but before fuel loading is authorized; the hearing is limited to determining whether the acceptance criteria associated with the ITAAC in the license have been met. Notwithstanding whether that hearing is held, the licensee may not load fuel unless the Commission has determined that the acceptance criteria are met.

In addition to establishing an alternative process for licensing new reactors, the requirements in part 52 formalized expectations for new designs contained in the Commission's Severe Accident Policy Statement. Specifically, the part 52 process requires new light-water reactor applications to contain information that relates to certain items described in § 50.34(f), "Additional TMI-related requirements," which requires applicants to provide a description and analysis of design features related to the prevention and mitigation of severe accidents, and to submit a description and the results of a probabilistic risk assessment (PRA), among other topics described in that policy statement.

Due to the perceived advantages of the part 52 process as compared to the part 50 process (e.g., early identification and resolution of safety issues, standardization), the

NRC expected that future applicants would choose the part 52 process for most if not all future licensing applications.

D. Commission Policy, Regulations, and Guidance Associated with Aligning Parts 50 and 52

Because the NRC has been focused on the part 52 licensing process since the 1980s, the NRC did not consistently align requirements developed for new reactor applications submitted under part 52 with the part 50 requirements. Several Commission policies and directions related to new reactors have been translated into explicit requirements and guidance only for applicants under part 52. As a result, the two licensing processes have different technical requirements in some areas. Nevertheless, an application under either part 50 or part 52 must meet the public health and safety and common defense and security standards of the AEA before the NRC will grant the applicant a license.

1. Application of Severe Accident Policy and Additional Commission Direction

On August 8, 1985, the Commission published the Severe Accident Policy Statement. In this document, the Commission stated that it "fully expects that vendors engaged in designing new standard (or custom) plants will achieve a higher standard of severe accident safety performance than their prior designs." The Commission also explained how applicants submitting new designs for NRC approval could acceptably address severe accidents.

The Severe Accident Policy Statement says that the NRC expects an applicant to consider a range of alternatives when addressing safety issues and reducing risk from severe accidents. The NRC conclusions about the acceptability of an applicant's design would be made through a review of the applicant's traditional engineering analysis, complemented by insights from the PRA.

In addition, the Commission's policy statement on "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (PRA Policy Statement) encouraged the use of PRA in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

Therefore, the Severe Accident Policy Statement sets an expectation that part 50 construction permit applications include a preliminary risk analysis. The regulations in §§ 52.47(a)(27) and 52.79(a)(46) require submittal of PRA information in part 52 DC and COL applications, respectively. However, these expectations have not been reflected in part 50 requirements for new construction permit or operating license applications.

The NRC staff completed several Commission papers in the late 1980s and early 1990s addressing issues arising from consideration of new reactor design and licensing reviews. In SECY-89-013, "Design Requirements Related to the Evolutionary Advanced Light Water Reactors," dated January 19, 1989, the staff informed the Commission of the planned approach to ongoing reviews of evolutionary new reactor designs and identified issues that should be resolved for these designs.

A year later, in SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990, the staff recommended positions on several issues fundamental to the review of evolutionary designs. The Commission approved most of these enhancements in its June 26, 1990, SRM. The NRC implemented this policy in its guidance for contents of applications for these designs in Regulatory Guide (RG) 1.206, Revision 0, "Combined License Applications for Nuclear Power Plants (LWR Edition)."

As the NRC began to review passive reactor designs (i.e., designs that do not rely on active systems for safe shutdown following an event), the staff asked the

Commission for direction on extending certain requirements to these types of designs, as well as direction on additional enhancements, in SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated April 2, 1993. In its SRM dated July 21, 1993, the Commission extended a few of its previous positions to passive designs. The NRC implemented this policy in its guidance for contents of applications for these designs in RG 1.206.

However, the NRC has not consistently updated similar regulations and guidance to support new part 50 applications.

2. Three Mile Island Requirements

The Three Mile Island (TMI) regulatory requirements were imposed on applicants and licensees in response to lessons learned from the March 28, 1979, accident at TMI, Unit 2. These requirements included § 50.34(f), which applies to two groups of applicants. The first group consists of specified part 50 applicants for a construction permit or manufacturing license whose applications were pending as of February 16, 1982. These applications are no longer active. The second group comprises applicants for a DC, an SDA, a COL, or an ML, as described in part 52 (part 52 imposes most of the § 50.34(f) requirements on these applicants).

Part 52 regulations that specify the contents of DC, COL, SDA, and ML applications state that these applications must supply information necessary to demonstrate compliance with the technically relevant portions of the TMI requirements in § 50.34(f), with certain exceptions. In contrast, new CP and OL power reactor applications are not among the types of applications that must address the TMI requirements in § 50.34(f).

3. Probabilistic Risk Assessment

One of the fundamental criteria used to assess the resolution of severe accident issues for new reactors is the performance of a PRA. For new reactor applicants under part 52, PRAs are addressed in three separate sets of requirements:

- Section 50.34(f)(1)(i), as referenced in various provisions of part 52, which directs applicants to perform a plant- or site-specific PRA. The PRA should be used to improve the reliability of core and containment heat removal systems.

- Sections 52.47(a)(27), 52.137(a)(25), and 52.157(f)(31), which direct DC, SDA, and ML applicants, respectively, to provide a description of their design-specific PRA and its results, as well as § 52.79(a)(46), which directs COL applicants to provide a description of their plant-specific PRA and its results.

- Section 50.71(h), which directs only COL holders to develop, maintain, and upgrade a PRA with a specific scope.

These requirements do not apply to new reactor license applications submitted under part 50.

4. Fire Protection

In SRM-SECY-90-016 and SRM-SECY-93-087, the Commission approved requirements recommended by the NRC staff on fire protection for all evolutionary and passive advanced light-water reactors. All part 52 applicants are required to provide a description and analysis of their fire protection design features. However, § 50.34, "Contents of applications; technical information," prescribing the content of a new CP or an OL application, does not include similar requirements.

E. Summary of Recent Experience with New Reactor Licensing

The NRC has issued a significant number of licensing actions under part 52 since 2007. These actions include the issuance of 3 DCs, 14 COLs, 6 ESPs, 4 SDAs, and many license amendments and exemptions. The NRC has also approved the renewal of one DC. This experience has given the NRC some lessons learned that warrant changes to the current regulatory structure. The NRC described this collection of lessons learned in SECY-19-0084, "Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)," dated August 27, 2019. The enclosure associated with SECY-19-0084, "List of Lessons Learned Items Included in the Scope of the Regulatory Basis for Aligning Licensing Processes and Lessons Learned from New Reactor Licensing," contains the list of the 52 lessons learned items, grouped under several topical areas.

1. Operator's Licenses

The NRC regulations governing the issuance of licenses to operators of utilization facilities do not discuss the issuance of operator licenses to individuals at utilization facilities that are under construction and not yet operating (i.e., cold plants). The NRC recently gained experience implementing the operator licensing program in these situations. For example, several groups of applicants for operator licenses have taken the requisite written examinations and operating tests at Vogtle Electric Generating Plant Units 3 and 4 (VEGP 3&4), which are utilization facilities that were under construction at the time of the written examinations and operating tests. In some cases, the NRC approved exemptions from the Commission's regulations to facilitate the administration of these examinations and applicants' performance of experience requirements because design and construction of the utilization facilities at VEGP 3&4 were not complete. This proposed rule discusses regulatory changes that would

improve the efficiency and effectiveness of the operator licensing program at cold plants based on lessons learned from this experience. The lessons learned are related to the criteria for simulation facilities that are used to administer the operating test and meet experience requirements, the plant walkthrough portion of the operating test, and continuing training of operator license applicants following their completion of the NRC's initial operator licensing examination. The lessons learned also relate to criteria for waivers for examination and test requirements at multiunit sites.

2. Physical Security

The language in §§ 73.55(a)(4) and 73.56(a)(3) potentially subjects special nuclear material (SNM) of low strategic significance (i.e., unirradiated reactor fuel) to the security requirements in § 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," and § 73.56, "Personnel access authorization requirements for nuclear power plants," after the § 52.103(g) finding and prior to initial fuel load into a reactor. The current NRC regulations require applicants for a power reactor OL under part 50 or holders of a COL under part 52 to implement the security requirements in §§ 73.55 and 73.56 before unirradiated fuel is allowed onsite. Based on experience from recent new reactor licensing reviews, the NRC recognized that licensees may seek to receive unirradiated fuel onsite before carrying out all of the security requirements in §§ 73.55 and 73.56. However, these security requirements would have to be implemented at some point just before fuel load to address the increased risk arising from irradiated fuel onsite. This proposed rule would amend these requirements to make clear that applicants and licensees may bring unirradiated nuclear fuel onsite and protect it in accordance with the NRC's requirements for physical protection of special nuclear material of moderate and low strategic significance until initial fuel load into the reactor.

The NRC identified instances where licensees have stored nonfuel special nuclear material at operating power reactors outside the protected area, but within an owner controlled area, without protecting the material in accordance with § 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance." The NRC views this practice as not providing an appropriate level of protection commensurate with the level of risk associated with this material, because the security measures typically implemented within the owner controlled area are less stringent than the security requirements required by § 73.67(d), "Fixed site requirements for special nuclear material of moderate strategic significance," and § 73.67(f), "Fixed site requirements for special nuclear material of low strategic significance," for the protection of special nuclear material of moderate and low strategic significance, respectively. Therefore, the NRC proposes to modify the regulations to better define, commensurate with the risk associated with the material, which physical protection regulations should apply for licensees. Additionally, the NRC is amending language in § 70.22(k) to be consistent with the changes proposed in § 73.67(d) and (f).

3. Fitness-for-Duty

The NRC has identified lessons learned from implementation of fitness-for-duty (FFD) programs at the VEGP and Virgil C. Summer Nuclear Station construction sites (VCSNS). This proposed rule would amend regulations that address issues concerning access to the construction site and procedures for Medical Review Officers. This proposed rule also would clarify regulatory language and revise part 26, "Fitness for Duty Programs," based on risk insights learned from operating experience.

4. Emergency Planning

The NRC has identified several lessons learned based on experience with the new reactor licensing process with respect to emergency planning. This proposed rule would amend the regulations to address the following lessons learned:

- There is a need to clarify whether the emergency plan change process in § 50.54(q), “Emergency plans,” applies to part 52 licensees before the Commission’s § 52.103(g) finding.
- The NRC identified that requirements related to the need for a subsequent exercise at multiunit sites is overly burdensome.
- The scope of the area surrounding the site for the identification of physical characteristics that could pose a significant impediment to the development of emergency plans under 10 CFR part 100, “Reactor Site Criteria,” and § 52.17(b)(1) is unclear. The NRC also identified that clarification is needed to distinguish the siting requirement from the review of measures proposed by the applicant to mitigate or eliminate any such impediment.
- The requirements related to the descriptions of contacts and arrangements with Federal, State, and local governmental agencies that are required to be included in an ESP application should be clarified.

5. Part 52 Licensing Process

The NRC has identified several lessons learned based on experience with the new reactor licensing process. This proposed rule would amend the NRC’s regulations to address the following:

- Design Certification Renewal and Design Certification Expiration Date
    - The requirements for updating the contents of a DC at renewal are unclear, and the NRC’s experience with the licensing framework has

demonstrated that a 15-year certification duration creates a significant regulatory burden with little safety benefit.

- Change Process

The NRC has identified the following areas, concerning the change process for new reactor permits, certifications, and licenses, that the NRC proposes to clarify or amend:

  - Requirements that a COL holder request a license amendment and an exemption to change Tier 1 information in its plant-specific design control document (DCD) (or FSAR) for administrative items such as the organization and numbering of the referenced DCD may cause an unnecessary burden.
  - Having distinctly different regulatory language for the applicability aspects of § 50.59, "Changes, tests, and experiments," and the DC "§ 50.59-like" change processes can result in confusion and can lead to questions about why those aspects of the two processes are not the same.
  - Requiring licensees subject to the DC change process to obtain NRC approval before making certain physical changes, while allowing part 50 licensees to proceed with the physical changes before asking for NRC approval may impose an unnecessary burden on those licensees subject to the DC change process.
  - Part 52 does not currently have variance or amendment processes for SDAs. Based on NRC experience, COL applicants referencing a certified design have taken multiple departures from the referenced

certified design and, therefore, a COL applicant referencing an SDA may require a similar process. An SDA holder may also seek to make generic changes to an SDA, but part 52 does not currently have an amendment process for approved SDAs.

- Referencing Applications Under Review
  - The regulations in §§ 52.26(c) and 52.55(c) allow an applicant for a CP or a COL, at its own risk, to reference in its application a site for which an ESP or a design for which a DC application, respectively, has been docketed but not granted. However, there are no such provisions in §§ 52.147, "Duration of design approval," and 52.173, "Duration of manufacturing license," for SDAs and MLs, respectively.
- Design Scope and Standardization

The NRC identified the following areas concerning the definition and control of the design scope and the implementation of the Commission's policy on standardization:

  - Currently, DC applicants are not required to include tiers in their applications. Design certification applicants can include no tiers, a different number of tiers than in the current part 52 DC appendices, or tiers with definitions that are different than those in current part 52 DC appendices. This can lead to inconsistencies and increased burden for DC and COL applicants in preparing applications and the NRC in reviewing applications. Moreover, the rulemaking practice of placing identical tier definitions in each part 52 appendix is repetitive. The tiers should be defined once, and this definition should be consistent across part 52 DC appendices.

- The term “essentially complete nuclear power plant design” is mentioned in several sections of the NRC’s regulations, but the term is not defined for those sections. The NRC is proposing a definition for an “essentially complete nuclear power plant design” in § 52.1, “Definitions.”
- Experience with the review of license amendment requests during construction has shown that review of amendment evaluation criteria that assess the impact of a proposed amendment on standardization did not yield insights that justified the burden of these evaluations.
- Section IV.A.2, which appears in both appendix A, “Design Certification Rule for the U.S. Advanced Boiling Water Reactor,” and appendix D, “Design Certification Rule for the AP1000 Design,” to part 52 describes the use of site parameters and site characteristics slightly differently than they are described in § 51.50(c)(2). A conforming change is necessary for appendices A and D to part 52.
- When the first DC rules were issued, it was not clear whether the requirements in section IV, “Additional Requirements and Restrictions,” of the DC appendices would be consistent in subsequent DCs. The NRC has now issued six DC rules, and each rule has many identical requirements in section IV. Rulemaking to relocate these identical requirements from the individual appendices to a single paragraph in part 52 is more efficient and would eliminate unnecessary repetition of requirements.

- Section IX, “Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC),” of appendix B, “Design Certification Rule for the System 80 + Design,” appendix C, “Design Certification Rule for the AP600 Design,” and appendix D to part 52 are redundant to §§ 52.99, “Inspection during construction; ITAAC schedules and notifications; NRC notices,” and 52.103, “Operation under a combined license.”

- Standard Design Approval

Some designers have informed the NRC that they are considering submitting applications for SDAs for major portions of the design. The NRC’s regulations do not clearly specify whether only one or more than one SDA may be referenced in CP, COL, and ML applications, although it is implied that more than one SDA could cover the final design of major portions of an entire facility. If more than one SDA exists for a particular design, and the scope of each of those SDAs covers only a major portion of the design as permitted under § 52.135(a), then an applicant for a CP, a COL, or an ML may want to reference more than one SDA. Clarifying the regulations would be beneficial to potential applicants as well as the NRC.

- Content of Applications

The NRC identified the following areas concerning the content of new reactor applications and the role of this information in the part 52 licensing process:

- Applicants expend significant resources to develop and submit an evaluation of the differences between their applications and NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP). While this extensive report has supported an increase in effectiveness for the

NRC review of the applications, the development of the report may be an unnecessary burden given the limited benefit.

- Section 50.100, “Revocation, suspension, modification of licenses, permits, and approvals for cause,” can be read to imply that a COL could be revoked, suspended, or modified for failure to achieve timely completion of the licensee’s proposed construction or alteration of the facility. This interpretation would be inconsistent with § 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses,” which is the controlling requirement regarding the timely completion of the construction or modification of a facility and requires a CP, but not a COL, to contain the earliest and latest dates for completion of the construction or modification of the facility.
- Section V.A of several design certification rules omitted inclusion of part 52 from the list of applicable regulations. The NRC began including a reference to part 52 in the section V.A list of applicable regulatory parts beginning with the Advanced Power Reactor 1400 (APR1400) design certified in appendix F, “Design Certification Rule for the APR1400 Design,” of part 52.
- Manufacturing license applicants are not currently required to submit a description of a § 50.49(b) environmental qualification (EQ) program. Section 50.49(a) requires a part 52 ML applicant to include a § 50.49(b) program for EQ of electric equipment in its final safety analysis report but § 52.157(f)(6) omits this requirement.

6. Environmental Review

A COL applicant that references an ESP, a DC, or an ML is allowed, under part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” § 51.50(c), to incorporate by reference an environmental document previously prepared by the NRC. Section 51.50(a) does not contain a similar option for an applicant for a CP that references an ESP, a DC, or an ML. This rulemaking would promote the objective of aligning requirements for parts 50 and 52 applicants.

7. Applicability of Other Processes to the Part 52 Process

The NRC has identified several lessons learned based on experience with the new reactor licensing process with respect to the applicability of other regulatory processes to the part 52 process. This proposed rule would amend the NRC’s regulations to address the following:

- Section 52.103(a) requires the NRC to issue a notice of opportunity of a hearing on compliance with the acceptance criteria in a COL not less than 180 days before the scheduled date of fuel load. Although an ITAAC hearing is treated as a contested proceeding under some regulations (e.g., § 2.340 is titled, in part, “Initial decision in certain contested proceedings,” and § 2.340(c) refers to initial decisions on findings in ITAAC hearings under § 52.103), the definition of “contested proceeding” in § 2.4, “Definitions,” does not include ITAAC hearings within its scope.
- The requirement to provide annual updates to the FSAR is an unnecessary burden for certain applicants. For those COL applicants that have asked the NRC to suspend its review of their applications, or for COL holders that are not pursuing construction, this burden may not be justified.

- The requirements pertaining to backfitting and issue finality in parts 50 and 52, respectively, overlap in some areas and create inconsistencies. These inconsistencies in the regulations may lead to confusion about the applicable criteria for imposing changes to SDAs, MLs, and ESPs.
- There is an error in the 2007 part 52 final rule in which the Commission's decision not to hold mandatory hearings for MLs is not fully reflected in the NRC's regulations.
- The NRC is proposing to amend section VIII.C.5 of the design certification rules in the appendices to part 52 to clarify the requirements that apply to a petition to admit a contention in an adjudicatory proceeding for specified licensing actions.

8. Miscellaneous Lessons Learned

The NRC has identified several miscellaneous lessons learned based on experience with the new reactor licensing process. This proposed rule would amend the NRC's regulations to address the following:

- Section 52.103(b) gives the public an opportunity to ask for a hearing under § 52.103(a) when one or more of the acceptance criteria of the ITAAC in the COL have not been met or will not be met. Although ITAAC hearings are supposed to be narrowly focused on the status of the acceptance criteria, a litigant wishing to challenge operation of the facility under § 52.103(b) may misread § 2.106(b)(2)(ii) to mean that a broad, additional opportunity to raise challenges under the AEA and the Commission's regulations is available during the ITAAC verification process.
- During the revision of part 21, "Reporting of Defects and Noncompliance" in the 2007 part 52 final rule to address part 21's applicability to part 52 licensees, the

NRC unintentionally omitted "10 CFR part 52" from the definitions of "Commercial grade item," "Critical characteristics," "Dedicating entity," and "Dedication" in § 21.3, "Definitions." This omission created inconsistencies with other definitions in § 21.3 that apply to part 52 licensees.

- The current regulatory language in § 50.34(f)(2)(iv) requiring a "console" does not clearly convey the range of safety parameter display system design options acceptable to the NRC. Revising the regulation to remove the term "console" would better convey that the purpose of the safety parameter display system requirements is functional and not necessarily focused on whether there is a dedicated console.
- The current requirements to report emergency core cooling system evaluation model changes and errors as soon as they are identified is overly burdensome to those applicants for or holders of DCs or SDAs whose design is not referenced by a COL holder.
- The current regulations identify the NRC Regional Administrator as a recipient of a notification from certain applicants or licensees under part 52 of information having a significant implication for public health and safety or common defense and security. However, the Regional Administrator is not involved in the issuance of either SDAs or DCs, nor is the Regional Administrator responsible for the receipt or review of applications for part 52 early site permits, limited work authorizations, or licenses. Therefore, there may be a delay in assessing and acting upon the information received by the Regional Administrator because the cognizant and responsible organization for these applications and approvals has not been notified.

- The language in §§ 52.47(a)(21) and 52.79(a)(20) does not reflect that the NRC has discontinued the use of the priority ranking model for generic issues and has used a screening process with the risk criteria in RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis."
- The "have been met" language in § 52.97(a)(2) does not align with the "are met" language of section 185b. of the AEA and § 52.103(g). The finding made under § 52.103(g) is that the acceptance criteria "are met" at the time of the finding. The words "have been met" could be understood to mean that the ITAAC were met at some earlier time but may not have been maintained, so they are no longer met at the time of the § 52.97(a)(2) finding. This language could call into question whether ITAAC have been maintained when the § 52.97(a)(2) finding is made.
- The fiscal year 2020 final fee rule, "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020," requires part 52 COL holders to start being assessed annual fees upon successful completion of power ascension testing, rather than after the Commission makes a finding under § 52.103(g). The rule requires new part 50 power reactor licensees to be assessed annual fees beginning when the licensee successfully completes power ascension testing. The NRC needs to know the date on which the licensee successfully completes power ascension testing so the NRC can begin assessing annual fees under part 171, "Annual Fees for Reactor Licensees and Fuel Cycle Licensees and Material Licensees, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC." The

NRC's regulations do not currently require part 50 reactor licensees or part 52 COL holders to notify the NRC of completion of power ascension testing.

F. Summary of Current Licensing Approach

The NRC has identified several areas that require alignment between parts 50 and 52 to ensure equivalent designs submitted for NRC review under each process are assessed against consistent technical standards that yield outcomes with equivalent demonstrations of adequate safety, security, and environmental protection. Overall, the NRC's experience confirms that the current processes for licensing new reactors ensure that applications provide reasonable assurance of adequate protection of public health and safety and are consistent with the common defense and security; however, the NRC has identified several regulatory changes intended to address lessons learned from new reactor licensing reviews, improve clarity, and reduce unnecessary burden on applicants and the NRC.

G. Initiation of This Proposed Rule

In a September 22, 2015, SRM associated with SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," dated January 8, 2015, the Commission directed the NRC staff to proceed with a rulemaking on the alignment of licensing requirements of parts 50 and 52. The Commission also directed the NRC staff to pursue rulemaking to incorporate lessons learned from recent new power reactor licensing reviews.

H. Scope Definition

The Commission approved the initial scope for the rulemaking in SRM-SECY-15-0002.

Enclosure 1 to SECY-15-0002 identified the issues associated with Commission policies, direction, and associated regulations where alignment between the new reactor

licensing processes in part 50 and part 52 can be improved. In SRM-SECY-15-0002, the Commission approved revision of the associated regulations in parts 50 and 52 to address the issues identified by the staff in Enclosure 1.

Enclosure 2 to SECY-15-0002 gave several examples of corrections, clarifications, and new requirements. The staff committed to informing the Commission and other stakeholders, in accordance with the NRC's standard rulemaking practices, about the specific rule changes that the staff would consider.

In addition, the NRC staff determined that the scope of this rulemaking would be focused on regulatory issues primarily related to the licensing of future LWRs, such as facilities similar to large LWRs operating today, large new LWR applications (e.g., similar to the APR1400 and AP1000), and small modular reactor designs (e.g., similar to the NuScale small modular reactor).

On January 15, 2019, the NRC held a Category 3 public meeting where the NRC gathered feedback from external stakeholders on the scope of this rulemaking. Also, in January 2019, the NRC's working group assigned to develop this proposed rule asked the entire NRC staff to provide input on an initial list of rulemaking items.

Using the input received from NRC staff and other stakeholders, the NRC aligned on the scope in July 2019. On August 27, 2019, the NRC issued SECY-19-0084, which informed the Commission the detailed scope of the regulatory basis for this proposed rule.

I. Regulatory Basis

The NRC published the regulatory basis in the *Federal Register* on January 29, 2021. In the regulatory basis, the NRC staff presented draft recommendations to update and align the NRC's regulations and guidance to incorporate lessons learned from new power reactor licensing reviews. The NRC asked for public comment on these

recommendations and asked specific questions about other possible revisions of the NRC's requirements. The NRC held a public meeting on March 2, 2021, to discuss the regulatory basis and issued a summary of the meeting on March 19, 2021.

The public comment period for the regulatory basis closed on May 14, 2021. The NRC received eight public comment submissions on the regulatory basis, which are available for review in regulations.gov under Docket ID NRC-2009-0196.

1. NRC Observations on Stakeholder Feedback on the Regulatory Basis

The NRC reviewed the stakeholder feedback received on the regulatory basis to inform the development of this proposed rule and the draft regulatory analysis. The NRC received stakeholder feedback in several technical areas included in the scope of the regulatory basis. In many cases, this was a result of the NRC's questions posed in the *Federal Register* notice (FRN) for the regulatory basis.

Table 2 provides references to the eight public comment submissions received on the regulatory basis. The NRC parsed each submission, depending on its length and complexity, into one or more comments reflecting discrete statements; this document presents the NRC's summaries of and responses to these comments.

Table 2 – ADAMS References for Public Comment Submissions on the Regulatory Basis

Submission Number	Commenter	Commenter Type	Accession Number
1	Nuclear Energy Institute (NEI), Marcus Nichol	Nuclear industry trade association	ML21068A357
2	Mark Miller	Private citizen	ML21084A471
3	Anonymous	Anonymous	ML21103A234
4	Nuclear Matters, Victoria Reynolds	Advocacy organization	ML21134A115
5	Westinghouse Licensing and Advanced Reactors Engineering, Michael Corletti	Nuclear industry company	ML21137A177

6	NEI, Marcus Nichol	Nuclear industry trade association	ML21144A164
7	NuScale Power, LLC, Gary Becker	Nuclear industry company	ML21152A282
8	NEI, Marcus Nichol	Nuclear industry trade association	ML21265A444

The NRC reviewed the public comment submissions referenced in Table 2 to find comments in several regulatory areas discussed in Section III of this document. Several comments resulted in changes to the staff recommendations stated in the regulatory basis. Section III includes details on how the NRC used stakeholder feedback to develop this proposed rule. Comments not related to a specific regulatory item are discussed in this section, “NRC Observations on Stakeholder Feedback on the Regulatory Basis,” and in the section that follows, “Specific Requests for Comments.”

General Comments

Comment Summary:

Nuclear Matters expressed support for the updated licensing process framework of the regulatory basis, writing that the successful deployment of advanced reactors is beneficial for U.S. energy security and carbon-reduction goals.

NRC Response:

The NRC agrees, in part, with the comment. The comment supports the rulemaking and suggests no changes to the NRC staff’s recommendations. However, the promotion of nuclear power, for any reason, is not one of the purposes of this rulemaking, nor is it permissible under the NRC’s statutory authority. Accordingly, the Commission did not change the NRC staff’s recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI expressed conditional support for the recommended changes, writing that the NRC should amend the regulations to be less burdensome to the industry, while maintaining high safety standards. (The NEI's specific objections are noted in Section III of this document.) Additionally, the NEI encouraged the NRC to incorporate lessons learned from implementation of part 52 because the changes made in this rulemaking ultimately will affect the future 10 CFR part 53 rulemaking.[1] Although the part 52 implementation has been largely successful, according to the NEI, several unintended consequences include:

- The inability to make changes to Tier 1 information during construction;
- The inability to issue COLs when the need for changes to the DC is identified; and
- The lack of clarity on the term "essentially complete" resulting in the inclusion of unnecessary details in the application.

NRC Response:

The NRC agrees, in part, with the comment. As part of this rulemaking effort, the NRC is proposing to add a definition for the term "essentially complete nuclear power plant design" in § 52.1.

The NRC disagrees with the comment regarding licensees' inability to make changes to Tier 1 information during construction and the NRC's inability to issue combined licenses when the need for changes to the design certification is identified. The NRC has provided a specific response to these statements in its response to public comments related to the part 52 change process in Section III of this document.

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[1] Information about the part 53 rulemaking, "Risk-Informed, Technology Inclusive Regulatory Framework for Advanced Reactors" (RIN 3150-AK31), can be found on the NRC website.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI noted that the regulatory basis did not address creating a regulatory process to help prevent delay in the issuance of COLs because of errors in the referenced DC. The NEI stated that such a process would be permitted by the AEA, contrary to the NRC's current assessment.

NRC Response:

The NRC disagrees with the comments. The AEA requires the NRC to make certain findings that a design meets the regulations before issuing a license. If the NRC identifies a significant error in a DCD that undermines the statutory requirements involved with a COL safety finding, then the NRC may issue the COL only after the error is adequately addressed such that the required finding can be made. As discussed in a letter dated September 8, 2020, from the NRC (Anna Bradford) to NEI (Doug True), there are regulatory processes in place that allow the NRC to proceed with the review and issuance of a COL despite identifying an error in the referenced DC. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI summarized an issue from the William States Lee III Nuclear Station, Units 1 and 2 and Levy County Nuclear Power Plant, Units 1 and 2 (Lee and Levy) COL proceedings, in which design errors were identified in the AP1000 DCD and the NRC required the errors to be corrected prior to issuance of the COLs for the Lee and Levy plants, causing significant delays while the NRC reviewed the design error corrections. The NEI stated that this decision by the NRC is incongruous with the NRC's decision on

a similar issue when DCD errors were identified in the VEGP 3&4 and VCSNS Units 2 and 3 COL licenses and the VEGP 3&4 and VCSNS 2&3 plants were allowed to continue construction during review of the errors. The NEI recommended that the NRC consider as a generic policy issue the delays in license reviews that result when applicants identify changes needed to the DC while a COL application is undergoing review. Additionally, NEI recommended that the NRC consider whether design error corrections can be addressed in DC rules, which it said would have avoided the delays in the Lee and Levy COL proceedings.

NRC Response:

The NRC disagrees with the comment. The NRC has discussed this issue with stakeholders in the past, and the Commission has weighed in on this matter in "Conduct of New Reactor Licensing Proceedings; Final Policy Statement." As discussed in a letter from the NRC staff to NEI, dated September 8, 2020, the NRC affirmed that the AEA requires the NRC to make certain findings before issuing a license. The approach proposed in the comment is inconsistent with the AEA in this respect, so the NRC declines to adopt it. The Commission additionally noted in the policy statement that applicants should coordinate with vendors to ensure that decisions on DC applications do not impede decisions on COL applications. If there is a delay in the DC rulemaking, a COL applicant may request an exemption from one or more elements of the requested DC or proceed by using the "custom COL" approach. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI said that although the regulatory basis did not include a review of the regulations applicable to non-LWRs, there are examples noted in the NRC's "Analysis of

Applicability of NRC Regulations for Non-Light Water Reactors” white paper (NRC white paper) that, if addressed, could resolve inconsistencies between parts 50 and 52. The NEI recommended that the NRC evaluate and determine what among the requirements deemed inapplicable to non-LWRs in the NRC white paper to include in the rulemaking which would help applicants rely less on the NRC’s exemption process.

NRC Response:

The NRC agrees, in part, with the comment. As the NRC stated in the regulatory basis, this rulemaking does not include specific regulatory issues related to non-LWRs. However, the amendment of regulations based on non-LWR technology could introduce inconsistencies between potential future part 50 and part 52 non-LWR applications. Revisions to these regulations do not represent technical changes in material that applicants must address. Accordingly, the NRC is including language in this proposed rule to minimize inconsistences between part 50 and part 52 with respect to non-LWR technology in response to this comment:

- For analysis of structures, systems, and components (SSCs) related to emergency core cooling systems, which by the terms of the referenced regulation(s) are applicable to boiling or pressurized light-water nuclear power reactors, the NRC provided an applicability statement in the following regulations: §§ 50.34(a)(4), 50.34(b)(4), 52.47(a)(4), 52.79(a)(5), and 52.137(a)(4);
- For the specific technical requirements associated with mitigating systems required to address an Anticipated Transient Without Scram (ATWS), which by the terms of the referenced regulation apply to light-water-cooled nuclear power plants, the NRC added an applicability statement to the following regulations: §§ 52.47(a)(15), 52.79(a)(42), and 52.137(a)(15);

- For the specific technical requirements associated with mitigating systems required to address a loss of all ac power, which by the terms of the referenced regulation apply to light-water-cooled nuclear power plants, the NRC added an applicability statement to the following regulations: §§ 52.47(a)(16), 52.79(a)(9), and 52.137(a)(16);
- For requirements associated with pressurized thermal shock events, which by the terms of the referenced regulation apply to pressurized water nuclear power reactors, the NRC added an applicability statement to the following regulations: §§ 50.34(b)(9), 52.47(a)(14), 52.79(a)(7), and 52.137(a)(14);
- For § 52.79(a)(12), which references a requirement related to containment leak rate specific to water-cooled power reactors, the NRC added an applicability statement;
- For § 52.79(a)(13), which references a requirement related to the reactor vessel surveillance program for nuclear power reactors, the NRC added an applicability statement; and
- For § 52.79(a)(16)(ii), which references a requirement related to effluent monitoring for nuclear power reactors, the NRC added an applicability statement.

Comment Summary:

The NEI requested a 30-day extension of the comment period, from April 14, 2021, to May 14, 2021. The NEI stated that the extension of the comment period would allow NEI sufficient time to thoroughly review the regulatory basis and provide substantive input.

NRC Response:

The NRC agreed with the comment. On March 18, 2021, the NRC extended the comment period for the regulatory basis by 30 days, from April 14, 2021, to May 14, 2021. That action addressed NEI's concern. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Other Comments

Comment Summary:

The NEI recommended that the NRC revise existing guidance in a way that would encourage COL holders to implement an effective process for maintaining the plant-specific technical specifications (TS) bases consistent with the plant design, the updated FSAR, and the plant-specific TS as amended. The NEI stated that promoting up-to-date maintenance of TS bases during the construction process between COL issuance and the § 52.103(g) finding serves the interests of both the NRC and the licensee (e.g., timely updating of TS bases is essential for operator training) and guidance development would help provide that assurance in an efficient manner. The NEI commented that because all programmatic requirements need to be current upon issuance of the § 52.103(g) finding, including having TS bases reflect the TS and be consistent with the FSAR, having a process in place to help maintain that fidelity should reduce the chance of delay between the § 52.103(g) finding and the commencement of fuel load.

The NEI asked the NRC to clarify a specific portion (underlined as follows) of its description in the regulatory basis (p. K-14) of Southern Nuclear Company's actions to improve and update the plant-specific TS bases for VEGP 3&4 since receiving the COLs for those units:

> As an example, since the NRC issued the COLs for VEGP 3&4 in February 2012, the licensee has been constructing the units and improving and updating the plant-specific TS bases in accordance with the change process specified by the TSs Bases Control Program in Section 5.5, "Programs and Manuals," of the VEGP 3&4 plant-specific TSs. However, plant-specific TS Subsection 5.5.6, "TS[s] Bases Control Program," is not compulsory until the VEGP 3&4 plant-specific TSs are made effective by the paragraph 52.103(g) finding.

The NEI explained that the licensee established a TS Bases Control Program in 2019 and, before 2019, had been updating the plant-specific TS bases voluntarily using a general licensing document change procedure, with the updated TS bases voluntarily submitted to the NRC as part of the annual updated FSAR submittal required by 10 CFR 50.71(e). The NEI asked the NRC to revise the description accordingly.

NRC Response:

The NRC disagrees with the comment. COL holders have sufficient incentive to maintain up-to-date TS bases before plant-specific TSs become effective. The NEI points out an additional incentive for a COL holder to voluntarily implement the TSs Bases Control Program during the construction process between COL issuance and the § 52.103(g) finding: it is essential for supporting licensed operator training. This comment further supports the recommended alternative for the NRC to take no action. The NRC considers that the guidance development alternative, which would insert this good practice recommendation into appropriate NRC guidance documents, would offer minimal additional incentive, and that would not justify the cost of amending the guidance. Therefore, the NRC is not pursuing rulemaking or guidance development on this item. With respect to the suggestion that the NRC should revise certain language in the regulatory basis, the NRC is addressing comments on the regulatory basis in this proposed rule and will not issue a revised regulatory basis document. Accordingly, the

Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated that the NRC had significantly underestimated, in the regulatory basis (Appendix K, Section 6.6), the benefits to utility licensees of allowing generic application of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) Code, Section XI. The NEI said the analysis did not reflect the costs licensees face from vendors, contractors, and industry agencies for development of code alternatives, as well as the direct costs to licensees for evaluation of time challenges and workarounds. The NEI objected to the NRC's conclusion that the expense of rulemaking was not warranted at this time because of the "the small number of potential COL holders that might implement this regulatory relaxation," saying the benefit to even a single future COL holder would justify the change (based on, e.g., VEGP 3 having to analyze costs and benefits every time a repair is needed on piping subject to ASME BPV Code, Section III).

NRC Response:

The NRC agrees, in part, with the comment. The cost analysis should reflect the costs licensees incur to develop code alternatives and evaluate the time challenges. The NRC will include this information in the cost analysis when reviewing code alternative requests if the requesting licensee provides the information. However, the NRC disagrees with the comment that the cost analysis significantly underestimated the benefits to utility licensees of allowing generic application of ASME BPV Code, Section XI, where the current regulations require a part 52 licensee to repair and replace Section III components in accordance with ASME BPV Code, Section III until the § 52.103(g) finding is made by the Commission. As stated in the regulatory basis, there is no

technical basis supporting a rulemaking to allow the use of Section XI; increasing the benefit to industry in the regulatory analysis does not change the NRC's position. Therefore, the NRC did not make any changes to the cost model in response to this comment.

Comments on Topics Outside of the Scope for This Rulemaking

Comment Summary:

Mr. Mark Miller wrote that the NRC should consider eliminating the use of the linear no-threshold (LNT) theory in order to simplify reactor design, operational planning, and emergency planning. Mr. Miller said that small modular reactors are critical to reducing global warming and delaying the review of small modular reactors would impair efforts to fight climate change.

NRC Response:

This comment is outside the scope of this rulemaking to align the part 50 and part 52 licensing processes. The issues of simplifying reactor design, operational planning, and emergency planning; reducing global warming; and fighting climate change are not within the scope of this rulemaking, and the promotion of nuclear power, for any reason, is not permissible under the NRC's statutory authority. Accordingly, the NRC did not make any changes in response to this comment. The NRC notes that several petitions for rulemaking that requested the type of change suggested by this comment were denied by the Commission. See the FRN for the denial of petitions for rulemaking "Linear No-Threshold Model and Standards for Protection Against Radiation" dated August 17, 2021.

<u>2. Specific Requests for Comments</u>

In the FRN for the regulatory basis, the NRC posed four general questions that applied to all regulatory areas and five requests for comment in specific regulatory

areas. The NRC received feedback on each of these questions, which it used in development of this proposed rule. The public comments can be found on regulations.gov under Docket ID NRC-2009-0196. Section III of this document discusses four of the specific requests for comment and the associated public comment themes pertaining to them. The NRC specifically requested comments on one subject that is not covered in Section III of this document: advanced reactors. The NRC is addressing these comments in this section because a fundamental element in any rulemaking is its scope. This rulemaking's scope is focused on aligning parts 50 and 52 and applying the lessons learned from part 52 licensing actions involving applicants employing light-water reactor technology. The NRC's request, a summary of the comments received, and the NRC responses follow.

Relationship to Advanced Reactors

The current regulations in parts 50 and 52 were largely written during a period when the NRC was licensing LWRs. Today, significant stakeholder interest exists in licensing new advanced non-LWR designs. As such, in this rulemaking and in subsequent rulemakings addressing new licensing regulations for advanced reactors, the NRC will consider stakeholder feedback on how regulatory changes would impact potential non-LWR applicants.

For example, in this proposed rule, the NRC is proposing to revise § 50.34(f) so that the TMI requirements in § 50.34(f), with the same exceptions currently given for part 52 applicants, apply to new power reactor applications submitted under part 50. Section 50.34(f) requires part 52 applicants to provide information necessary to demonstrate compliance with any "technically relevant" positions of the requirements in § 50.34(f)(1) through (3) with the exception of § 50.34(f)(1)(xii), (2)(ix), (2)(xxv), and (3)(v). The NRC

is considering whether and how these regulations would apply to non-LWRs. In addition, the NRC is considering the applicable requirements in part 50 and part 52 during the development of part 53. As part of the development of the licensing framework within the part 53 rule, the NRC is using a technology-inclusive approach while retaining relevant language where appropriate from parts 50 and 52 to ensure a consistent level of safety between the different licensing frameworks. The NRC asked for feedback on potential impacts of imposing the TMI requirements on non-LWR applicants that the NRC should consider in the scope of the proposed rule.

The NRC received two comments on the consideration of advanced reactors in this rulemaking.

Comment Summary:

The NEI suggested the NRC evaluate all TMI requirements for their applicability to non-LWRs or other future generation plants and apply to non-LWRs only those TMI requirements necessary for coverage of safety and risk issues not addressed under other regulations and guidance. The NEI wrote that this approach could be cost-beneficial due to the resulting improvements in regulatory clarity and certainty.

The NEI also recommended that the NRC review the “entry conditions” for applying certain part 50 and 52 regulations with an eye toward identifying and correcting disparities that may result in different licensing actions being required based solely on wording/language structure rather than substantive technical differences in the designs under review.

The NEI supported the NRC’s inclusion of the “technically relevant” concept, which NEI said would allow applicants to show that certain technology-specific regulations do not apply to new designs, but still expressed concern about applicants facing undue burden from having to prove that a problem unique to LWRs does not

affect non-LWRs. The NEI wrote that having to prove technical relevance raises unnecessary barriers to entry for new nuclear technologies and unduly burdens applicants, while relying on the exemption process to address regulations that do not apply to non-LWRs burdens the NRC. The NEI recommended the NRC review the NRC white paper for improvements it can make related to not only TMI requirements but also other areas where requirements that clearly do not apply to some types of reactors result in numerous exemption requests.

NRC Response:

The NRC agrees, in part, with the comment. The current requirements in part 52 include requirements for applicants to provide only that information to demonstrate compliance with “technically relevant” portions of the part 50 TMI requirements. In response to this comment, as part of this rulemaking, the NRC is proposing revisions to § 50.34(f) that clarify the applicability of the TMI requirements where needed. These changes are discussed in more detail in Section III.C. of this document. These proposed changes would allow designers to provide more focused justifications commensurate with the relevance of the concept (i.e., a designer need not provide any information for a concept stated as applicable to LWRs only) without requesting an exemption. The proposed changes should reduce the need to prove that a problem unique to LWRs does not affect non-LWRs.

The NRC disagrees that the NRC should review the NRC white paper for changes that can be made beyond those proposed in the rulemaking in other areas where requirements do not apply to some types of reactors. The NRC white paper was a generic effort focused on regulatory applicability for all non-LWRs, and the NRC is proposing changes in this rule where they are within the scope of this rulemaking. A

detailed review for specific reactor types as suggested by the comment is outside the scope of this rulemaking.

Comment Summary:

The NEI reiterated its view that the purposes of the rulemaking should include clarifying which requirements in parts 50 and 52 do not apply to non-LWRs and ensuring consistency in the treatment of such requirements in the respective licensing processes. The NEI asked the NRC to incorporate into the rulemaking the feedback NEI submitted to the NRC on October 30, 2020, regarding the NRC white paper. The NEI also requested that the NRC clearly identify in the rule all regulations that are broadly not applicable to non-LWRs, using “entry conditions” as needed, and said the rulemaking is the appropriate vehicle for providing that clarification to industry. The NEI recommended the NRC base its determinations about applicability on the technical aspects of the design and the underlying safety purpose of the regulation, because those criteria are independent of the licensing process used. The NEI suggested including in the regulations new entry conditions sufficient to identify the underlying safety purpose of each requirement and its applicability to a particular design given the technical aspects of the design. The NEI stated that addressing these issues in the rulemaking would ensure that applicants are treated consistently regardless of whether they pursue licensing under part 50 or part 52.

NRC Response:

The NRC agrees, in part, with the comment. This proposed rule includes applicability statements in several regulations in parts 50 and 52 to ensure not all regulations in parts 50 and 52 generically apply to non-LWRs. The NRC applied the rationale explained in the NRC white paper to determine which regulations in parts 50 and 52 can be clarified as part of this rulemaking. The NRC disagrees with the comment

that this rulemaking is the appropriate vehicle for identifying all regulations that are broadly not applicable to non-LWRs. Such an undertaking is outside the scope of this rulemaking, which is intended to align the part 50 and 52 licensing processes and apply lessons learned from the part 52 licensing experience with applicants employing light water reactor technology. In response to this comment, the NRC is proposing the insertion of applicability statements in those regulations in § 50.34(f) that can apply generically to non-LWRs.

III. Discussion

Objectives of this Proposed Rule

This proposed rule would amend the current requirements for new nuclear power reactor license applications. During recent years, several potential applicants have informed the NRC of their intentions to consider using the part 50 process. By issuing an alignment of parts 50 and 52 and lessons learned rule, the NRC would be able to establish regulations that would ensure consistency in new reactor licensing reviews, regardless of which licensing process an applicant chooses to use. By addressing lessons learned from new reactor licensing reviews, the NRC also would be able to improve the clarity and effectiveness of these regulations for preparation and review of future new reactor license applications.

Applicability

The NRC envisions that some or all of this proposed rule would apply to applicants for, and current holders of, nuclear power reactor licenses issued under parts 50 or 52, applicants for and holders of nuclear power reactor SDAs under part 52, and applicants for DCs under part 52.

This rulemaking proposes revising requirements in 11 technical areas.

A. Severe Accident Treatment Requirements

The NRC is proposing to amend § 50.34(a) to identify additional information on severe accidents that would be required in applications for light-water power reactor construction permits. The NRC also proposes to amend § 50.34(b) to identify similar information that would be required in applications for a light-water power reactor operating licenses issued under part 50.

The NRC proposes to amend § 50.59 to add § 50.59(c)(2)(ix) and (x). These paragraphs would require licensees of power plants that are licensed under part 50 after the effective date of the final rule to seek an amendment to the operating license if a proposed change, test, or experiment would significantly increase the probability or consequence of an ex-vessel severe accident. This proposed requirement would apply to only future licensees because current OL holders are not required to have previously evaluated ex-vessel severe accidents. Consequently, they would be unable to comply with the proposed changes to § 50.59 because the licensees would have no baseline evaluation to use to determine whether a proposed change, test, or experiment would significantly increase the probability or consequence of an ex-vessel severe accident.

For a light-water power reactor, part 52 requires each applicant for a design certification, standard design approval, or manufacturing license to address the prevention and mitigation of severe accidents. Part 52 also requires applicants for amendments to part 52 combined licenses to evaluate the impact of the modification on the facility’s ability to mitigate severe accidents. The proposed revisions to § 50.34 would align these part 52 requirements to consider certain severe accidents for light-water power reactors with requirements for construction permit or operating license

applicants under part 50. The revised regulations would specify that this technical information must be supplied with future power reactor license applications under part 50. Similarly, the proposed revision to § 50.59(c)(2) would align the part 52 requirements to consider certain severe accidents for light-water power reactors with requirements for certain license amendments under part 50.

These changes to the regulations would fulfill the purpose of SECY-15-0002 by aligning parts 50 and 52 on design requirements to mitigate severe accidents and of the Commission's Severe Accident Policy Statement. Part 50 power reactor applicants would be required to provide a description and analysis of design features for the prevention and mitigation of severe accidents. Subsequent modifications to the plant would be evaluated for potential impact on these design features. If the change is significant, then NRC approval would be required before implementation.

<u>Public Comments Related to This Item</u>

The NRC received five comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI commented that the recommended rulemaking, which would revise part 50 to require applicants to provide descriptions and analyses of severe accident design features, does not adequately specify how applicants would comply with the requirement and could necessitate detailed analysis not available when a CP application is filed. The NEI requested that the NRC provide more details about the proposed requirement, specifically guidance about what a preliminary risk analysis for a CP application needs to accomplish and document.

NRC Response:

The NRC disagrees with this comment. A CP applicant determines what kind of reactor it wishes to build. If that reactor is an LWR, then the applicant determines how best to prevent and mitigate ex-vessel severe accidents and evaluates the phenomena involved. The level of detail in the analysis need only be sufficient for the applicant to determine that the features would be effective. As stated in § 50.34(a)(3)(iii), the standard applied is reasonable assurance that the *final* design will conform to the design bases with adequate margin for safety.

The NRC will follow SRM- SECY-90-016. Furthermore, as stated in the Commission Policy Statement on the Regulation of Advanced Reactors, dated October 14, 2008, the Commission expects that advanced reactors will provide enhanced margins of safety and/or use simplified, inherent, passive, or other innovative means to accomplish their safety and security functions.

The description and analysis provided under the proposed rule changes could support development of a PRA model, but this does not mean that the design of these features would be final, that the design would be supported by detailed analysis that would be required to demonstrate adequate protection, or that the PRA would meet the requirements of § 50.71(h)(1). Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated that the description in the regulatory basis of the existing regulatory framework for severe accidents is incomplete as it does not reflect all regulatory requirements relevant to the NRC's Severe Accident Policy Statement (e.g., it omits the need to demonstrate compliance with TMI requirements).

NRC Response:

The NRC agrees, in part, with this comment. The NRC agrees that the regulatory basis discussion of severe accidents did not include a discussion of TMI items in the context of severe accident treatment requirements. That is because the purpose of the recommended alternative to address severe accidents was to complement the TMI-related requirements of § 50.34(f) and other regulations related to severe accidents (e.g., §§ 50.44, "Combustible gas control for nuclear power reactors" and 50.62, "Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants"). Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI asserted that language in the regulatory basis indicating applicants must address severe accident issues in a manner like that prescribed by part 52 in order for the NRC to reach an adequate protection determination conflicts with the Severe Accident Policy Statement. The NEI referred to language in the Severe Accident Policy Statement providing that "plant-specific review of severe accident vulnerabilities using this approach is not considered to be necessary to determine adequate safety."

NRC Response:

The NRC disagrees with this comment. The text from Section A of the Severe Accident Policy Statement that NEI quoted is referring to plants under construction that had not received an operating license when that Policy Statement was issued in 1985. The Commission goes on to state that one of the main purposes of the Severe Accident Policy Statement is to clarify the procedures and requirements for licensing a new nuclear plant. Section B, "Policy for New Plant Applications," of the Severe Accident Policy Statement, states that new nuclear power plant designs can be shown to be

acceptable for severe accident concerns if they meet the specified criteria and procedural requirements. Among those requirements are the completion of a PRA and consideration of the severe accident vulnerabilities.

For existing plants, Section A of the Severe Accident Policy Statement explains that, at that time, the Commission planned to formulate an approach to ensure that there is no undue risk to public health and safety. In response to the Severe Accident Policy Statement, the NRC issued Generic Letter 88-20, "Individual Plant Examination of External Events for Severe Accident Vulnerabilities," on November 23, 1988 under § 50.34(f), to all holders of operating licenses and construction permits. The Generic Letter stated that each of these entities should perform an individual plant examination for severe accident vulnerabilities.

For new plants, the NRC will review the design using an approach that stresses deterministic engineering analysis and judgment; these are complemented by insights from the PRA. Severe accident vulnerabilities are currently addressed in the review of a DC, an SDA, or an ML application, as well as COL applications that do not reference a DC, SDA or ML. In order to align licensing processes in parts 50 and 52, these vulnerabilities should be subject to review in a CP or an OL application as well. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI asked the NRC to clarify whether part 50 applicants must comply with the provisions in part 52 that require applicants to resolve applicable unresolved safety issues (USIs) and medium- and high-priority generic safety issues (GSIs).

NRC Response:

The NRC agrees with the comment that clarification is needed. The NRC is proposing changes to part 52 to require applicants to provide in their applications proposed technical resolutions of all generic issues (GIs) identified since July 21,1999, USIs, and medium- and high-priority GSIs identified before July 21,1999, that are relevant to the applicant's design, as described in Section III.K.6 of this document. The requirements for applications under part 50 should apply in the same manner to applications made under part 52 for these issues. Accordingly, the NRC is proposing that similar text as that being proposed in part 52 also be added to § 50.34(a) and (b) in response to this comment.

Comment Summary:

The NEI suggested that, to account for variation in the state of design and analysis at the CP application stage, the severe accident-related information required of applicants should be preliminary only. The NEI said supplying preliminary information would comport with requirements for the preliminary safety analysis report in § 50.34(a) and recommended revising SRP Section 19.0 in line with that approach.

NRC Response:

The NRC agrees, in part, with this comment. A CP application would specify only preliminary information with respect to severe accident features. However, such features should not be proposed without a technical basis for concluding that they will be effective. This proposed rule's changes to § 50.34 would result in the alignment of SRP Section 19.0 with the requirements for a CP PSAR and for an OL FSAR as described in proposed § 50.34(a) and (b), respectively. The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

B. Probabilistic Risk Assessment Requirements

B.1. Use of Probabilistic Risk Assessment in Design

The NRC proposes to amend § 50.34(a) to require applicants for future part 50 power reactor CPs to submit a description of the plant-specific PRA and its results in the CP application. The NRC proposes to amend § 50.34(b) to require applicants for future part 50 power reactor OLs to submit a description of the plant-specific PRA and its results in the OL application.

Part 52 requires that a PRA be described in a DC, an SDA, a COL, or an ML application. The proposed edits to § 50.34(a) and (b) would ensure that similar risk information is supplied in applications for new power reactor CPs or OLs under part 50.

This change to the regulations fulfills the intent of SECY-15-0002 to align parts 50 and 52 on the use of PRA in the design of the facility. Further, this proposed amendment would enable the NRC's reviews of CP and OL applications to benefit from the results of and insights gained from a PRA for a proposed design. The NRC would be able to risk-inform its review of part 50 applications, thereby substantially increasing the safety focus of the NRC's review. Without this change, the inconsistency between parts 50 and 52 poses a conflict with the Commission's PRA Policy Statement, in which the Commission affirmed that PRA should be used in the design of new reactors.

Public Comments Related to This Item

The NRC received 10 comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI expressed concern that requiring a PRA for a CP application could align the level of design and analysis finality required of a part 50 CP application with that required of a part 52 COL application and advised the NRC against imposing such a

requirement, saying that needing to attain the same level of finality would threaten the viability of part 50 as a beneficial licensing pathway distinct from part 52.

NRC Response:

The NRC disagrees with this comment. The Commission's Severe Accident Policy Statement calls for the use of PRA in the design phase. The NRC proposes to require a CP applicant to include a description of that PRA and its results in the PSAR. This does not imply or confer finality for the design. Instead, finality for a design applies to a standard design when it is certified. The design of a plant for which a construction permit is sought is more nearly analogous to a proposed standard design before approval or certification.

Under part 52, a proposed design may be modified prior to certification or a certified design may be amended. The effects of such modifications on risk would be documented and assessed before the modified or amended design is certified. Similarly, a COL applicant may request an exemption from the referenced design rule and depart from the certified design. This, too, would be assessed by the NRC. During construction, a COL holder may still depart from the certified design through an exemption or a license amendment.

Compared to a COL holder, a CP holder may have somewhat greater latitude during construction to depart from the design described in the PSAR because the CP holder can depart from the design without prior NRC approval. However, the acceptability of such departures will be subject to NRC review when an application is submitted for an operating license, if not sooner.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated that a PRA is not needed for a CP applicant to establish the safety basis for a preliminary safety analysis or for the NRC to make a safety determination based on the preliminary information required of a CP application. The NEI recommended maintaining the policy that preliminary information is adequate for a CP application and that NRC approval of a CP application does not mean an applicant has a license to operate the subject plant. The NEI remarked that for advanced plants, whether an LWR or a non-LWR, a PRA developed at the CP stage may differ significantly from a PRA developed at the OL stage or in support of operations, with the information needed for a full and final PRA becoming available at different stages. The NEI suggested that at the CP application stage, the NRC should require only a preliminary risk assessment (the parameters of which NEI asked the NRC to clearly define) and not a PRA as part of the preliminary safety analysis. The NEI also recommended that as the NRC develops the rule, it also should develop draft regulatory guidance that identifies, for each stage of licensing for an advanced plant, acceptable approaches for PRA development and use. The NEI additionally suggested limiting the scope and role of a PRA at the CP application stage and not subjecting non-power reactors licensed under part 50 to PRA requirements.

NRC Response:

The NRC agrees, in part, with this comment. The NRC agrees that non-power reactors licensed under part 50 should not be subject to PRA requirements. The proposed new regulations in § 50.34(a)(14) and (b)(14) for future applicants for CPs and OLs, respectively, would apply only to power reactors.

The NRC disagrees that the NRC has stated expectations for complete development of the design and analysis for a CP application. A CP application must propose a preliminary design but need not describe a final design. In accordance with

§ 50.35, “Issuance of construction permits,” however, a CP application may specifically request Commission approval of a design feature and that the Commission incorporate the approval, if granted, into the CP. The degree of completeness therefore depends on the extent to which an applicant requests approval of design features in the CP application and provides adequate support for such requests. Although a CP application is unlike an application for standard design certification, as there will be no rulemaking associated with the CP when it is issued, the design may or may not be final depending on the information in the application.

On the other hand, the Commission has a clearly established policy that states its expectation that PRA should be used in the design phase. The scope and detail of that PRA will improve as the design matures.

A CP applicant is required by § 50.34(a)(1)(ii) to show that the nuclear power plant it intends to build is extremely unlikely to have an accident that releases significant quantities of radioactivity. This demonstration can be accomplished only after a systematic assessment of risk. The assessment need not be as comprehensive as one that is adequate for operation or for other risk-informed applications.

The NRC also disagrees that, as part of this rulemaking, the NRC should develop regulatory guidance that identifies, for each stage of licensing for an advanced plant, acceptable approaches for PRA development and use. As previously stated in this document, this rulemaking is intended to align the part 50 and 52 licensing processes and apply lessons learned from recent part 52 large LWR licensing experience.

Accordingly, the Commission did not change the NRC staff’s recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated that the information required to complete a PRA may not be available to the applicant when developing a CP application and requested that the NRC clarify what would be needed with respect to a PRA to meet the additional TMI-related requirements in § 50.34(f). The NEI recommended limiting PRA requirements in part 50 to § 50.34(b), which applies to the final safety analysis report at the OL stage.

NRC Response:

The NRC agrees, in part, with this comment. The Commission's PRA Policy Statement calls for a systematic assessment of risk in the design of nuclear power plants. This proposed rule would make that policy a requirement for power reactor CP and OL applicants. If a CP or OL applicant's PRA is consistent with the PRA standard as endorsed by RG 1.200, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," then many TMI-related requirements would be met. This would obviate the need for many specific requirements of § 50.34(f). For that reason, the NRC proposes to remove TMI-related requirements that would be redundant if an acceptable PRA is described and its results are included in the PSAR and FSAR, as appropriate. However, as explained in the preceding comment response, the NRC disagrees with limiting PRA requirements in part 50 to § 50.34(b). Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI cited language in the NRC's PRA Policy Statement indicating that use of PRA should be done "in a manner that complements the NRC's deterministic approach" and "where practical within the bounds of the state-of-the-art" to support its suggestion that use of PRA at the CP stage beyond details developed as a part of a preliminary risk analysis should be voluntary, so that applicants may choose to pursue that option as

appropriate (e.g., where they seek to use other risk-informed applications), but otherwise applicants can develop a preliminary risk analysis only and use a deterministic approach to show they meet regulatory requirements. The NEI commented that quantification in a PRA should not be mandated for a preliminary risk analysis, instead allowing for qualitative approaches.

NRC Response:

The NRC agrees, in part, with this comment. The NRC disagrees that the use of PRA at the CP stage should be voluntary. The proposed regulation would require the description and results of a PRA at the CP stage. However, the NRC's determination of the acceptability of the PRA would depend on how the applicant intends to use it. The NRC agrees that a CP applicant also can use deterministic or qualitative methods (e.g., a seismic margins analysis in lieu of a seismic PRA or a vulnerability evaluation in lieu of a fire PRA). Such methods have already been accepted in support of standard design certification applications. An applicant also could avail itself of risk-informed categorization of SSCs but may need to develop a more detailed and better quantified PRA than is needed for a CP, even if it does not meet the requirements of § 50.71(h)(1). Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI requested clarification about the impact of the recommended rulemaking on part 50 applications, saying the NRC assumes CP applicants would have a new "opportunity to develop their designs to avoid or mitigate severe accident vulnerabilities found using the PRA" but applicants already may need to address severe accident mitigation alternatives (SAMAs) to satisfy part 51 requirements.

NRC Response:

The NRC agrees, in part, with this comment. The Commission's PRA Policy Statement established the expectation that PRA is used during the design process. The regulations in part 52 make this an explicit requirement. The proposed rule would do the same in part 50. Although the NRC agrees that performance of a PRA could support SAMA for the environmental report that is needed to support a CP, performance of a PRA to support the environmental report is not required. Since the design proposed in a CP is not necessarily finalized, this design may be refined or modified for many reasons throughout the construction phase. These refinements could include avoidance or mitigation of severe accident vulnerabilities. One way to discover (and evaluate) the value of such modifications is through use of the PRA. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI suggested that the discussion of the interaction between the proposed PRA requirements and the existing part 51 environmental report requirements should be expanded and corrected to clarify such issues as the role, content, and timing of PRA with respect to an applicant's SAMA analysis.

NRC Response:

The NRC disagrees with this comment. The NRC recognizes that a PRA developed in the design phase would inform decisions about SAMAs. Under § 51.45(c), applicants must document SAMA assessments before a proposed site is determined to be suitable and a construction permit is issued. However, the part 51 regulations are not the place to establish procedural direction on how to use PRAs. The NRC has developed detailed guidance separate from the part 51 regulations on how to conduct PRAs. Examples include RG 1.200 and RG 1.174.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI asked the NRC to confirm that a CP PRA based on a preliminary design need not be as complete as a part 52 or OL PRA and said formalizing this understanding would impact the proposed changes to SRP Section 19.0.

NRC Response:

The NRC disagrees with the comment. The NRC evaluates the adequacy of the PRA based on the type of application the PRA is used to support. This proposed rule would require the use of PRA in the design of new reactors licensed under part 50, aligning part 50 with part 52 in this regard. Several standard design certifications and combined license applications have included a description and the results of a PRA. Part 52 requires SDA and ML applicants to include a description and the results of a PRA. A description of a PRA of similar scope and level of detail would be adequate for and should be used to support a CP application. Because the CP encompasses site-specific elements, a PRA for a CP would have the same scope as a COL's PRA.

The CP application must include information on the preliminary design of the facility. This preliminary design information must be sufficient to provide reasonable assurance that the final design will conform to the design bases with adequate margin for safety. The NRC anticipates that the preliminary design will be refined and modified in the course of construction. In other words, the preliminary design that supports a construction permit may not be final. However, the scope of the preliminary design must be adequate to support the development and use of a PRA in the design phase.

The preliminary nature of the design means that it is likely that the PRA for a CP would have to be updated to support an OL application. The OL applicant would have to

include all design modifications and refinements that affect the PRA (to reflect the *final* design).

As a result of these proposed rule changes, the NRC has proposed extending the applicability of SRP Section 19.0 to cover review of a PSAR submitted under § 50.34(a) and an FSAR submitted under § 50.34(b).

It is important to note that an OL applicant would not have to upgrade the PRA under proposed § 50.71(h)(1). That requirement need not be met until the scheduled date for the initial loading of fuel. However, the OL applicant's PRA to satisfy proposed § 50.34(b)(14) would have to reflect the final design of the plant, not the preliminary design.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated that the information required to complete a PRA may not be available to the applicant when developing a CP application. The NEI recommended that if a PRA is to be required for a CP application, the use of that PRA in the application should be accommodated without creating a de facto requirement for a complete and final design at the CP stage. The NEI also recommended that as the NRC develops the rule it also develop draft regulatory guidance on the use of "preliminary risk analysis" to reach preliminary conclusions at the CP application stage.

NRC Response:

The NRC disagrees with this comment. First, performance of a PRA does not constrain subsequent design decisions (though it may inform them). Second, the NRC requires the application to include the necessary information for the NRC to make its safety finding. This information should be sufficient for the applicant to develop a

preliminary PRA, the results of which would produce meaningful insights. The NRC has issued guidance to address other aspects of a PRA that cannot be performed until the as-built configuration can be determined. See DC/COL-ISG-020, "Implementation of a Probabilistic Risk Assessment-Based Seismic Margin Analysis for New Reactors," and DC/COL-ISG-028, "Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application." This guidance may change slightly as it is incorporated in regulatory guidance and review plans, but it explicitly acknowledges the differences between a PRA that is adequate for a preliminary design and one that is adequate for the operating phase. As part of this rulemaking effort, the NRC does not need to finalize related review and regulatory guidance to implement the proposed change to the regulations. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI recommended the NRC add a discussion on how § 50.34(f)(1)(i) applies to part 52 applications and how it relates to the other PRA rules in part 52.

NRC Response:

The NRC disagrees with this comment. As discussed in Section III.C. of this document, the NRC is proposing to remove § 50.34(f)(1)(i) because it would be redundant with proposed § 50.34(b)(14). Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI claimed that reworking a CP application PRA that was based on a preliminary design into a PRA suitable for an OL application would require the same

level of effort as developing an entirely new PRA and, thus, is approximately 15,000 hours rather than the estimated 1,000 hours.

NRC Response:

The NRC disagrees, in part, with this comment. The proposed regulatory changes would require an OL applicant to update the plant-specific PRA to reflect modifications and refinements to the design that were made between the CP and OL phases. The cost analysis in the regulatory basis reflected this update, so the NRC did not change the cost model for the PRA for the OL application.

The NRC's regulatory basis cost analysis did not consider the cost for PRA upgrade for the operating phase. However, the proposed regulations would not require upgrading the PRA until the scheduled date for the initial loading of fuel under § 50.71(h)(1). Therefore, the NRC changed the cost model to reflect the significant effort required to complete an upgrade prior to loading fuel.

B.2. Risk-Informed Categorization of Structures, Systems, and Components

The NRC proposes to amend § 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors," to allow LWR CP and COL holders and applicants for DCs to make use of this regulation. Section 50.69 allows certain entities to categorize structures, systems, and components (SSCs) according to safety significance and, for safety-related SSCs of low safety significance, the ability to adopt alternatives to certain special treatment requirements that are in addition to the customary treatment of SSCs in industrial applications. The regulations permit this for holders of an OL, holders of a renewed license under part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," applicants for a CP or an OL under part 50, and applicants for an SDA, a COL, or an ML under part 52. The NRC proposes to amend its regulations to extend this option to others.

Specifically, § 50.69 would be available to holders of an LWR construction permit under part 50 as well as applicants for an LWR DC and holders of an LWR COL granted under part 52. In addition, the NRC is proposing to clarify § 50.69(b) to make the applicability of the regulation more explicit.

This proposed change would allow for a risk-informed development and review of a DC application. This would provide a safety benefit by permitting the applicant and the NRC to focus their efforts on the most risk-significant SSCs during design and design review. Risk-informed classification of SSCs in the design phase also would allow the use of alternative special treatment requirements for establishing the suitability of SSCs for the proposed design. This can result in cost savings for applicants and CP holders that reference the design (e.g., in procurement and maintenance). Further, allowing OL holders but not COL holders to apply § 50.69 lacks a technical basis. Once the operating phase begins, there is no longer any technical difference between an OL and a COL. This change also would be consistent with the Commission's PRA Policy Statement, which calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA.

In SRM-SECY-18-0106 (Staff Requirements - SECY-18-0106 – Consideration in the Rulemaking Process of Issue Raised in Petition for Rulemaking on Applicability of Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors (PRM-50-110) (NRC-2015-0028), dated September 10, 2020), the Commission directed the staff to consider in the rulemaking process the issue of whether to allow holders of a COL to adopt risk-informed classification of SSCs under § 50.69. These proposed changes would address the Commission's direction.

Public Comments Related to This Item

The NRC received five comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI questioned whether a stated benefit of the rulemaking (i.e., CP applicants could take advantage of risk-informed licensing actions significantly earlier in the process) would apply to a CP application PRA. The NEI commented that such a PRA likely would not satisfy the NRC's expectations for risk-informed licensing actions because it would be based on a preliminary design information. The NEI recommended that the NRC clarify its expectations for how that type of PRA could be used in such actions. The NEI advocated for using a "preliminary risk analysis" at the CP application stage to support a risk-informed review.

NRC Response:

The NRC disagrees with this comment. The proposed regulatory changes, which would require an applicant to develop a PRA in the design phase, should allow the NRC to risk-inform its review of the CP application. The proposed regulatory changes would not require an applicant to develop this PRA such that it can be used for other risk-informed applications; the proposed revised regulations would permit an applicant to do so, however. For example, § 50.69 explicitly authorizes a CP applicant to use a risk-informed categorization of SSCs. Industry guidance for this has already been endorsed in RG 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance." Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI stated it is unclear whether the NRC's previous efforts to risk-inform application reviews have resulted in material benefits and questioned the expectation that the benefit of making regulatory changes that facilitate risk-informed licensing actions significantly earlier in the licensing process would exceed its costs.

NRC Response:

The NRC disagrees with the comment. The benefit of the availability of risk information during previous reviews of part 52 DC applications enabled the NRC to risk-inform its reviews of those applications. Consequently, the quality and safety focus of the NRC's review was greatly improved. By using risk information from a PRA that is developed for the design phase, the NRC can risk-inform its reviews of part 50 CP and OL applications. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis or the cost model in response to this comment.

Comment Summary:

The NEI stated that the current guidance related to the technical adequacy of a PRA is insufficient. NRC guidance does not address how a preliminary risk analysis at the CP stage could support initial implementation of § 50.69. The NEI stated that guidance is needed for applicants to both reflect that the implementation of § 50.69 is voluntary and provide flexibility on the time at which they elect to use § 50.69.

NRC Response:

The NRC agrees, in part, with this comment. Risk-informed categorization of SSCs in a license application is voluntary. Applicants that are authorized to use this option also have some flexibility to determine when to do so. Under the current regulation, CP and OL applicants may implement risk-informed categorization. In this proposed rule, the NRC is proposing to extend such authorization to CP holders. However, existing industry guidance, endorsed for trial use by the NRC in RG 1.201,

Revision 1, identifies how to determine whether a PRA is adequate to support risk-informed categorization of SSCs. The NRC expects that industry guidance will be updated to reflect the lessons learned in preparing license amendment requests (to use § 50.69) and experience gained while applying this regulation. Similar activities related to design reliability assurance programs for new reactors may also inform guidance updates. If the NRC endorses this revised industry guidance, then a PRA may entail a more mature design than the minimum required for a CP application. Because § 50.69 is a voluntary alternative regulation, it does not impose any requirement on a CP application (or the PRA adequate to support the application). The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI expressed concern that implementation of § 50.69 could impose undue burden on certain categories of applicants, such as those referencing a DC that did not implement § 50.69 or those referencing an SDA. The NEI recommended making conforming changes to parts 50 and 52 to facilitate implementation of § 50.69 without the burden of having to demonstrate under § 50.12, "Specific exemptions," that special circumstances exist to justify the decrease in standardization.

NRC Response:

The NRC disagrees with this comment. An entity intending to build a nuclear power plant determines which regulatory process to pursue (part 50 or 52). A DC, COL, or CP applicant determines whether to develop a PRA that is adequate to risk-inform the categorization of SSCs. These choices carry different costs, but the fact that a cost is entailed does not mean that it is an undue burden. A decrease in standardization may be a consideration for plants licensed under part 52 but does not pertain to part 50

licensees. Therefore, a licensee would not need to request an exemption under § 50.12 regarding a decrease in standardization. Moreover, in this proposed rule, the NRC is proposing to remove the part 52 requirement to consider standardization as a criterion for justification for making changes in a certified design, a combined license, or a manufacturing license.

Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI commented that permitting DC applicants to use § 50.69 could result in savings and reduced burden for them.

NRC Response:

The NRC agrees, in part, with the comment. Allowing applicants for standard design certification to use § 50.69 could be beneficial, but whether this is the case is likely to vary substantially from one design to another. In each case, the applicant is in the best position to determine the cost and value for its particular situation, and it probably will adopt the regulation only if it perceives a net benefit. The proposed change to the regulation is for consistency and safety, not to reduce cost. Therefore, the NRC made no change to the cost model in response to this comment.

B.3. Maintaining and Upgrading the Plant-Specific PRA

The NRC proposes to amend § 50.71(h), regarding the maintenance and upgrading of plant-specific PRAs, to make it applicable to those license holders under part 50 that are required to develop a PRA. The NRC also proposes to change this regulation to establish a more flexible schedule for PRA upgrades to promote a more stable and equitable regulatory environment.

Section 50.71(h) requires COL holders to develop a plant-specific PRA before loading fuel, to upgrade it as necessary, and to maintain it until the permanent cessation of operations. For plants licensed in the future, the lack of a similar requirement in part 50 conflicts with the Commission position stated in the PRA Policy Statement that it expects a plant-specific PRA that accurately represents the as-built, as-operated plant to be available to manage risk effectively during the operational phase.

The regulations for maintaining and upgrading each plant-specific PRA were added in the 2007 part 52 final rule when PRA consensus standards were undergoing rapid change. These regulations were intended to encourage timely adoption of rapidly evolving PRA methods. When these regulations were published, the NRC and industry had not yet established a mature peer review process for PRA upgrades.

Subsequently, the NRC has endorsed consensus standards for all light-water reactor initiating events and hazards during full power operation. The time it takes to complete an upgrade has been extended by a well-structured process of peer review with formal methods for addressing findings. Moreover, the current requirement to tie upgrade schedules to the scheduled date of the initial loading of fuel is no longer necessary. In the case of identical units on the same site, the NRC observed the potential to impose a burden without commensurate safety benefit. This is because the current regulations might have required different PRAs for the plants, solely because of different construction schedules. For a plant under construction, this problem has been resolved by requesting an exemption from the regulations. The proposed rule would make such a request unnecessary.

<u>Determining the PRA Standards to Be Met Before Beginning Operations</u>

Section 50.71(h)(1) requires each holder of a COL to upgrade the PRA before the initial loading of fuel. The potential still exists for the NRC to endorse a PRA

standard that covers a new mode or initiating event. If, for a particular licensee, this endorsement occurs less than a year before the scheduled date of the initial loading of fuel, then the current regulation allows that licensee nearly five years to modify its PRA to cover the associated risk. In contrast, if the NRC's endorsement of a new standard becomes effective even slightly earlier than one year before the scheduled date of the initial loading of fuel, then the current regulation requires the licensee to modify its PRA in a year. The current variation in the time for implementation is not justified. The NRC has determined that changing the regulations would improve regulatory stability and efficiency. Only those standards endorsed when the construction permit or combined license is issued (under proposed § 50.71(h)(1)) or that had been endorsed for at least five years (under proposed § 50.71(h)(2)) would be required no later than the scheduled date for initial loading of fuel.

Determining When PRA Upgrades Must Be Done During Operations

Section 50.71(h)(2) requires each holder of a COL to determine, every four years after the initial loading of fuel, whether an upgrade to the PRA is required. The current regulation creates an unwarranted variation in the implementation of the upgrade. The timing could vary such that an upgrade is required just one year after a consensus standard is endorsed, or a licensee would be allowed nearly five years until the upgrade is required. The implementation schedule is determined based on the scheduled date for initial loading of fuel. The NRC has determined that it would be simpler and more equitable to apply a uniform timeline for any upgrade required: within five years of the NRC endorsement of a consensus standard on PRA. This proposed change to the regulation would eliminate this variation and eliminate unwarranted upgrade schedule differences among reactors that were licensed at the same time.

Public Comments Related to This Item

The NRC received four comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI agreed with the recommendation to require future CP and COL holders to upgrade the plant-specific PRA to cover all initiating events and modes endorsed by the NRC when the CP and COL were issued. The NEI requested the NRC clarify the requirements for as-built walkdowns during plant construction. The NEI said some parts of the plant may first be ready for walkdowns just before fuel load and asked that applicants be given more time than the "at fuel load" point to incorporate the results of as-built walkdowns.

NRC Response:

The NRC agrees, in part, with this comment. The NRC maintains that for the operational phase, the PRA model of record should realistically reflect the as-built, as-operated plant. Walkdowns must be completed before entering the operational phase since only walkdowns can confirm some relevant details. While some walkdowns must take place at the end of construction, much of the as-built information needed to update the PRA can be collected as construction progresses.

Any significant changes to the PRA model that result from walkdowns must be reflected in updates put into effect before the initial loading of fuel. What the NRC considers to be a significant change to the PRA has been described in DC/COL-ISG-3, "Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications." Given the current state of practice in PRA and in plant construction, updating the PRA at this point is not expected to be onerous or time-consuming if normal PRA maintenance practices were applied during construction.

Before loading fuel, § 50.71(h)(1) requires that the PRA cover those initiating events and modes for which NRC-endorsed standards exist at a specific point in time. The current regulations set this date as one year prior to the scheduled date of the initial loading of fuel. The NRC is proposing to change its regulations to achieve greater regulatory stability by setting this date to when a CP or COL is issued. An applicant or license must consider risk from all of these initiating events and modes when they are relevant to risk evaluations in the operating phase. Other requirements (e.g., § 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," and § 50.36, "Technical specifications") address risk in plant modes (low power and shutdown) for which standards have not yet been endorsed by the NRC.

Section 50.71(h)(1) does not state that the PRA must meet NRC-endorsed consensus standards before the initial loading of fuel, only that it must cover the initiating events and modes they address. This distinction is important. It is certainly feasible to develop a PRA model to cover a specific initiating event in the time before initial loading of fuel. It is also practicable to update the PRA to model the as-designed plant and to match the as-built plant. The licensee or applicant should confirm that it is a realistic model (e.g., by benchmarking). Completing peer reviews to meet the applicable PRA standards is not required.

However, since 2007, consensus standards in PRA for LWRs have evolved to the point where a model that meets them in the operating phase will most likely be an upgrade from the model used to license the plant. Moreover, an upgrade is not finished until a peer review and related follow-up actions are completed. As NEI suggests, this is a time-consuming process. As noted, § 50.71(h) does not require that the PRA be upgraded until the scheduled date for the initial loading of fuel.

Because the proposed regulation would give licensees adequate flexibility, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI commented that language used in the regulatory basis for this proposed rule to describe the challenges that a specific licensee had faced in developing, maintaining, and upgrading different PRA models for essentially identical plants, namely "One licensee has already requested a license amendment to address this problem," was inaccurate. The NEI stated that because the licensee requested an exemption rather than a license amendment, the regulatory basis for this proposed rule should be amended to reflect the actual request made and to note that it was granted.

NRC Response:

The NRC agrees, in part, with the comment. The regulatory basis did refer to a license amendment instead of an exemption in that sentence. However, the NRC is not re-issuing the regulatory basis, and the statement in question does not repeat in this proposed rule. As such, there is no opportunity or need to revise it. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI recommended revising § 50.71(h)(3) to conform to statements in both the regulatory basis and interim staff guidance (DC/COL-ISG-3) that limit the modes and initiating events that must be covered by PRA upgrades at operating license renewal to those for which consensus standards on PRA are endorsed by the NRC.

NRC Response:

The NRC disagrees with this comment. The purpose of § 50.71(h)(3) is to require at license renewal that the PRA models address all initiating events and all modes. The NRC expects that, by the time any COL or OL comes up for renewal, PRA technology will be sufficiently mature to achieve this objective, whether the NRC has endorsed a consensus standard or not. For that reason, the requirement will not be qualified as suggested. For LWRs, endorsed PRA standards address a set of initiating events at power that the NRC considers to be exhaustive. For low power and shutdown modes, a PRA standard has been issued for trial use (but this standard has not been endorsed by the NRC). The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI remarked that the impact analysis for Section 3.0 of Appendix B of the regulatory basis, "Maintaining and Upgrading the Plant-Specific Probabilistic Risk Assessment," seems premised on adoption of the recommended rulemaking alternative for Section 1.0 of that appendix, "Use of Probabilistic Risk Assessment in Design." The NEI asked for clarification of the Section 3.0 alternatives, their impacts, and their relationship to the rulemaking alternative in Section 1.0.

NRC Response:

The NRC agrees, in part, with the comment. The NRC is proposing in this rule the recommended alternative for Section 1.0 of Appendix B, which is to extend the current PRA requirements in part 52 to part 50 applicants. With that proposal, the NRC can propose to make § 50.71(h) applicable to those license holders under part 50 that are required to develop a PRA. However, the NRC is not performing the assessment suggested by NEI because the NRC is not re-issuing the regulatory basis. Therefore, the NRC made no change to the cost model in response to this comment.

C. Three Mile Island Requirements

The NRC is proposing to revise § 50.34(f) so that the TMI requirements in § 50.34(f), with the same exceptions currently given for part 52 applicants, apply to new power reactor applications submitted under part 50. In addition, the NRC is proposing to delete requirements in § 50.34(f) that are included in other regulations or are no longer needed or applicable.

Applicability of TMI Requirements

The introductory text of § 50.34(f) limits its applicability to two groups of applicants: power reactor applicants for a CP or an ML whose application was pending as of February 16, 1982, all of whom no longer have active applications; and applicants for a DC, an SDA, a COL, or an ML under part 52, although these applicants are excepted from certain TMI requirements. Therefore, new CP and OL applicants under part 50 are not currently required to comply with the additional TMI items in § 50.34(f).

The NRC would revise the introductory text of § 50.34(f) so new CP and OL applicants under part 50 would be required to comply with § 50.34(f). This change to the regulations would fulfill the intent of SECY-15-0002 by aligning parts 50 and 52 on requirements related to the TMI accident and would ensure consistency in new reactor licensing reviews.

Development and Maintenance of Plant Procedures

The NRC is proposing to amend the language and applicability of the plant procedures requirement in § 50.34(f)(2)(ii). The NRC proposes to replace the phrase “integrating and expanding current efforts to improve plant procedures” with “developing and maintaining plant procedures.” The proposed change would eliminate a reference to post-TMI activities that are no longer current. The NRC is proposing a conforming

change to amend § 50.34(f)(2)(ii) to eliminate the requirement that the scope of the program include "coordination with INPO and other industry efforts" that were "current" in 1982 when this rule provision was added. The NRC also proposes to amend § 50.34(f)(2)(ii) to delete the text "(Applicable to construction permit applicants only)." This proposed change would make the requirement applicable to both CP and OL applicants, consistent with the current rule language that the program is to "begin during construction and continue into operation."

Redundant Three Mile Island Requirements

The NRC is proposing to delete redundant requirements in § 50.34(f) that are covered by other regulations or are no longer needed or applicable.

The NRC is proposing to delete § 50.34(f)(1)(xii), (2)(ix), and (3)(v), which address hydrogen control within containment. The same requirements are in § 50.44.

The NRC is proposing to delete § 50.34(f)(2)(xxv), which requires an onsite Technical Support Center, an onsite Operational Support Center, and, for CP applications only, a near site Emergency Operations Facility. The same requirements are in appendix E, "Emergency Planning and Preparedness for Production and Utilization Facilities," to part 50.

The NRC is proposing to delete § 50.34(f)(1)(i) through (xi), which require an applicant to perform a plant/site-specific PRA; perform evaluations on the auxiliary feedwater, high pressure coolant injection, reactor core isolation, and automatic depressurization systems; perform evaluations of the potential for and impact of reactor coolant pump seal damage following small-break loss-of-coolant accident; perform evaluations of the effect on all core-cooling modes under accident conditions; perform an analysis of the probability of a small-break loss-of-coolant accident caused by a stuck-open power-operated relief valve; and perform a study that would reduce challenges and

failures of relief valves. As discussed in Section III.B.1 of this document, the NRC is proposing to revise its regulations to apply current PRA requirements under part 52 to applications made under part 50. These proposed changes to the regulations related to PRA would make § 50.34(f)(1)(i) through (xi) redundant.

The NRC is proposing to delete § 50.34(f)(2)(i), which requires simulator capability that correctly models the control room and includes the capability to simulate small-break loss-of-coolant accidents. The same requirement is in § 55.59(c)(3)(i)(G)(*3*).

The NRC proposes to delete § 50.34(f)(2)(vi), which addresses the capability of high point venting of incondensable gases from the reactor coolant system. The same requirements are now located in § 50.46a, "Acceptance criteria for reactor coolant system venting systems."

The NRC is proposing to delete § 50.34(f)(2)(xxiv), which requires boiling water reactors to have the capability to record reactor vessel water level. This requirement is in part 50, appendix E, section VI, "Emergency Response Data System."

The NRC proposes to delete § 50.34(f)(3)(vi), which requires, for plants that are designed with external hydrogen recombiners, redundant dedicated containment penetrations so that, assuming a single failure, the recombiner systems can be connected to the containment atmosphere. In the "Combustible Gas Control in Containment" final rule (September 16, 2003), the NRC eliminated requirements in § 50.44(b)(3) and (c)(3)(ii) for hydrogen recombiners to address design basis accidents.

The NRC proposes to delete § 50.34(f)(2)(xvi), (xxii), and (xxiii), because these requirements apply only to pending construction permits for Babcock & Wilcox designed plants as of 1982. There are currently no licensing applications under NRC review that are related to these plants.

Public Comments Related to This Item

The NRC received three comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI recommended amending § 50.34(f) as follows (with conforming changes to other provisions in parts 50 and 52 as needed) to remove what it characterized as irrelevant, misleading, redundant, and/or ambiguous language:

1. Delete from the introductory text language that describes applicability to inactive CPs and MLs.
2. Replace paragraphs (f)(1) through (3) with clear direction on the content needed and the timing thereof for the various application types (e.g., PSAR vs. FSAR), with similar changes to individual TMI requirements that contain irrelevant or misleading language on the timing of implementation.
3. Remove references to the TMI action plan items in NUREG-0718, “Licensing Requirements for Pending Applications for Construction Permits and Manufacturing Licenses,” and NUREG-0660, Volume 1, “NRC Action Plan Developed as a Result of the TMI-2 Accident,” and develop new guidance to describe the applicability and acceptance criteria of the TMI requirements for all designs.

NRC Response:

Item 1 – The NRC agrees with this comment. The NRC proposes to edit this portion of the regulation to remove references to the applications that were pending at the time the rule was promulgated but are now no longer active.

Item 2 – The NRC agrees, in part, with this comment. The NRC proposes to delete § 50.34(f)(1)(xii); (2)(i), (vi), (ix), (xvi), and (xxii) through (xxv); and (3)(v) and (vi)

because these provisions are redundant with other provisions of part 50. The NRC also proposes to remove § 50.34(f)(1)(i) through (xi) consistent with the proposal discussed in Section III.B.1 of this document. The NRC disagrees that the entirety of items in § 50.34(f)(1) through (3) should be replaced because doing so would be outside the scope of this rulemaking. The provisions in § 50.34(f)(1) through (3) that the NRC is not proposing to revise or remove are not redundant to existing or proposed requirements and are still applicable.

Item 3 – The NRC agrees, in part, with this comment. The NRC agrees that certain references to NUREG-0718 and NUREG-0660 can be deleted because some of the references to NUREG-0718 and NUREG-0660 have been in incorporated in standard review plans and regulatory guides, thereby eliminating the need of having these references listed within the regulations. The NRC disagrees that new guidance needs to be developed because the guidance as currently written provides adequate direction to the NRC staff and developing guidance for all designs is out of scope for this rulemaking.

Comment Summary:

NuScale agreed with, and summarized in its submission, the NEI comment about § 50.34(f) previously discussed. NuScale also said the TMI requirements make the licensing process uncertain and confusing for new power reactor applicants like NuScale. NuScale described challenges it faced during pre-application activities and the review of its DC application and stated there is difficulty and uncertainty involved in applying the TMI requirements to a new design.

NuScale and the NEI suggested that the NRC's regulatory and safety assessment to determine which TMI requirements may be applicable to non-LWRs should consider the TMI requirements' applicability to all new reactor designs, not just

non-LWRs, with any irrelevant provisions eliminated. NuScale specifically requested that those TMI requirements not eliminated as part of that assessment be revised to include "new performance-based, technology-neutral acceptance criteria."

NRC Response:

The NRC agrees, in part, with these comments. The NRC is proposing removal of those provisions in § 50.34(f) that are covered in other sections of the NRC's regulations. The NRC is not addressing the applicability of § 50.34(f) to non-light-water reactors in this rulemaking. The NRC has a separate rulemaking effort (see footnote 1 of this document) in which it intends to address this issue for those technologies. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to these comments.

Comment Summary:

The NEI noted that, while Table C-2, NRC Rulemaking Costs, in the regulatory basis indicates that rulemaking to amend § 50.34(f) would include development of a regulatory guide, regulatory basis Appendix C, Section 5.0, "NRC Guidance, Policy, and Implementation Issues," says that no new regulatory guidance would need to be developed under rulemaking.

NRC Response:

The NRC disagrees with the comment. There is no inconsistency between Table C-2, which shows that rulemaking to align the regulations would include costs related to guidance, and Section 5.0 of Appendix C. As stated in Section 5.0, while no new guidance would need to be developed, existing guidance used for a part 52 license application submittal could be updated to be used for a part 50 license application submittal. Accordingly, the NRC is proposing to revise RG 1.57, "Design Limits and Loading Combinations for Metal Primary Reactor Containment System Components,"

and RG 1.136, “Design Limits, Loading Combinations, Materials, Construction, and Testing of Concrete Containments,” to conform to these regulatory changes. The updates to these guidance documents can be done at the next scheduled update of these regulatory guides after the publication of the final rule. Accordingly, the Commission did not change the NRC staff’s recommendations in the regulatory basis in response to this comment.

D. Fire Protection Requirements

The NRC proposes to amend § 50.34(a) and (b) to improve the clarity, consistency, and alignment of new nuclear power reactor licensing requirements related to the description of fire protection design features and fire protection plans.

The regulatory framework that the NRC has established for nuclear power plant fire protection programs consists of General Design Criterion (GDC) 3, “Fire protection,” in appendix A, “General Design Criteria for Nuclear Power Plants,” to part 50, as described in § 50.48, “Fire protection.” Section 50.48 requires each holder of an OL or COL to have a fire protection plan that satisfies GDC 3. General Design Criterion 3 provides substantive fire protection requirements.

Under part 52, applicants for a DC, a COL, an SDA, or an ML are required to provide information describing the fire protection design features necessary to comply with GDC 3 and § 50.48. In addition, under part 52, an applicant for a COL is required to describe how its fire protection program will be carried out.

Part 50, specifically § 50.34, has no explicit equivalent requirement for an applicant for a CP or an OL. For a CP applicant, § 50.34(a)(3)(i) only requires that the preliminary safety analysis report include the preliminary design of the facility including the principal design criteria of the facility. Although the principal design criteria include the GDC, and therefore GDC 3, the requirement in § 50.34(a)(3)(i) lacks the specificity of

the part 52 requirements to provide a description and analysis of the fire protection design features necessary to comply with GDC 3.

A similar lack of clarity exists on application requirements under part 50 for the OL phase. Section 50.34(b) states that each application for an OL shall include an FSAR, but unlike part 52, there is no specific requirement in § 50.34(b) stating that the applicant needs to provide information about how they meet GDC 3 or § 50.48 requirements not addressed at the CP stage. In addition, unlike for COL applicants in § 52.79(a)(40), there is no clear requirement for OL applicants to describe the implementation of the fire protection program required by § 50.48.

The NRC proposes to amend § 50.34(a) to add a provision requiring the applicants for a CP to provide information about how the fire protection design features comply with GDC 3, and to amend § 50.34(b) to add a provision requiring the applicants for an OL to provide information about how the fire protection design features comply with GDC 3 and § 50.48.

The changes would improve the clarity, consistency, and alignment of new nuclear power reactor licensing requirements between parts 50 and 52, thereby fulfilling the intent of SECY-15-0002.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

E. Operators' Licenses

E.1. Criteria for Simulation Facilities

The NRC is proposing to amend the criteria in part 55, "Operators' Licenses," § 55.46(c), "Plant-referenced simulators," that a plant-referenced simulator must meet when it will be used to complete the control manipulations required by § 55.31(a)(5) by operator license applicants at nuclear power plants that are under construction. The

NRC is also proposing to amend the definitions of “plant-referenced simulator” and “reference plant” in § 55.4, “Definitions,” to clarify that these terms are also applicable to simulators that model nuclear power plants that are under construction. These proposed changes to the regulations governing simulation facilities would affect only facilities currently under construction or future facilities.

In § 55.31(a)(5), the NRC requires, in part, operator license applicants to provide evidence that the applicant, as a trainee, has successfully manipulated the controls of either the facility for which an operator’s license is sought or a plant-referenced simulator that meets the requirements of § 55.46(c), including using models related to nuclear and thermal-hydraulic characteristics that replicate the most recent core load in the nuclear power reference plant for which an operator’s license is being sought. However, before initial fuel load into the reactor, it is not possible for operator license applicants at nuclear power reactors that are under construction to meet the existing requirement because the plant cannot yet be used, and a simulator cannot yet “replicate the most recent core load.”

The Commission has previously granted holders of facility licenses for plants under construction exemptions from the control manipulation requirement, allowing operator license applicants at the facilities to satisfy the control manipulation requirement on a Commission-approved simulator in lieu of the plant or a plant-referenced simulator (See “Vogtle Electric Generating Plant Units 3 and 4; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia,” April 8, 2016; and “South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Units 2 and 3,” August 18, 2016).

The NRC is proposing to amend § 55.46(c)(2)(i) to allow applicants for operator licenses to do the control manipulations required by § 55.31(a)(5) on a simulation facility that replicates the intended initial core load for the nuclear power reference plant for which an operator's license is being sought when the license is sought before initial fuel load into the reactor.

Additionally, terms used in the existing regulations such as "reference plant" and "plant-referenced simulator" assume that the plant systems and control room have been constructed before the establishment of a simulation facility that models the reference plant. However, the NRC has observed that vendors of new nuclear power reactor designs are using plant simulators during the plant design process, and facility licensees at new reactors under construction are using plant simulators to train plant personnel well before the plant is constructed. It is possible to establish a simulation facility that models the design of the plant control room and the expected response of the plant systems during normal and abnormal events using data generated through engineering analyses, such as those analyses discussed in the transient and accident analysis section of a facility's FSAR; data from subject matter expert estimates; and other relevant data sources when data collected directly from the as-built plant are not yet available because the plant is under construction.

Therefore, the NRC is also proposing to amend the definition of "reference plant" in § 55.4 to state that the reference plant may or may not be actually constructed, and the definition of "plant-referenced simulator" would be amended to state that for a nuclear power plant that is being constructed, a plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator will interface in the control room. The changes would eliminate the need for licensees to ask for Commission approval of a simulation facility at a reactor under construction when

that simulation facility meets the criteria in § 55.46(c) to be used for the administration of the operating test and to meet experience requirements in § 55.31(a)(5). This would reduce the administrative burden on the licensees and the NRC associated with the processing of requests for Commission approval of the simulation facility. The NRC proposes to revise RG 1.149, "Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements," to include the revised definitions and criteria.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

E.2. Plant Walkthrough

The NRC is proposing to amend the plant walkthrough requirement in § 55.45, "Operating tests," to give facility licensees of new reactors under construction the option of using suitable alternatives to in-plant testing while the plant is under construction.

In § 55.45(b), "Implementation – Administration," the NRC requires that the operating test be administered in a plant walkthrough and in either a simulation facility that the Commission has approved for use after application has been made by the licensee under § 55.46(b), "Commission-approved simulation facilities and Commission approval of use of the plant in the administration of the operating test," a plant-reference simulator, or the plant, if approved for use in the administration of the operating test by the Commission. In § 55.40(a), the NRC requires, in part, that the Commission use the criteria in NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," to prepare the operating tests required by § 55.45, and to evaluate the operating tests prepared by power reactor facility licensees. As discussed in NUREG-1021, Revision 12, Section ES-3.1, "Overview of the Operating Test for Operator Licensing Initial Examinations," the walkthrough portion of the operating test consists of

a set of job performance measures. Each applicant for an operator's license must complete a certain number of job performance measures in the plant.

The plant walkthrough was the subject of exemption requests for VEGP Unit 3 and for VCSNS Unit 2. In the FRN granting approval of the exemption for VEGP Unit 3 ("Vogtle Electric Generating Plant Unit 3; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia"; June 30, 2016) and in the FRN granting approval of the exemption for VCSNS Unit 2 ("South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Unit 2"; August 22, 2016), the NRC also approved alternatives to the in-plant methods of testing described in NUREG-1021. Specifically, the NRC approved the use of discussion and performance evaluation methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups while the plant is under construction.

A substantial number of the plant systems must be constructed before doing a plant walkthrough during the NRC initial licensing examination so that the plant walkthrough portion of the operating test is not predictable. Predictable examinations may prevent the examiner from distinguishing applicants who have mastered the required knowledge and skills from those who have not. The completion of plant construction occurs relatively close in time to the scheduled date for fuel loading and later operation of the facility. Thus, administration of the NRC initial licensing examinations would need to occur relatively close in time to the scheduled date for fuel loading at the cold plant. Delaying the administration of the NRC operating test, which includes in-plant job performance measures, until plant construction is complete is not desirable for the following reasons:

- The NRC examination will likely overlap with preoperational testing activities; applicants may be required to participate in preoperational testing at the same time the NRC exam is administered.
- Insufficient NRC exam throughput (i.e., the number of applicants that pass the NRC exam) could cause preventable delays in the facility licensee's ability to begin fuel loading.
- There would be missed opportunities for early identification and timely incorporation of lessons learned into the operator training and licensing process without a safe and deliberate approach of administering exams to smaller groups of applicants in succession.
- The NRC's ability to administer exams for the large number of new reactor applicants necessary to staff a single large LWR unit (40–50 operators) in time for fuel load, while also carrying out exams and inspections at operating reactor sites, could be challenged.

Therefore, the NRC is proposing to amend § 55.45(b) to combine the existing requirements in § 55.45(b)(1) through (3) in § 55.45(b)(1) and to add the following statement as a new § 55.45(b)(2): "If a facility is under construction, suitable alternatives may be used in lieu of the plant walkthrough portion of the operating test." NUREG-1021, Section ES-3.7, "Alternatives for In-Plant Job Performance Measures at Plants under Construction," currently provides guidance that would be applicable to the proposed rule and is based on experience using "suitable alternatives" to the plant walkthrough portion of the operating test at VEGP Unit 3. The NRC anticipates only minor edits would need to be made to Section ES-3.7 of NUREG-1021 to reflect this proposed rule change.

Although the proposed amendment to § 55.45(b) is based on experience licensing operators at a new power reactor that is under construction, the proposed amendment to § 55.45(b) would apply also to non-power facilities that are under construction because similar challenges may exist for future non-power facilities that are under construction.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

E.3. Continuing Training for Operator License Applicants

The NRC is proposing to amend the requirements in § 55.31(a)(4) to establish a new requirement for facility licensees at cold plants to maintain the knowledge, skills, and abilities of operator license applicants who have successfully completed the NRC initial licensing examination.

Following the administration of an NRC initial licensing examination, the NRC staff reviews the examination grading and completes other administrative tasks that are necessary to issue operators' licenses. An applicant who meets all the requirements to receive an operator's license before taking the NRC initial licensing examination typically receives his or her license within approximately 30 days after passing the NRC's operator licensing examination. NUREG-1021, Section ES-5.3, "Maintaining, Changing, and Renewing Operator Licenses," Section A.1.b states that newly licensed operators must enter the requalification training and examination program required by § 55.59, "Requalification," promptly upon receiving their licenses. Newly licensed operators typically enroll in the facility licensee's requalification training program within approximately eight weeks after receiving an operator's license. The facility licensee's licensed operator requalification program must meet the requirements in § 55.59, which includes the requirement for the requalification program to be done for a continuous

period not to exceed two years, and upon conclusion must be promptly followed, under a continuous schedule, by successive requalification programs. In addition to keeping licensed operators informed of facility design changes, procedure changes, and facility license changes, the requalification program helps to ensure that licensed operators maintain the knowledge, skills, and abilities obtained during the initial license training program. Participation in a requalification program helps to provide assurance that those personnel who are licensed to operate the facility retain the essential skills necessary to safely operate the plant and maintain awareness of design and procedure changes that affect the tasks that licensed operators do. Accordingly, by the establishment of the requalification training and examination requirements of § 55.59, the Commission has acknowledged that knowledge and skills are perishable, and it is necessary for operators to receive periodic re-training and examination of their skills and knowledge.

However, the NRC has observed that in some cases, because of construction schedules, months and years may pass after an applicant for an operator's license passes the NRC examination and before he or she can complete all of the experience requirements for an operator's license. For example, at VEGP Unit 3, some applicants took and passed an NRC examination in 2015, but they were unable to complete all of the experience requirements (e.g., participation in preoperational testing) to be issued an operator's license until approximately five years later because of delays in the construction schedule that resulted in delays completing the experience requirements. Because operator license applicants are not yet licensed, they are not required to be enrolled in a continuing training program that meets the requirements of § 55.59 to retain their knowledge, skills, and abilities and to remain cognizant of design and procedure changes. The NRC observed at VEGP Unit 3 that the facility licensee made changes to

the plant design and procedures since 2015, some of which directly affected the tasks that licensed operators will do at the plant. The NRC also observed that the facility licensee voluntarily established and carried out a continuing training program for the applicants based on a systems approach to training that closely models a requalification program.

The current regulatory framework could foster a decline in an applicant's level of knowledge, skill, and ability to safely operate the plant when there will be a significant amount of time that passes between when the applicant successfully completes the NRC initial licensing examination and when the applicant can complete all the other requirements to be licensed. Applicants for operator licenses at cold plants also may not be trained on the design and procedure changes that may affect tasks that they will be licensed to do when the plant commences operation and they have completed all the other requirements to be licensed. Therefore, the NRC is proposing to amend § 55.31(a)(4) to add a new paragraph so that when an operator license application is submitted before the facility licensee is required to have the requalification program described in § 55.59 in effect as described under § 50.54(i-1), the application must describe how the applicant's knowledge, skills, and abilities will be maintained after the applicant passes the written examination and operating test and before participation as a licensed operator in the requalification program described in § 55.59. In lieu of this description, the Commission would accept a statement that the applicant will participate in a Commission-approved continuing training program developed by using a systems approach to training within three months of receiving notice that the applicant has passed the written examination and operating test. The NRC also intends to add a new subsection to NUREG-1021, Section ES-2.2, to include guidance for acceptable ways to maintain the applicants' knowledge, skills, and abilities to comply with the new rule.

Although the proposed amendment to § 55.31(a)(4) is based on experience licensing operators at a new power reactor that is under construction, the proposed amendment to § 55.31(a)(4) would apply also to non-power facilities that are under construction because similar circumstances may exist for non-power facilities while they are under construction.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI expressed concern about how licensees would comply with the planned amendment to § 55.31(a)(4) that would require a licensee of a new reactor under construction to explain, using NRC Form 398, how the licensee will maintain the knowledge, skills, and abilities of operator license applicants for whom the licensee requests an NRC examination be administered before they have completed the requirements to receive operator licenses. The NEI recommended that the NRC provide more specific guidance about what is needed to ensure that knowledge, skills, and abilities will be maintained.

NRC Response:

The NRC agrees with the comment. The proposed rule includes a provision (i.e., § 55.31(a)(4)(ii)) explaining that the NRC will accept a statement that the applicant will participate in a Commission-approved continuing training program developed using a systems approach to training in lieu of a description of how the applicant's skills, knowledge, and abilities will be maintained. Additionally, the NRC prepared draft guidance for acceptable ways of ensuring knowledge, skills, and abilities of applicants will be maintained. Specifically, the NRC is proposing a new Section H, "Continuing

Training for Applicants at New Reactors under Construction," to Section ES-2.2, "Applications, Medical Requirements, and Waiver and Excusal of Examination and Test Requirements," of draft NUREG-1021, Revision 13. Accordingly, the Commission changed the NRC staff's recommendation in the regulatory basis in response to this comment.

E.4. Waiver of Examination and Test Requirements

The NRC is proposing to amend the criteria in § 55.47, "Waiver of examination and test requirements," to include provisions for licensing of operators at subsequent new units at multiunit sites.

In § 55.47, the NRC may allow for any or all the requirements for a written examination and operating test to be waived if the applicant has had "extensive actual operating experience at a comparable facility." However, in some situations where a waiver may be justified, the waiver criteria in § 55.47 cannot be practically applied. For example, in the situation of a modular reactor (as defined in § 52.1) or multiple units of a standard design (as defined in § 52.1) at the same site, there are likely to be few differences between the units, and those differences are not likely to have a significant impact on operation of the facility. Operators may be licensed on one unit first, subsequent units may be added, and the operators of the first unit may apply to be licensed on the subsequent unit(s).

In these situations, § 55.31(a)(3) requires that an authorized representative of the facility licensee submit a request for an operating test and written examination for the subsequent unit(s) to be administered before issuance of the amended license. When the differences between subsequent units do not impact the ability of the operators to operate any of the units safely, administration of another examination is not necessary, nor is it an efficient use of facility licensee or NRC resources. In these situations, the

facility licensee may ask for an exemption from § 55.31(a)(3), which will be granted if the criteria of § 55.11, “Specific exemptions,” are satisfied. Such exemptions would be granted if the differences between the units are not so significant that they could affect the operator’s ability to operate each unit safely and competently, and the applicant has been sufficiently trained on the differences between the units.

Therefore, to eliminate the need for portions of the examinations and tests that are unnecessary when these circumstances are met, the NRC is proposing to amend § 55.47. The NRC is proposing to add a new set of criteria that, if met, would justify a waiver of portions or all of the written examination and operating test for applicants to be licensed on subsequent units at a multiunit site. The NRC proposes to revise NUREG-1021, Section ES-2.2, to provide guidance for facility licensees about requesting these waivers and guidance for the NRC to evaluate such requests.

Although the proposed amendment to § 55.47 is based on experience licensing operators at a new power reactor that is under construction, the proposed amendment to § 55.47 also would apply to non-power facilities that are under construction because the proposed waiver criteria also could be used by applicants at these facilities to justify waiver of examinations.

This item was not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

F. Physical Security and Fitness-for-Duty Requirements

F.1. Physical Security Requirements

The NRC proposes to amend its regulations to clarify that applicants and licensees may bring unirradiated reactor fuel onsite and protect it in accordance with § 73.67 until initial fuel load into the reactor. Additionally, the NRC proposes to amend §§ 70.22(k), 73.67(d), and 73.67(f) to clarify the appropriate security requirements for

special nuclear material (SNM) of moderate to low strategic significance brought onsite at nuclear power reactors.

Based on recent new reactor licensing experience, the NRC identified an issue in 10 CFR part 73, "Physical Protection of Plants and Materials," §§ 73.55(a)(4) and 73.56(a)(3), that may result in an unnecessary burden on power reactor applicants and licensees under parts 50 and 52. Under § 50.34(c)(2) and (3), each part 50 applicant for an OL must have, in part, a physical security plan that describes how the applicant will meet the physical security requirements of part 73. Similarly, § 52.79(a)(35)(i) and (ii) requires an applicant for a COL under part 52 to include in its FSAR a physical security plan that describes how the applicant will meet the physical security requirements of part 73 and a description of the implementation of the physical security plan. For applicants or licensees under parts 50 and 52, their physical security plans must carry out the requirements in § 73.55 and § 73.56. Sections 73.55(a)(4) and 73.56(a)(3) require applicants for a power reactor OL under part 50 or holders of a COL under part 52 to carry out the requirements of § 73.55, governing physical protection at the site, and § 73.56, governing access authorization at the site, respectively, before unirradiated reactor fuel is allowed onsite (i.e., within the protected area) at nuclear power reactors. Based on the NRC's assessment that licensee implementation of existing requirements in § 73.67 will appropriately protect unirradiated reactor fuel brought onsite in the period prior to initial fuel load, the NRC proposes to change this deadline to ease the potential burden on these applicants and licensees.

Both parts 50 and 52 licensees have applied for and been issued a license under part 70, "Domestic Licensing of Special Nuclear Material," authorizing possession and use of SNM, typically in the form of unirradiated reactor fuel, but also non-fuel SNM, such as intermediate range detectors and other devices. A part 50 OL will generally

contain a license condition that authorizes the licensee to receive, possess, and use SNM. A part 52 combined license will typically contain two license conditions. The first COL license condition would authorize the licensee to receive and possess, but not use SNM as reactor fuel, subject to certain limitations and as described in the FSAR. The second license condition would authorize the licensee to use SNM as reactor fuel, after the Commission has made its § 52.103(g) finding.

As required by § 70.22(k), licensees possessing SNM of moderate strategic significance (also known as a Category II quantity of SNM) or licensees possessing SNM of low strategic significance (also known as a Category III quantity of SNM), as defined in § 70.4, "Definitions," must have a security plan that identifies how the licensee will meet the applicable security requirements in § 73.67(d) through (g) for the protection of the SNM. However, § 70.22(k) contains an exception from the requirement for a security plan for a licensee that possesses or uses these categories of SNM in the operation of a nuclear power reactor licensed under part 50. Similar exception language is found in § 73.67(d) and (f) for a Category II and a Category III quantity of SNM, respectively. Therefore, consistent with these provisions, the need for a security plan under § 70.22(k) and the security requirements in § 73.67(d) and (f) do not apply to part 50 power reactor licensees. There is no equivalent provision in §§ 70.22(k), 73.67(d), and 73.67(f) for part 52 licensees. Therefore, part 52 licensees are subject to the requirement to have a security plan, as well as the applicable security requirements in § 73.67. Part 50 and 52 licensees are subject to the same requirements in §§ 73.55 and 73.56.

Unirradiated Reactor Fuel and Implementation Requirements in §§ 73.55 and 73.56

As required by § 73.55(a)(4), applicants for an OL under the provisions of part 50, and each holder of a COL under the provisions of part 52, shall establish and

maintain a physical protection program which will have as its objective to provide high assurance that activities involving SNM are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety. Section 73.56(a)(3) requires applicants for an OL and holders of COLs to establish, implement, and maintain an access authorization program which provides high assurance that individuals are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security, including the potential to commit radiological sabotage.

The language in §§ 73.55(a)(4) and 73.56(a)(3) potentially subjects a Category II or a Category III (i.e., unirradiated reactor fuel) quantity of SNM to the security requirements in §§ 73.55 and 73.56 after the § 52.103(g) finding and prior to initial fuel load into a reactor. Unirradiated reactor fuel is typically the most significant quantity of SNM brought onto a power reactor site before the reactor begins operation. However, after further consideration, the NRC finds that the application of these requirements to unirradiated reactor fuel is not consistent with the risk associated with the possibility of unauthorized removal of SNM of moderate to low strategic significance. Rather, licensee implementation of the requirements in § 73.67 is adequate to protect unirradiated reactor fuel brought onsite prior to initial fuel load. This is true whether the fuel is stored onsite either inside the protected area or within a controlled access area, prior to initial fuel load into the reactor, because there is no change in risk caused by the location of the fuel. Risk only increases once the material is irradiated or if the physical protection requirements are relaxed from those required by § 73.67. Therefore, applying §§ 73.55 and 73.56 security requirements to the protection of unirradiated reactor fuel stored onsite prior to initial fuel load into the reactor is inconsistent with the NRC's regulatory framework for the protection of SNM of moderate or low strategic significance.

The NRC finds that the security requirements in § 73.67 provide adequate protection for unirradiated Category II or III quantities of SNM brought onsite before initial fuel load into the reactor. The NRC has further determined that there are no security considerations or other factors that justify imposing on licensees the regulatory burden and costs that may potentially result from requiring the premature implementation of the more stringent §§ 73.55 and 73.56 security requirements on unirradiated Category II or III quantities of SNM brought onsite before initial fuel load into the reactor. Accordingly, imposing the security requirements in §§ 73.55 and 73.56 on this type of material before initial fuel load into the reactor is not justified to protect the public health and safety and environment, and promote the common defense and security.

Modifying the rule language as proposed by the NRC would remove the regulatory requirements in §§ 73.55(a)(4) and 73.56(a)(3) applicable to the receipt and storage of unirradiated reactor fuel in the protected area before initial fuel load into the reactor. This amendment would allow unirradiated reactor fuel stored onsite, including in a fuel receiving facility in the protected area, to be protected in accordance with the applicable security requirements in § 73.67 rather than the more stringent §§ 73.55(a)(4) and 73.56(a)(3) requirements before initial fuel load into the reactor. Amending these requirements in § 73.55(a)(4) would: (1) eliminate the need for applicants or licensees to carry out two separate sets of security requirements to protect SNM onsite; (2) reduce the need for requests for an exemption or for an alternative measure from §§ 73.55(a)(4) and 73.56(a)(3) to meet these requirements during the timeframe when a licensee has obtained its § 52.103(g) finding and before initial fuel load into the reactor; (3) clarify the security requirements for the protected area; and (4) permit licensees or applicants to complete construction, security systems tests, train and certify appropriate security

personnel, and ensure that operational readiness milestones for plant operations are fully completed before implementation of the security requirements for § 73.55 (although the modified rule text would not excuse SSCs that perform security functions from applicable ITAAC). Modifying the rule language in § 73.56(a)(3) would eliminate the need for applicants or licensees to prematurely implement access authorization requirements to grant personnel unescorted access to the protected area during construction and make implementation of this regulatory provision consistent with the revised requirements in § 73.55(a)(4).

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Requirements for Special Nuclear Material of Moderate or Low Strategic Significance

The potential risk to the public health and safety and common defense and security associated with unirradiated SNM is the theft or diversion of the SNM for its use in an improvised nuclear device (IND). The NRC's regulations classify SNM in three categories considering the ease with which the SNM can be fabricated into an IND based on the SNM isotope, quantity, and uranium-235 enrichment. In part 73, these categories are a Category I quantity, or a "formula quantity" of material; a Category II quantity, or "special nuclear material of moderate strategic significance"; or a Category III quantity, or "special nuclear material of low strategic significance." For example, some forms of Category I SNM could be directly used by an adversary to construct an IND, whereas an adversary would need to steal multiple Category III quantities of SNM and perform significant additional processing to construct an IND.

The potential risk posed by the theft or diversion of SNM is mitigated by requiring entities licensed to possess and use these materials to develop and implement a physical protection program. The physical protection program requirements in part 73

are graded commensurate with the IND risk posed by the different categories of SNM. As the risk significance of the material increases, so does the rigor of the required physical protection measures. Compliance with these requirements provides for adequate protection of the public health and safety and the common defense and security considering the risk significance of the material being protected.

Consistent with this risk-informed approach, the security requirements in § 73.67 are much less stringent than the security requirements in § 73.55, which are designed to protect irradiated fuel from sabotage events at nuclear power reactors. For example, the requirements in § 73.67 for Category II and Category III quantities of SNM include detection, assessment, and notification requirements to help ensure proper custody and control and response to indications of an unauthorized removal, whereas those in § 73.55 require, in part, robust intrusion detection and assessment systems, armed response to interdict and neutralize adversaries, and protected and vital areas to provide layers of delay.

The NRC has established a regulatory framework that protects SNM in a manner commensurate with the risk associated with the material. The NRC has determined that it is appropriate to protect unirradiated reactor fuel and other nonfuel SNM brought onsite at a nuclear power reactor in accordance with § 73.67 until that material is protected in accordance with § 73.55. Notwithstanding the exceptions in §§ 70.22(k) and 73.67(d) and (f), most part 50 licensees that store SNM in the owner-controlled area, outside of an operating protected area, voluntarily comply with the applicable § 73.67 security requirements. However, the NRC is aware of instances where part 50 licensees have stored nonfuel SNM at operating power reactors outside the protected

area without protecting the SNM in accordance with § 73.67.[2] Therefore, the NRC proposes to clarify the regulations to better define, commensurate with the risk associated with the material, which physical protection regulations should apply for licensees. Furthermore, there is no technical basis for the inconsistency in how parts 50 and 52 licensees are treated when it comes to the application of the § 73.67 security requirements. Thus, the NRC finds that the exception in § 70.22(k) should be clarified to also except part 52 licensees when the material is protected in accordance with § 73.55. Modifying the rule language also would address the inconsistency between the treatment of parts 50 and 52 licensees in § 70.22(k) and clarify that the security requirements and associated exception in § 73.67(d) and (f) apply to both classes of licensees. Amending these requirements would not result in any change in the effectiveness of a licensee's physical protection program. Therefore, this modification would have no impact on the protection of public health and safety and would not be inimical to the common defense and security.

As discussed in Section VIII of this document, these proposed changes to the regulations could impose a change to those licensees' required physical security programs, thereby meeting the definition of "backfitting" in 10 CFR 50.109(a)(1). These proposed backfits would be justified on the basis that the proposed changes are necessary to ensure that these facilities provide adequate protection to the health and safety of the public and are in accord with the common defense and security.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

F.2. Fitness-for-Duty Requirements

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[2] In these cases, the licensees agreed to protect the SNM under § 73.67(d) or (f) or relocate the SNM into the protected area and safeguard the material in accordance with § 73.55 requirements.

The NRC is proposing to revise part 26, “Fitness-for-Duty Programs,” to address lessons learned from implementation of FFD programs at the VEGP 3&4 and VCSNS 2&3 construction sites. The amendments would address issues concerning construction worker access to the construction site, Medical Review Officer (MRO) procedures, clarifications to regulatory language, and a change to part 26 implementation based on risk insights learned from operating experience.

Escorting Construction Workers

The NRC proposes to revise its regulations to enable licensees and other entities to assign individuals to escort construction workers who implement the duties or responsibilities specified in § 26.4(f). This would be accomplished by amending: § 26.5, “Definitions,” to define the word “escort”; § 26.4(e) to add a new requirement that the escort must be subject to an FFD program that meets all part 26 requirements, except subparts I, “Managing Fatigue,” and K, “FFD Program for Construction”; § 26.4(f) to state that individuals who are escorted and constructing or directing the construction of safety- or security-related SSCs need not be subject to the licensee’s FFD program; and § 26.403(a) and (b) to require the licensee or other entity to establish, carry out, and maintain a procedure for escorts and those individuals under escort. The NRC is proposing these changes to improve regulatory flexibility and potentially reduce costs by enabling licensees and other entities the opportunity to better plan and carry out construction activities with individuals who may only be onsite for a short period of time.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Medical Review Officer Evaluation of a Donor’s Urine Specimen

The NRC is proposing to revise its regulations to enable licensees and other entities constructing nuclear power plants the option to require their MRO to review a

laboratory test result indicating that a urine specimen is dilute, in addition to a laboratory test result which may find that the individual's urine specimen was positive, adulterated, substituted, or invalid. This option is currently available to licensees and other entities described in § 26.3(a), who are authorized to operate a nuclear power plant under part 50 or 52, and § 26.3(b), who are authorized to possess, use, or transport formula quantities of strategic special nuclear material under part 70. The proposed change would be accomplished by amending § 26.405(g) to enable an MRO review of a laboratory test result indicating that the specimen is dilute during the construction of a nuclear power plant. This review is important for three reasons. First, the MRO's review of a laboratory test result indicating that the specimen is dilute benefits the donor because dilute urine could be an indication of an adverse physiological condition related to the donor's muscular metabolism or kidney function. Since the specimen is dilute as determined by laboratory testing and reviewed by the MRO, the MRO may have a discussion with the donor to ascertain whether the dilute test result was caused by a legitimate medical reason. The proposed change also would enhance consistency by more closely aligning the MRO review requirement in § 26.405(g) for licensees and other entities described in § 26.3(c) and the requirement in § 26.183(c) for licensees and other entities described in § 26.3(a) and (b). Another benefit of this MRO review would be informing the licensee's or other entity's assessment of the donor's trustworthiness and reliability because a dilute urine specimen, with no acceptable medical explanation, could be indicative of a subversion attempt.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Clarifications

The NRC has identified four instances where clarifications of the part 26 regulatory language are warranted consistent with the NRC's *Principles of Good Regulation*. The NRC proposes to amend § 26.401(b) to add the phrase "licensees and other" immediately before the word "entities," to be consistent with other sections of part 26. The NRC proposes to amend § 26.419, "Suitability and fitness evaluations," to clarify that this requirement also is applicable to those individuals who direct the construction of safety- and security-related SSCs. Currently, this requirement only addresses those individuals who construct safety- and security-related SSCs, which is contrary to the stated intent of this provision described in the preamble to the 2008 part 26 final rule. The NRC also proposes to amend the § 26.5 definition of *Reviewing official* to clarify that this definition is applicable to an FFD program that meets the requirements of subpart K. Lastly, the NRC proposes to revise § 26.3(a) to remove outdated regulatory text.

Although operating experience from industry implementation of part 26 and NRC inspections has not identified examples where the lack of clarity in these regulations has resulted in safety or security concerns, the unclear language could have an adverse impact on licensees or other entities. Under § 26.419, depending on the types of construction activities being done, a significant population of the construction site workforce (i.e., those individuals who direct the construction of safety- and security-related SSCs) are not subject to fitness determinations.

Also, the lack of clarity in the definition of *Reviewing official* could potentially cause programmatic problems. As defined in § 26.5, the reviewing official is an employee of a licensee or other entity specified in § 26.3(a) through (c), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not

limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain FFD authorization. A licensee or other entity described in § 26.3(c) that implements a subpart K FFD program is not required to use a reviewing official to disposition potentially disqualifying FFD information or evaluate an individual's fitness to safely and competently perform their duties. However, these licensees or other entities also must implement an FFD program that meets all of part 26, except subparts I and K, for those individuals who perform the construction-related activities specified in § 26.4(e), and licensees or other entities must use a reviewing official in an FFD program that meets all of part 26, except subparts I and K. There is no regulatory basis for requiring the use of a reviewing official in one FFD program but not the other.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule. The NRC also proposes to revise § 26.3(a) to remove outdated regulatory text. The current rule provision refers to the date of the publication of the part 26 final rule in 2008. Because this date has passed, it is no longer relevant to the timing of licensees' implementation of their FFD programs. Instead, the NRC would require all OL holders and COL holders after the § 52.103(g) finding to comply with the requirements of part 26 except for subpart K and implement their FFD programs before their initial fuel load into the reactor.

Part 26 Implementation Changes from Lessons Learned from Reactor Plant Construction

Based on operating experience and associated insights learned from the construction of VEGP 3&4 and VCSNS 2&3, the NRC reassessed the risks presented during the construction of these nuclear power reactors and finds that implementation of §§ 26.3(a) and (c) and 26.4(e)(1) is not commensurate with current risk insights. Section

26.3(a) requires, in part, that licensees authorized to operate a nuclear power reactor under part 50 and holders of a COL under part 52 after the Commission has made the finding under § 52.103(g) shall implement the FFD program before the receipt of SNM in the form of fuel assemblies. Under § 26.3(c), licensees and other entities constructing a nuclear power plant must implement their FFD program no later than receipt of SNM in the form of fuel assemblies. The risk associated with unirradiated fuel does not increase when the fuel is onsite because its engineered safety features, storage, and configuration have not changed from when the fuel was in transit. For transit and receipt onsite, the same physical protection requirements (i.e., § 73.67) are applied to protect the fuel. Safety and security risks associated with unirradiated nuclear fuel only begin to increase after the nuclear fuel begins to be placed in the reactor vessel following the authorization to operate or the Commission's finding under § 52.103(g).

Therefore, the NRC proposes to amend §§ 26.3(a) and (c) and 26.4(e)(1) to permit a licensee to delay the implementation of an FFD program that meets all part 26 requirements except those in subparts I and K before initial fuel load into the reactor because this operational milestone corresponds more closely to the start of NRC-licensed activities that could result in consequences adverse to public health and safety or the common defense and security than does the receipt of nuclear fuel onsite.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

G. Emergency Planning

G.1. Emergency Plan Change Process

The NRC is proposing to amend § 50.54 to align the introductory text of § 50.54 with the text in § 50.54(q)(2). The introductory text of § 50.54 currently lists those paragraphs in § 50.54 that are applicable only after the Commission makes its

§ 52.103(g) finding but does not include any portion of § 50.54(q) in that list. This could cause confusion on the applicability of § 50.54(q)(2) prior to the Commission making its § 52.103(g) finding because § 50.54(q)(2) states clearly that the requirements of § 50.54(q)(2) do not apply until after the finding. Section 50.54(q)(2) requires a licensee to follow and maintain the effectiveness of its emergency plan. However, § 50.54(q)(2) also excepts a COL holder from this requirement prior to a § 52.103(g) finding. The other requirements in § 50.54(q) apply to COL holders regardless of whether the Commission has made a finding under § 52.103(g). So, a COL holder will have an approved emergency plan, but at the time the COL is issued, some or all of that plan will not be implemented or "in effect." This is why, until the Commission makes the § 52.103(g) finding, the COL holder is not required to follow and maintain the effectiveness of the plan. However, if the licensee decides to change its emergency plan before a finding under § 52.103(g), then the licensee would need to evaluate that change under § 50.54(q)(3) and (4).

Inclusion of § 50.54(q)(2) among those provisions listed in the introductory text of § 50.54 as inapplicable before the § 52.103(g) finding would eliminate uncertainty in the applicability of § 50.54(q)(2) and emphasize that the rest of § 50.54(q) applies before the § 52.103(g) finding.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

G.2. Emergency Preparedness Exercises

The NRC is proposing to revise paragraphs IV.F.2.a.(i) through (iii) and j of part 50, appendix E. These changes are intended to align the requirements for part 52 licensees in paragraph IV.F.2.a.(ii) with the requirements for part 50 licensees in paragraph IV.F.2.a.(i). The changes would eliminate the requirement in paragraph

IV.F.2.a.(iii) for licensees to conduct emergency planning exercises for each new reactor constructed on a site with an identical operating reactor and would clearly define and align the beginning of the 8-year exercise cycle in paragraph IV.F.2.j for both part 50 and part 52 licensees.

Clarifications

In part 50, appendix E, section IV.F.2.a.(i) and (ii) require licensees to conduct an initial emergency preparedness exercise under parts 50 and 52, respectively. The NRC is proposing to standardize the language in section IV.F.2.a.(i) and (ii) by replacing instances of “one” and “two” with their numeral equivalent and inserting the word “before” in paragraph (ii) to parallel the language in paragraph (i) in relation to the timing of the exercise.

This item was not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

Subsequent Exercises

Paragraph IV.F.2.a.(iii) of appendix E to part 50 requires, in part, that a full or partial participation exercise must be conducted for each new reactor at a site with an existing operating reactor. The NRC has determined that if the new reactor has emergency plans that rely on the same emergency plan features, capabilities, and resources (e.g., same reactor technology, equipment, facilities, emergency response organizations and procedures) as the existing reactor, then additional exercises for the new reactor may not be necessary to demonstrate the effectiveness of the emergency plan and establish reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. The NRC is proposing to amend the regulations to account for circumstances in which additional exercises for a new reactor would not demonstrate any new emergency planning functions for the

licensee at that site. Under the proposed regulations, an applicant could include in its combined license application an analysis that an exercise for the new reactor is not required to demonstrate any new emergency plan features or capabilities beyond those in the emergency plan for the existing reactor(s) at the site.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Exercise Planning

The NRC is proposing to revise paragraph IV.F.2.j of appendix E to part 50 to align the timing for the beginning of the required 8-year emergency preparedness exercise cycle by establishing a common starting point for part 50 and 52 licensees' exercise cycles. The NRC is proposing that, for a licensee that receives its operating license issued under part 50 or combined license issued under part 52 after the effective date of the final rule, the first exercise conducted under paragraphs IV.F.2.b and c would be the first exercise of an 8-year exercise cycle. In conjunction with establishing a common starting point, the NRC would remove and reserve the text in current paragraphs IV.F.2.j.(v) and (vi). These provisions require initiation of the exercise cycle through the conduct of a hostile action-based exercise for licensees currently licensed to operate. In place of these regulations, the NRC would include a requirement for licensees to maintain their site exercise cycles. The NRC would also clarify that, for each new reactor at a site with an existing operating reactor, the new reactor licensee's exercises conducted to meet the requirements in paragraphs IV.F.2.b and c could be conducted in accordance with the existing operating reactor licensee's exercise cycle. The requirement to initiate these 8-year exercise cycles has already been met, so these regulations are no longer relevant.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

G.3. Significant Impediments to Development of Emergency Plans

Extent of Siting Analysis

The NRC is proposing to revise § 52.18, “Standards for review of applications,” to distinguish the siting requirements from the emergency planning (EP) considerations in § 52.17, “Contents of applications; technical information,” and to clarify that NRC consultation with the Federal Emergency Management Agency (FEMA) is for the purpose of evaluating whether significant impediments identified by the applicant can be mitigated or eliminated by the measures proposed by the applicant.

Section 52.17 describes the contents that must be included in applications for an ESP under part 52. This section provides the requirements for, among other things, the applicant’s site safety analysis report (SSAR), environmental reports, and emergency plan. In accordance with § 52.17(b)(1), the SSAR for an ESP must identify the physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. Because the ESP phase of the licensing process is relatively early in the overall part 52 licensing process, emergency plans are not always fully developed at the time of application. Therefore, § 52.17(b) provides three distinct options for the development of the SSAR and the information the application must include based on the level of emergency plan approval and finality sought by the applicant: (1) no emergency plan information (i.e., ESP only) under § 52.17(b)(1); (2) major features of the emergency plan under § 52.17(b)(2)(i); or (3) complete and integrated emergency plans under § 52.17(b)(2)(ii).

Siting requirements are contained in part 100, “Reactor Site Criteria.” As stated in § 100.1, “Purpose,” siting factors and criteria are important in assuring radiological doses from normal operation and postulated accidents will be acceptably low, natural phenomena and potential manmade hazards will be appropriately accounted for in the design of the plant, site characteristics are such that adequate security measures to protect the plant can be developed, and physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified. When determining the acceptability of a site for a power reactor, the Commission will consider, under § 100.20(a), whether physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified. Section 100.21(g) requires applications for site approval of commercial power reactors to identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. This is similar to the language of § 52.17(b)(1), except that under § 52.17(b)(1), if physical characteristics are identified that could pose a significant impediment to the development of emergency plans, then the ESP application must identify measures that would, when carried out, mitigate or eliminate the significant impediment. Section 100.21(g) does not require the applicant to propose methods to mitigate or eliminate any identified significant impediments to the development of emergency plans.

As required by § 52.17(b)(1), the SSAR for an ESP application must include an evaluation of the physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. However, the regulations and guidance are not clear how to determine the size and shape of the “site” or “area surrounding the site” that should be evaluated. The statement, “such as egress limitations from the area

surrounding the site," does not go far enough to distinguish whether the exact area under consideration is the site, the plume exposure pathway emergency planning zone (EPZ) within which protective actions may be warranted, or some other area. In addition, because the phrase "such as egress limitations from the area surrounding the site" appears in § 52.17(b)(1), that language remains unclear with respect to what extent the "site" should be evaluated, particularly if the size of the EPZ has not yet been determined at the ESP stage.

Regulatory Guide 4.7, "General Site Suitability Criteria for Nuclear Power Stations," describes a method the NRC considers acceptable to implement the part 100 site suitability requirements for nuclear power stations:

> The site and its vicinity, including the population distribution and transportation routes, should be examined and evaluated to determine whether there are any characteristics that would pose a significant impediment to taking actions to protect the public in an emergency.

However, "site" and "vicinity" are not defined in RG 4.7; rather, in RG 4.7, the NRC recommends that an evacuation time estimate (ETE) be made for the entire plume exposure pathway EPZ. Similar guidance is provided in NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," which recommends that an ESP applicant identify unique physical characteristics of the site by performing a preliminary analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, noting major impediments to the evacuation or taking of other protective actions.

Although an ETE for the EPZ is one acceptable method of demonstrating the suitability of the site, both guidance documents assume the existence of a 10-mile EPZ.

This assumption is also contained in SRP Chapter 13, “Conduct of Operations,” which provides guidance for the NRC’s review of an applicant’s emergency plan. However, as described in NUREG-0396, “Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,” the EPZ is only a planning tool to aid in the development and implementation of pre-planned protective actions. In addition, EPZs are scalable in size, as appropriate to the facility (e.g., a site-boundary EPZ, a 5-mile EPZ) and as allowed by the regulations in § 50.33(g). Furthermore, as discussed in NUREG-0396, protective actions, in general, are not constrained to areas within the EPZ, nor does the capability for taking protective actions rely solely on the establishment of an EPZ. As such, the EPZ may not necessarily be the same area under consideration for the siting requirements.

The NRC is issuing proposed changes to RG 4.7 and SRP Chapter 13 for public comment that include guidance on how to meet the requirements of § 52.17(b)(1) and the siting criteria in part 100 as they relate to siting and emergency planning for ESP reviews.

In the FRN for this proposed rule’s regulatory basis, the NRC included a specific request for public comment on the appropriate distance within which to perform the analysis to demonstrate compliance with the siting criteria for identifying site characteristics that could pose significant impediments to the development of emergency plans. The NRC received one response to the specific request for comment.

<u>Public Comments Related to This Item</u>

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI noted several relevant policy matters the NRC is considering that would affect the NEI's response, including the use of radiological consequence-based EPZs and changes to siting policies to permit greater population density near potential plant locations. The NEI provided additional comments regarding significant impediments, including:

- The NRC should adopt a flexible approach for ESP applicants to determine the distance at which site characteristics that could pose significant impediments are evaluated. The NRC's decision on significant impediments does not determine the adequacy of applicants' emergency plans, so the extent of significant impediments review is a commercial decision.
- Applicants conduct reviews of significant impediments to develop the completed and integrated emergency plan. Applicants also conduct ETE analyses focused on the EPZ to satisfy regulatory requirements, but the EPZ radius may vary with plant design.
- For some ESP applicants, the appropriate distance within which to perform the significant impediments review could be the exclusion area, or the EPZ radius, or some distance beyond the EPZ, with finality considerations influencing the selection.
- The NRC guidance should include basic minimum thresholds for the size of significant impediments review in ESP applications. For example, large LWRs may require a 10-mile EPZ and consider significant impediments within a 5-mile evacuation zone. For distances between those limits, the NRC should provide guidance to inform applicants' selection of an appropriate area for significant impediments review.

NRC Response:

The NRC agrees, in part, with this comment. The NRC agrees that the guidance should adopt a flexible approach. A flexible approach is necessary because: (1) the emergency planning information required in an ESP application is optional; and (2) EPZ size is specific to the facility under consideration. The NRC also agrees that a recommended threshold for the size of the significant impediments review is needed in guidance. However, the NRC does not agree that the exclusion area boundary is an appropriate distance for the analysis. The threshold must consider egress limitations from the area surrounding the site, as required by § 52.17(b)(1). Additionally, for a facility with a site-boundary EPZ, although planning for predetermined, prompt protective actions offsite would not be warranted, such actions could occur *ad hoc* beyond the EPZ. Therefore, the siting analysis should include determinations on factors beyond the site boundary including: (1) there are no egress limitations from the site; and (2) the site is suitable for public protective actions, if necessary. The NRC is proposing revisions to RG 4.7 to provide flexible guidelines for selecting an appropriate area for the siting analysis. The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Clarifications on NRC consultation with FEMA

Section 52.18 provides the standards of review for ESP applications. It generally incorporates into part 52 all the relevant regulatory requirements for review from parts 50 and 100. This includes the planning standards for emergency plans contained in § 50.47(b) and for the content of emergency plans contained in appendix E to part 50. Section 52.18 further describes the review standards for the application in relation to the three distinct sets of requirements within § 52.17(b) based on the level of emergency plan details that the applicant provides. This regulation states that the Commission shall

determine, after consultation with FEMA, whether the information required of the applicant by § 52.17(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with the applicable standards of § 50.47 and the requirements of appendix E to part 50, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Although the site characteristics are accounted for in components of the emergency plan, none of the siting factors and criteria are planning standards for emergency plans, such as those in § 50.47(b). More importantly, the site characteristics are not material to findings on the adequacy of the emergency plan. This distinction was made in the preamble for the reactor siting criteria final rule (December 11, 1996), in which the Commission stated:

> emergency planning is required as a matter of prudence and for defense-in-depth, and that the adequacy of an emergency plan was to be judged on the basis of its meeting the 16 planning standards given in § 50.47(b). Hence, the characteristics of the site, which determine the evacuation time for the plume exposure pathway emergency planning zone, have not entered the determination of the adequacy of an emergency plan. Emergency plans developed according to the above planning standards will result in reasonable assurance that adequate protective measures can be taken in the event of emergency.

An ESP applicant may propose major features of its emergency plan under § 52.17(b)(2)(i) or propose a complete and integrated emergency plan under § 52.17(b)(2)(ii). Section 52.17(b)(2)(i) and (ii) require the NRC's review and approval to include consultation with FEMA. Section 52.18 requires consultation with FEMA during the NRC review of the acceptability of emergency plans. These consultation

requirements are consistent with the regulations in § 50.47(a) on how the NRC and FEMA will make their findings and determinations on the adequacy of emergency plans. Section 52.18 also requires consultation with FEMA if, as required by § 52.17(b)(1), an applicant provides information on measures to eliminate or mitigate a significant impediment to the development of emergency plans. However, without further clarification, § 52.18 could be interpreted to impose an additional requirement for consultation with FEMA on the siting information required by § 52.17(b)(1).

The phrase "in consultation with FEMA" is an explicit requirement of § 52.17(b)(2)(i) and (ii), but it is not explicitly stated as a requirement in § 52.17(b)(1). As such, the purpose of the consultation with FEMA under § 52.18 in considering the information required by the applicant under § 52.17(b)(1) requires clarification. The first part of § 52.17(b)(1) is a siting criterion. It requires the SSAR to identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. This is aligned with the siting criteria of part 100. However, part 100 does not require consultation with FEMA to support the NRC finding on the suitability of the site. Under part 50, the mitigation of physical impediments would be addressed in the preliminary safety analysis report in the application for a CP. In accordance with section II.G of appendix E to part 50, applicants are required to do a preliminary analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, noting major impediments to the evacuation or implementation of protective actions. As stated in the introductory text of section II of appendix E, the preliminary safety analysis report must contain sufficient information to ensure the compatibility of proposed emergency plans for both onsite areas and the EPZs with respect to considerations such as access routes, surrounding

population distributions, land use, and local jurisdictional boundaries for the EPZs. As such, any identified major impediments would be reviewed for compatibility with offsite plans and the NRC would consult with FEMA as required by § 50.47(a)(2).

After the siting criteria, § 52.17(b)(1) contains additional language stating that if significant impediments to the development of emergency plans are identified, then the applicant must identify the measures that would, when carried out, mitigate or eliminate the significant impediments. This part of § 52.17(b)(1) relates directly to the development of emergency plans because, if significant impediments are identified, then consultation with FEMA would be needed in accordance with § 52.18. But § 52.18 does not make the distinction between the two parts of § 52.17(b)(1) or specify which part requires consultation with FEMA and why. Also, confusion may arise from the use of a double negative on the identification of significant impediments. Specifically, § 52.18 requires, in part, that the NRC determine, after consultation with FEMA, whether the information required of the applicant by § 52.17(b)(1) shows that there is <u>not</u> significant impediment to the development of emergency plans that <u>cannot</u> be mitigated or eliminated by measures proposed by the applicant. This language in § 52.18 could be interpreted to impose a requirement to consult with FEMA on the ESP application that is not consistent with the review that would be done under part 100 for reactor siting. The NRC is proposing to revise the sentence in § 52.18 that contains the double negative to clarify the meaning of the regulation.

G.4. Offsite Contacts, Arrangements and Certifications

The NRC is proposing to revise the requirements for contents of ESP applications in § 52.17(b)(4) to clarify what information is required regarding contacts, arrangements, and certifications with Federal, State, and local governmental authorities

in the SSAR. The NRC determined that the regulations do not clearly define the differing requirements for applications under § 52.17(b)(1), (2)(i), and (2)(ii).

An application for an ESP must include an SSAR that describes the physical characteristics of the proposed site. Applications under each of § 52.17(b)(1), (2)(i), and (2)(ii) require differing levels of detail in this report. Section 52.17(b)(1) establishes the minimum scope of information required in the SSAR. The NRC proposes to amend the regulations in § 52.17(b)(4) to clarify that a description of contacts, arrangements, and certifications are not required in the SSAR unless the SSAR identifies that these have been made to mitigate one or more site physical characteristics that pose a significant impediment to the emergency plan.

In addition to the minimum amount of information required in the SSAR under § 52.17(b)(1), § 52.17(b)(2)(i) and (ii) describe additional emergency plan information an ESP application may contain. The NRC is proposing to amend the regulations to separate the requirements for applications with emergency plan information submitted under § 52.17(b)(2)(i) or (ii). The proposed change would clearly affirm that the required description of contacts, arrangements, and certifications is commensurate with the level of finality sought on emergency plans.

The current regulations in § 52.17(b)(4) for applications submitted under § 52.17(b)(1) and (2)(i) could be interpreted as requiring applicants to include, under § 52.17(b)(1) and (2)(i), a description of <u>all</u> contacts, arrangements, and certifications (and/or compensatory utility plans as necessary) necessary for a complete and integrated emergency plan. The submittal of all contacts, arrangements, and certifications that are necessary for a complete and integrated emergency plan under § 52.17(b)(2)(ii) may not be necessary under § 52.17(b)(1) and (2)(i) because the Commission does not make a reasonable assurance finding for emergency plans

submitted with applications under § 52.17(b)(1) and (2)(i) as it does for emergency plans submitted with applications under § 52.17(b)(2)(ii). Therefore, the NRC is proposing to revise the regulations to clarify the requirements for an ESP application that includes the necessary information under § 52.17(b)(1) and the optional information under § 52.17(b)(2)(i).

The NRC is proposing to clarify in § 52.17(b)(4) that an applicant under § 52.17(b)(1) would be required to describe any contacts and arrangements that have been made and provide certifications that were obtained for those arrangements only as necessary to show that any significant physical impediment(s) to the development of emergency plans that was identified by the applicant can be mitigated or eliminated.

Proposed § 52.17(b)(4) would require an applicant under § 52.17(b)(2)(i)to provide any contacts, arrangements, and certifications that have been made and certifications of those arrangements and/or compensatory utility plans as necessary to support the NRC's review of the major features of the emergency plan for which finality is sought.

The proposed changes to § 52.17(b)(4) would state that, under both § 52.17(b)(1) and (2)(i), an applicant would be required to submit a complete description of all contacts and arrangements that have been made to support implementation of the emergency plan, including certifications and/or compensatory utility plans as necessary, when subsequently applying for a COL.

The proposed rule would not impact ESP applicants that elect to submit complete and integrated emergency plans under § 52.17(b)(2)(ii). The NRC would continue to require applications under § 52.17(b)(2)(ii) to provide complete descriptions of all contacts and arrangements, and all certifications and/or compensatory utility plans that are necessary for implementation of the emergency plan and for the Commission to

make its reasonable assurance determination on the applicant's complete and integrated emergency plan.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI recommended an editorial correction to address the inconsistency between regulatory basis Appendix G, Section 5.5, which says guidance documents would not be revised or developed, and the description of Alternative 2, which says associated guidance would be revised.

NRC Response:

The NRC agrees with the comment. The regulatory basis was unclear as to whether Alternative 2 (rulemaking to amend § 52.17(b)) would affect guidance. The proposed rule does not involve developing new guidance or revising existing guidance for these proposed changes. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

H. Part 52 Licensing Process

H.1. Design Certification Renewal

The NRC is proposing to revise its regulations to remove the duration of design certifications (DCs), the requirements for DC renewals, and the expiration dates for part 52 DC appendices currently in effect.

Current regulations establish the duration of DCs in § 52.55, "Duration of certification," for a period of 15 years from the date of issuance of the DC. The NRC sets the requirements for applicants seeking to renew the DCs in § 52.57, "Application for renewal," and requirements for the NRC to grant a renewal in § 52.59, "Criteria for

renewal." Section 52.61, "Duration of renewal," sets the duration for a DC renewal. The DCs that are currently in effect are in appendix A, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," appendix D, "Design Certification Rule for the AP1000 Design," appendix E, "Design Certification Rule for the ESBWR Design," and appendix F, "Design Certification Rule for the APR1400 Design," to part 52. Appendices B, "Design Certification Rule for the System 80 + Design," and C, "Design Certification Rule for the AP600 Design," have expired because no timely renewal applications were submitted in accordance with § 52.57.

The NRC is proposing to revise these regulations based on lessons learned from carrying out the DC renewal process. The proposed changes would reduce unnecessary regulatory burden on applicants and save NRC resources. Other existing requirements ensure that the goals accomplished by DC renewals are met (e.g., availability of amendment requests under § 52.63, "Finality of standard design certifications," to update information, maintenance of DC requirements in Section X in each part 52 appendix). In particular, a seemingly obsolete design can still provide adequate protection of the public health and safety, but if this is not the case, § 52.63 includes tools that would allow the NRC to address any issue. Additionally, an important lesson learned is that the 15-year certification period poses a problem if there is no license applicant referencing the design prior to DC renewal. In this situation, both the DC renewal applicant and the NRC expend resources to review a design renewal application that does not reflect additional insights derived from the implementation of a DC within the context of a license application. However, because of the inflexibility of the DC renewal regulations, application for renewal of the DC under the timely renewal provisions must be submitted, or else the design certification expires. This is an unnecessary regulatory burden on design vendors.

Therefore, the NRC proposes to amend §§ 52.55, 52.57, 52.59, and 52.61 and the applicable appendices to remove the duration of DCs, the requirements for DC renewals, and the expiration dates for the part 52 DC appendices that are in effect when this final rule goes into effect. The proposed changes would result in DC rules that do not expire and hence, the proposed changes would eliminate the need for the submittal of a DC renewal application. By eliminating these requirements, DC vendors would not be required to provide all information necessary to bring up to date the information and data contained in previous DC applications as currently required in § 52.57(a). Because the NRC is proposing to eliminate the 15-year duration of DCs, DC vendors would continue to be subject to DC information maintenance requirements, such as applicable requirements in Section X in each part 52 appendix, unless the design certification is rescinded. The NRC notes that a DC vendor may seek recission of the design certification by submitting a request under current requirements in § 52.63(a)(1); if a rescission request is granted, this would eliminate the burden of maintaining the DC information for an extended period of time. For the purposes of assessing the added burden associated with maintaining DC information, the NRC assumed that a DC vendor that did not want to maintain this information beyond the current 15-year DC duration would request, with minor burden, rescission of its design certification. Therefore, the NRC finds that the burden of maintaining the design certification information as described above would be offset by the reduction in unnecessary regulatory burden associated with the review of a DC renewal application.

In addition, the NRC proposes to amend § 52.57 to eliminate the need for NRC review of DC renewal applications to determine whether they meet the criteria in § 52.59(a) to grant renewal of a DC rule. Notwithstanding the proposed changes, the regulations retain the finality requirements under § 52.63(a)(1). These requirements

provide the NRC the ability to modify, rescind, or impose new requirements on the certification information. The criteria in § 52.63(a)(1)(i), (ii), and (vi) are like the DC renewal criteria in § 52.59(b) for the NRC to impose other requirements on a DC rule. The NRC, in making a determination under § 52.63(a)(1), would consider information of the same type (i.e., bulletins, generic letters, operating experience) in making a determination that certification information would meet the underlying purpose of the current update requirement under § 52.57(a). Thus, the NRC retains the flexibility to address significant issues that affect a DC rule in a manner like the processes provided by the DC renewal regulations that the NRC proposes to eliminate through this rulemaking. In addition, the NRC retains the requirements in § 52.63 that permit any person to petition the NRC to modify, rescind, or impose new requirements on the certification information. Therefore, the proposed changes would continue to allow DC vendors to request amendments to the DC rule in accordance with the requirements in § 52.63. These changes could include technology advances as well as correction of errors.

<u>Public Comments Related to This Item</u>

The NRC received seven comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

Westinghouse expressed appreciation for proposed changes to DC renewal being given high priority within this rulemaking and commented that changes would bring predictability and efficiency to the DC process.

NRC Response:

The NRC agrees with the comment. The comment supports the rulemaking and suggests no changes to the staff's recommendations. Accordingly, the Commission did

not change the NRC staff’s recommendations in the regulatory basis in response to this comment.

Comment Summary:

Westinghouse, NEI, and NuScale supported rulemaking to remove duration and renewal requirements for all DCs. Westinghouse said the change would reduce undue burden on applicants and the NRC. The NEI stated that the change would resolve inconsistencies in the information provided in DC renewal applications and address inefficiencies in the NRC’s review of such applications. NuScale and NEI noted that the NRC still would be able to use § 52.63(a) as needed to require any necessary or justified changes to a certified design that otherwise would have been addressed through renewal.

NuScale and NEI also stated that the removal of duration and renewal requirements should apply to existing DCs as well as to new DCs going forward. The NEI asserted that this approach would not raise issue finality considerations, because it would not modify the “certification information” under § 52.63(a)(1), but said applicants with existing DCs would continue to face recordkeeping requirements related to the DCs indefinitely. NuScale commented that there is no technical basis for treating existing and future DCs differently with respect to duration and renewal requirements and claimed that the regulatory impacts of extending the change to applicants with currently approved DCs would be minor and manageable.

Westinghouse and NEI commented that SECY-19-0084 indicated the regulatory basis would address streamlining the change process requirements for DCs and aligning the DC change process with the requirements in § 50.59 but this item was omitted from the regulatory basis. They suggested including in the proposed rule new provisions allowing a DC vendor to align the DC with a constructed reference plant’s licensing

basis, saying changes aligned with an operating facility's updated FSAR should require no NRC review or approval—because the updated FSAR already has been assessed as safe, compliant, and not adversely impacting the facility—and other changes should be evaluated under a § 50.59-like process to determine whether NRC review and approval is needed. Westinghouse added that this approach would be consistent with language in RG 1.206, Revision 1, Section C.2.14, regarding a COL application that references a DC and would remove undue burden on design vendors, applicants, and the NRC without affecting health or safety.

NRC Response:

The NRC agrees, in part, with these comments. The NRC agrees that removal of duration and renewal requirements should apply to existing DCs as well as to new DCs going forward. This is consistent with the regulatory basis, Appendix H.1, Section 3.4.1, which described the recommended alternative, Alternative 4, as removing the 15-year duration for DCs in § 52.55 and DC renewal requirements in §§ 52.57, 52.59, and 52.61 and in the part 52 DC appendices. In addition, in Section 7 of Appendix H.1, the NRC stated that the changes to NRC regulations and guidance in Alternatives 2 through 6 would affect future DC renewal applicants. In the context of Alternative 4, future DC renewal applicants referred to an applicant that would need to request the renewal of a DC to avoid the expiration of such DC. As such, any DC in effect at the time of the issuance of this rule in final form would no longer expire as a result of the implementation of Alternative 4. The NRC asked a question in the FRN for the regulatory basis pertaining to expired DCs. This question and the public's responses to it are discussed separately in this document.

The NRC disagrees with the comments regarding use of a "§ 50.59-like process" to afford flexibility regarding generic changes to a design certification. The § 50.59-like

process is a change process applicable to COL applicants or licensees referencing a DC. Using the § 50.59-like process allows an applicant or licensee who references a DC rule to depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the technical specifications, or requires a license amendment under paragraph B.5.b or B.5.c of section VIII of each part 52 DC appendix. The scope of changes subject to that process applies only to the applicant(s) or licensee(s) requesting the change or departure from the referenced design.

Generic changes to a standard design are made through either the rulemaking process or the standard design approval process or both. For generic changes, these processes are appropriate because of the potential generic impact of the changes. Rulemaking affords an increased level of NRC review and public participation for design certifications. The comments implied that SECY-19-0084 intended for the regulatory basis to include an alternative generic change process for DCs that does not involve rulemaking. The NRC disagrees with that assessment. SECY-19-0084 indicates that the NRC was planning to address processes that apply only to applicants and licensees that intend to depart from the referenced DC. The NRC's position is that the § 50.59 process used by licensees of part 50 plants and the § 50.59-like process discussed in each appendix for part 52 plants should be similar to the extent possible. From its beginning, the part 52 licensing process included a requirement that the design of a nuclear power plant provided in a DC application must be "essentially complete." Moreover, the NRC purposefully created a restrictive change process for DC information to promote standardization, make the NRC's review of COL applications more efficient, and improve safety. With respect to issue resolution, section VI.B.6 of each part 52 DC appendix clearly indicates that issue resolution is only applicable to the plant under

consideration. The NRC is not considering changes to section VI.B.6. Regarding changes in § 52.59, SECY-19-0084 only discussed the need for a renewal period.

In addition, the comments reference the assessment of a rulemaking alternative to remove the duration of design certifications, discussed in Appendix H.1 of the regulatory basis. The assessment included a statement, "design vendors could amend the certification per § 52.59(c) to address new information and incorporate voluntary changes to support future COL applications." The NRC notes that the regulatory basis incorrectly cited § 52.59(c) as the regulation that would govern amendments to the design under that alternative. While this provision describes the ability for applicants to seek amendments to the design, it does so within the bounds of a DC renewal application, which that alternative proposed to remove. Section 52.63 references the petition for rulemaking process—that any person can petition the NRC to modify, rescind, or impose new requirements on the certification information. This current provision is the applicable regulation to generically amend a design that is not undergoing a renewal review. As such, if design certification renewals would no longer be required, DC vendors still could request amendments to the DC rule in accordance with the requirements in § 52.63. These changes could include technology advances as well as correction of errors.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to these comments.

Comment Summary:

The NEI stated that the NRC should modify the duration requirements for MLs, writing that there is no safety reason to limit the duration of MLs because an ML license holder is bound by other NRC regulations for the safety of manufacturing reactors. The NEI added that the NRC can always modify the ML if a safety issue does arise. For

similar reasons, NEI and NuScale stated that the NRC should modify the duration requirements for SDAs because, for designs that received an SDA, the NRC already determined the assurance of adequate protection, which is not expected to change over time.

NRC Response:

The NRC disagrees, in part, with these comments. An SDA is an NRC staff approval; it does not reflect the final determination of the NRC on adequate protection of public health and safety because it is not binding on the Commission or the Atomic Safety and Licensing Board. To issue an SDA, the NRC staff reviews whether the SDA application complies with the standards set out in parts 20, 50 and its appendices, 73, and 100. The Advisory Committee on Reactor Safeguards (ACRS) also reviews portions of the application related to safety. The SDA does not affect the authority of the Commission or Atomic Safety and Licensing Board, and issues within the scope of the SDA are still subject to a hearing in a licensing proceeding. Thus, there is a greater level of finality for DCs, which are certified through rulemaking, than for SDAs. However, the NRC agrees that, similar to its duration and renewal requirement proposals for DCs, duration requirements for SDAs can be eliminated without impacting public safety and health.

For MLs, section 103c. of the AEA requires that licenses shall be issued for a specified period, as determined by the Commission, depending on the type of activity to be licensed, but not exceeding 40 years from the authorization to commence operations and may be renewed upon the expiration of such period. Thus, the NRC cannot eliminate the duration of MLs. Similar to the reasons for eliminating the duration of DCs and SDAs, the NRC proposes to extend the duration of initial and renewed MLs to 40 years.

Accordingly, and in response to these comments, the NRC proposes to revise §§ 52.147, 52.173, and 52.181 to remove such requirements.

Comment Summary:

The NEI stated that the NRC had overstated the negative impacts that could result from having to address departures (or opting to address new information) outside of a regular renewal process, because such design changes could either be imposed by the NRC under § 52.63(a) or be pursued voluntarily by the applicant through amendment, and a renewal process itself does not assure fewer departures or greater standardization.

NRC Response:

The NRC disagrees with the comment. The NRC does not conclude that the potential negative impacts associated with addressing departures by COL applicants that may have otherwise been addressed during a DC renewal review were overstated. Section 52.63(a) imposes more restrictive limits on the type of changes that may be made while a design certification rule (DCR) is in effect than what § 52.59(c) allows for a DC renewal applicant in seeking changes to the DC. DC renewal applications that include amendments to the certified design are not required to address the criteria in § 52.63 (e.g., the DC renewal applicant need not identify specific criteria in § 52.63(a)(1) as the basis for proposing an amendment to the certified design). In addition, addressing changes to the design as part of the DC process (assuming COL applicants do not depart from the implemented design change to the DC) is a more efficient process than COL applicants individually departing from the referenced DC. The NRC acknowledged in the regulatory basis that these potential inefficiencies can be averted or minimized by amending the design or by COL applicants adopting departures submitted

by other COL applicants. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

The NEI objected to the NRC's conclusion that, because Alternative 4 in Appendix H.1 of the regulatory basis would apply to future DC renewal applicants, that alternative does not raise backfitting or issue finality considerations. The NEI said that the impacts of Alternative 4 are based on the assumptions of Alternative 2, and Alternative 2 is based on impacts to existing DCs, so Alternative 4 assumes that removing DC duration would affect existing DCs. The NEI asked the NRC to clarify that removing DC duration would impact existing DCs. The NEI also recommended the NRC consider changes to lessen the burden of indefinite reporting obligations for both existing and future DC applicants whose certified designs would never expire.

NRC Response:

The NRC disagrees, in part, with the comments. The NRC disagrees that the impacts of Alternative 4 (removing duration and renewal requirements for DCs) described in Appendix H.1 of the regulatory basis are inconsistent with the statement about backfitting and issue finality in Section 7.0 of that appendix. The projected impacts of Alternative 4 are based on the four existing DCs because it would not be appropriate to include designs that have not been certified at this time. However, consistent with the discussion in Section 7.0, Alternative 4 will apply to all DCs in effect at the time this rule becomes effective.

The NRC agrees with the comment that Alternative 4 does not raise issue finality considerations because it does not modify the "certification information." The Commission explained in the 2007 part 52 final rule that § 52.63(a), which provides the criteria for making changes to certified designs, applies to changes to the certification

information but does not apply to changes to the certified design rule language (e.g., section VIII). The NRC disagrees with the comment requesting to lessen the burden of indefinite reporting obligations for both existing and future DC applicants whose certified designs would never expire. The NRC finds that the impact of the reporting obligations is offset by the reduction in unnecessary regulatory burden, consistent with the NEI's comment.

Furthermore, the DCR concept, as implemented in part 52, subpart B, "Standard Design Certifications," embodies the idea that, within each period that a DCR may be referenced, the design certification and any referencing applications and licenses share a co-extensive regulatory life until the last referencing license is terminated or the referencing application is denied. Therefore, the only additional impact of implementation of Alternative 4 is for DCRs that do not have a referencing license or application as described previously. For these DCRs, the practical effect of implementation of Alternative 4 is that applicants for current DCs will not be able to let the DCR lapse and thereby terminate the reporting obligations. Current regulations in § 52.63 already establish a process for voluntarily requesting the Commission to rescind a DC. Therefore, Alternative 4 results in vendors having to petition the NRC to rescind the DC in accordance with § 52.63 should the vendor wish to terminate the DC and associated reporting obligations. However, as stated previously, this potential additional burden is offset by the benefits of removing the requirement to seek renewal of DCs.

Moreover, when the Commission discussed requirements for reporting defects and noncompliance in accordance with part 21 in the preamble of the 2007 part 52 rulemaking, it provided several key principles of reporting. In the second principle, "Notification Occurs When Information Is Needed," the Commission explained that, for those part 52 processes that do not authorize continuing activities required to be

licensed under the AEA, but that are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the part 52 process is first referenced. The Commission's view is based upon its determination that a defect with respect to part 52 processes should not be regarded as a "substantial safety hazard," because the possibility of a substantial safety hazard becomes a tangible possibility necessitating NRC regulatory interest only when those part 52 processes are referenced in an application for a license, such as a COL or an ML. As such, part 21 reporting requirements can be deferred, thereby minimizing the impact to the applicants for current DCs for the case in which the DC is not referenced by an applicant or licensee.

The Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

An anonymous commenter inquired why the NRC is not proposing to address fuel reanalysis in renewal and described the fuel reanalysis for the ABWR renewal as "useless." The commenter recommended excluding fuel from renewal.

NRC Response:

The NRC disagrees with this comment. Section 52.57(a) specifies that a DC renewal application must contain all information necessary to bring up to date the information and data contained in the previous application. The issue regarding fuel reanalysis in the ABWR design certification renewal was that the applicant had not updated the Design Control Document to incorporate error corrections to the emergency core cooling system evaluation model since the original certification of the ABWR design in 1997. This issue was addressed as part of the renewal of the ABWR DC.

Additionally, as described in this proposed rule, the NRC is proposing to amend the regulations in part 52 to remove the 15-year duration for DCs established in § 52.55 and DC renewal requirements in §§ 52.57, 52.59, and 52.61 and in the part 52 DC appendices. Under this proposed rule, the reactor designs certified under part 52 will not need to be renewed. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Comment Summary:

Westinghouse and the NEI wrote that because the DC rules require significant investment by both applicants and the NRC to provide and approve the designs as safe, the expired DC rules should not be removed from part 52.

NRC Response:

The NRC agrees, in part, with these comments. The NRC agrees that the expired certifications required a significant investment by the NRC and industry. The NRC disagrees that there is any impact to this investment with the removal of the expired certifications from the *Code of Federal Regulations*. Their removal would not include the removal of any NRC records associated with the expired certifications. Removal of the expired content would have the benefit of clarifying the NRC's regulations. Therefore, the NRC proposes to remove and reserve appendices B and C to part 52.

H.2. Change Process

The NRC has identified several areas concerning the change process for new reactor permits, certifications, and licenses that need to be clarified or amended.

<u>Public Comments Related to This Item</u>

The NRC received one comment on the change process relating to a topic that was not discussed in the regulatory basis associated with this proposed rule. The NRC

also received one comment on the change process for the site safety analysis report and limited work authorization safety analysis report. This topic was discussed in the regulatory basis, where the staff recommended no action for that item.

Comment Summary:

NuScale and the NEI expressed concern about uncertainty with respect to how SDA departures impact the finality of the standard design. The NEI asserted that because the SDA regulations in part 52, subpart E, "Standard Design Approvals," do not include a change process for SDAs, and § 52.145, "Finality of standard design approvals; information requests," says the NRC and ACRS must rely upon an "approved design" when reviewing a license application that incorporates by reference a standard design approved under subpart E, any departure from that SDA in the license application could be taken to mean the application has not incorporated by reference the "approved design" and the NRC need not rely on the SDA. NuScale and the NEI commented that COL applicants' use of DCs shows how unlikely it is that a site-specific application could incorporate by reference an SDA without departing from the approved design. NuScale and the NEI said a § 50.59-like process requiring review of departures that affect the approved design while maintaining finality for the rest of the design would be the only change process needed for SDA departures as SDAs do not include Tier 1 information. NuScale also recommended the NRC revise subpart E so that it would enable SDA holders to amend the SDA on a generic basis and, if the NRC does not remove SDA durations as part of the rulemaking, renew the SDA.

NRC Response:

The NRC agrees, in part, with these comments. The NRC's regulations currently do not include a change process for SDAs. Upon consideration of the comments, the NRC has determined that providing a change process for SDAs would be appropriate.

Accordingly, as discussed in section III.H.2 of this document, and in response to these comments, the NRC is including language in this proposed rule to allow SDA holders to make generic changes to SDAs and to govern how specific departures (referred to in this proposed rule as variances) can be taken from one or more SDAs that are referenced in an application for a CP, an OL, a COL, or an ML.

The NRC disagrees that a § 50.59-like process is needed to preserve finality or would be effective for generic changes to SDAs or variances from SDAs. The NRC considered a § 50.59-like regulatory approach, a process similar to that used by applicants or licensees that reference a DCD, in response to this comment. This process is described in section VIII.B.5 of each DCR, codified in appendices to part 52. The NRC evaluated whether a process that permitted departing from an approved standard design without prior NRC approval would be appropriate for applicants that reference SDAs.

Section 50.59 allows licensees to make certain changes and conduct tests and experiments without prior NRC approval. An SDA is not a license, so § 50.59 is not applicable to SDAs. The NRC is proposing changes to § 52.145 in this proposed rule such that the SDAs will be subsumed into licenses once granted. With this proposed change, a licensee then would be able to use the § 50.59 process or another applicable change process.

The NRC concluded that a § 50.59-like process would be inappropriate for entities such as SDA holders. Such a process would require supporting programs such as a quality control program to be in effect for the duration of the SDA, to provide assurance that program records are kept up to date and available for NRC inspection. An SDA holder would have to establish quality control of the recordkeeping of all the change evaluations and changes they have made to the standard design. Since SDAs

would no longer have an expiration date, this program would have to be maintained for an indefinite period in the future, regardless of the commercial interest in the design. This is not likely to happen and is an unrealistic expectation of SDA holders.

The NRC concluded that a § 50.59-like process for applicants that reference SDAs would neither be appropriate nor provide a net benefit. Therefore, the NRC is not proposing a § 50.59-like process for these changes.

Comment Summary:

With respect to Appendix H.2, Section 5.0, of the regulatory basis, NEI recommended that the NRC pursue rulemaking to establish a § 50.59-like graded change process for ESP SSARs and limited work authorization safety analysis reports, stating that this approach would eliminate undue burden for ESP holders and make the regulations more consistent.

NRC Response:

The NRC disagrees with the comment. As discussed in the regulatory basis (Appendix H.2, Sections 5.6.2.2 and 5.6.2.3), the number of future SSAR changes considered by ESP and limited work authorization holders is difficult to predict. To date, the NRC has issued six ESPs for which only three amendments (all for one site under construction) have been received and reviewed by the NRC. For issued ESPs that are not under construction pursuant to a limited work authorization, the incentive to modify the SSAR is not apparent, especially for minor changes having minimal safety significance. Furthermore, the rulemaking cost to the NRC and the continuing administrative reporting obligation for the ESP holders as a result of a rulemaking to provide for a change process would not result in significant efficiency gains for either the NRC or the ESP holders. Therefore, the NRC believes the number of future SSAR changes that would be avoided by a change process would not support a need for the

change process suggested in the comment. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

Move the § 50.59-Like Change Process from Part 52 Appendices to Part 52, Subpart B

In the regulatory basis for this proposed rule, the NRC staff recommended that the regulations be revised to add a paragraph to § 52.63 in part 52, subpart B. The new paragraph would have included the change process information currently stated in section VIII.B.5.b of the part 52 DC appendices. The new regulation would have applied to design certifications established after the effective date of the final rule. The NRC would have proposed a revision to § 52.98(c)(1) in subpart C, "Combined Licenses," of part 52 to reference the new regulation in § 52.63(b). The revised regulation would have contained identical language as section VIII.B.5.b of the part 52 DC appendices. The purpose of this change would have been to improve efficiency in the regulations by eliminating the need to describe the Tier 2 change process in every DC appendix.

Section VIII of the part 52 DC appendices, "Processes for Changes and Departures," section VIII.B.5, describes the change processes for Tier 2 information used by COL applicants or licensees referencing the corresponding certified design. Section VIII.B.5.b is a process similar to § 50.59 (it is sometimes referred to as a "§ 50.59-like process") for departures from the generic DCD Tier 2 information. This regulation states how an applicant or licensee determines whether a prospective change to DCD Tier 2 information requires prior NRC approval or, for a licensee, whether the licensee can proceed with the change without prior NRC approval. In cases where the change to Tier 2 information involves a change to Tier 1 information, Tier 2* information, technical specifications, or an exemption, the process directs that prior NRC approval is required before making the change.

However, during the development of this proposed rule, the NRC recognized that the requirements in section VIII.B.5.b are integrated with other sections in the change process in DC appendices in such a way that they are not easily separable from other sections in the appendix. The NRC also determined that moving only a small portion of a change process described in the appendices may not result in an improvement to efficiency. The new regulation would be more difficult to follow than the existing regulations. Based on this new assessment of the proposed change, the NRC is not proposing changes to the regulations related to moving the § 50.59-like process from the part 52 DC appendices to § 52.63.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Process for Making Changes to the Plant-Specific Design Control Document (PS-DCD) Organization and Section Numbering

The NRC is proposing to amend all DC appendices in effect at the time the final rule goes into effect, to delete the requirement for the plant-specific DCD to use the same organization and numbering as the generic DCD.

Section IV.A.2.a of each part 52 DC appendix contains a similar requirement for a COL applicant to use a specific organization and numbering format in its PS-DCD. Specifically, section IV.A.2.a of each DC appendix requires that an applicant for a COL that wishes to reference a certified design must include, as part of its application, a PS-DCD containing the same type of information and using the same organization and numbering as the generic DCD for the design being referenced. This requirement is intended to make clear that the initial application must include a PS-DCD and assures, among other things, that the applicant clearly commits to complying with all of the Tier 1

and Tier 2 information in the generic DCD, as modified and supplemented by the applicant's exemptions and departures as of the time of submission of the application.

The proposed changes in the rule will eliminate the organization and numbering requirement in section IV.A.2.a in each of the existing part 52 DC appendices, and future appendices could be developed without this requirement. Under the proposed rule, a COL applicant could follow any organization and numbering scheme for the FSAR in their COL application without needing to ask for an exemption.

The NRC recognizes that the organization and numbering of a PS-DCD is an administrative requirement not related to safety that was established to facilitate the use and review of the PS-DCD (or FSAR). The current requirement in section IV.A.2.a of each of the part 52 DC appendices, while intended to facilitate the review by having information presented "at appropriate points" and make the FSAR "easier to use," as discussed in SECY-96-077, "Certification of Two Evolutionary Designs," may not give sufficient flexibility to COL applicants because it requires the organization and numbering of FSAR sections to be "the same" as in the generic DCD.

The proposed change to the regulations would give applicants the flexibility to include a PS-DCD using any organization and number scheme without the need for an exemption. Changing the organization and numbering scheme of a PS-DCD would not affect the outcome of the safety decision.

Existing COL holders would not be affected by this proposed change because they are no longer applicants. For any future COL applicant referencing a certified design, the applicant could include in its application a PS-DCD that has organization and numbering that differs from that of the generic DCD without having to ask for an exemption. The NRC has determined that the organization and numbering of a PS-DCD serves no safety purpose and is not the type of administrative requirement that results in

significant resource savings to the NRC. Accordingly, the NRC need not control PS-DCD by regulation.

Public Comments Related to This Item

The NRC did not receive any public comments on PS-DCD organization and numbering as it was discussed in the regulatory basis associated with this proposed rule.

Include § 50.59(c) Provisions in Part 52 Change Process

The NRC is proposing to revise section VIII.B.5 in each of the part 52 DC appendices to include provisions similar to those in § 50.59(c)(4). Section 50.59(c)(4) states that § 50.59 does not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes. The part 52 regulations do not include a similar provision. The NRC is proposing to change the "§ 50.59-like" process for part 52 to add a requirement similar to § 50.59(c)(4) that directs that the change process does not apply to departures from Tier 2 when the applicable regulations establish more specific criteria for accomplishing such departures. Also, some change in terminology from § 50.59(c)(4) is necessary to reflect how the change process would work in part 52. The term "departure" is used in section VIII.B.5.b in part 52 instead of the term facility or procedure "change" in part 50.

The proposed revisions would better align the parts 50 and 52 change processes. With conforming changes, the existing guidance provided in Appendix C to NEI 96-07 would apply. The current guidance adequately describes how this proposed revision to the regulation would apply to part 52 licensees.

In the regulatory basis for this proposed rule, the NRC staff recommended rulemaking to revise the § 50.59-like process in part 52 to add provisions similar to the requirements in § 50.59(c)(1). However, after further evaluation in the development of

this proposed rule, the NRC determined that it is unnecessary to add a provision similar to § 50.59(c)(1) to the § 50.59-like process.

As stated in § 52.98, "Finality of combined licenses; information requests," changes to combined license information that is outside the scope of the DC are controlled by the part 50 change process. The part 52 change process involves a two-part approach. Changes to combined license information that is within the scope of the DC must be evaluated to consider the impact of the change on Tier 1 and Tier 2* information in the referenced DC. If the Tier 2 change would affect Tier 1 or Tier 2* information, then an exemption and a license amendment or a license amendment, respectively, is necessary to make those changes. Section 50.59(c)(1) does not have (or need) such a provision for controlling such changes for plants licensed under part 50. The difference between § 50.59(c)(1) and section VIII.B.5.a in the part 52 DC appendices is necessary in order to apply the basic design control process in part 52.

<u>Public Comments Related to This Item</u>

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule. The NRC received one other comment related to allowing Tier 1 changes without prior NRC approval.

Comment Summary:

The NEI disagreed with the limitation of the scope of the proposed changes to just Tier 2 and Tier 2* information. The NEI asked the NRC to revise the part 52 DC appendices and RG 1.237, "Guidance for Changes During Construction for New Nuclear Power Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR Part 52," to allow a licensee constructing a facility to make changes to Tier 1 information without prior NRC staff approval to facilitate timely construction.

NEI indicated that, currently, COL holders are required to comply with Tier 1 information at all times regardless of whether public health and safety would be impacted by the proposed changes to Tier 1 information. The NEI emphasized that enabling Tier 1 changes without prior NRC approval would permit licensees to depart temporarily from the approved licensing basis during construction subject to configuration control, corrective measures, or license amendments to realign the facility with its licensing basis. The NEI commented that the NRC's implementation of COL-ISG-025, "Changes During Construction Under 10 CFR Part 52," has enabled licensees to change Tier 1 information during construction before the NRC has finished reviewing the associated LAR. The NEI said this example shows that there is nothing that would prevent rulemaking that would enable licensees to make changes to Tier 1 information without prior NRC approval.

The NEI said resolution of this issue is very important to the viability of part 52 as a licensing process for future applicants. The NEI recommended that the NRC staff raise the issue to the Commission for consideration as a policy issue. The NEI remarked that the NRC has itself acknowledged that permitting licensees to depart from Tier 1 information without the NRC's prior approval would reduce burden on licensees related to construction delays while not necessarily raising safety concerns. The NEI referenced its past recommendations on this topic, including in two papers from 2018—"Ensuring the Future of U.S. Nuclear Energy: Creating a Streamlined and Predictable Licensing Pathway to Deployment" and "Assessment of Licensing Impacts on Construction: Experience with Making Changes during Construction under Part 52."

The NEI acknowledged that there are policy and legal bases for the current two-tiered framework and that modifying the existing framework would present challenges. However, NEI claimed that the long-term benefits of creating a more flexible change

process for Tier 1 information (e.g., avoiding reliance on the preliminary amendment request process and the associated costs to licensees and the NRC) would outweigh those short-term challenges. The NEI concluded that a change in approach to Tier 1 departures would not harm design standardization, would reduce burden on both licensees and the NRC, and would address a longstanding industry concern.

The NEI recommended amending RG 1.237 and making conforming changes to paragraph VIII.B.5.a of each part 52 DC appendix to provide that a licensee may make changes to or departures from Tier 1 information during construction without prior approval. The NEI noted that if such revisions were implemented, licensees still would need to secure amendments relating to the changes before declaring a changed SSC operable or placing it in service. The NEI asserted that the NRC's rationale for permitting changes during construction without prior approval to Tier 2 and Tier 2* information that ultimately would require a license amendment also would seem to cover changes to Tier 1 information with the addition of the need for an exemption.

NRC Response:

The NRC agrees, in part, with this comment. The NRC agrees that the construction experience from VEGP 3&4 has shown that many license amendment requests (LARs) could have been avoided had the DC applicants designated certain information as Tier 2, instead of Tier 1, in their applications. The staff issued SECY-19-0034, "Improving Design Certification Content," in April 2019 to describe its efforts to refine the general principles for Tier 1 and Tier 2* content so that NRC approval would not be required for design changes of minimal safety significance. Accordingly, in this rulemaking, the NRC has proposed modifications to the definitions of Tier 1 and Tier 2* information under § 52.1 to be consistent with SECY-19-0034. These proposed changes are discussed in section III.H.3 of this document.

The Commission approved the two-tier structure in SRM-SECY-90-377, "Requirements for Design Certification Under 10 CFR Part 52." Regarding flexibility, the Commission stated that changes to the approved design should be minimized, but "a certain amount of flexibility will be needed to finalize procurement information and to construct the facility." The Commission provided specific direction on the level of detail to be included in design certification applications, including use of a graded approach where the level of detail is commensurate with the safety significance of the SSC in question. The proposed modifications to the Tier 1 and Tier 2* definitions would minimize the changes in Tier 1 and Tier 2* information.

The NRC, however, disagrees with the recommendation to permit licensees to forgo prior NRC approval before making changes to Tier 1 information. A goal of the DC finality regulations is to minimize unnecessary changes to certified designs. Ensuring the ongoing reliability of the bases underlying referenceable approvals by maintaining appropriate change control processes advances safety and regulatory efficiencies. Furthermore, applicants should minimize the use of the resource- and time-consuming process of LARs and exemption requests, especially for those LARs that have minimal safety significance. The NRC has made significant progress in reducing the undesired impact of Tier 1 information changes on plant construction by refining the approach to identifying the amount of necessary Tier 1 information, to narrow the scope of such information, and providing additional flexibilities for changing Tier 2 and Tier 2* information. As explained in the following discussion, the NRC does not propose any changes in the existing Tier 1 change process.

The Commission approved the two-tier approach after a long deliberation of the policy. The policy was based on increasing standardization and limiting changes after the design was approved, including the concept of one design and one review to

minimize changes and potential delays during construction. The regulations require that systems be built as designed and as approved. Compliance with the licensing bases must be maintained during construction in order to maintain the validity of the NRC's safety findings. Based on the VEGP 3&4 experience, there have been some unintended consequences of having strict control over the change process for certified information. However, the NRC concludes that construction experience from VEGP 3&4 is not adequate justification to change this fundamental policy of one design and one review. The large number of LARs by VEGP 3&4 to complete the construction of the first plant of the AP1000 design is not a reason to reconsider this policy.

The part 52 process depends, in part, on obtaining a safety finding on the complete design of the plant and then ensuring the safety finding remains valid through construction. This requires that the plant is built as designed and as approved. The NRC recognizes that there may be some circumstances where unforeseen changes are necessary during construction. To avoid any unnecessary delays from changes during construction, the NRC and industry have successfully used a preliminary amendment request process (as described in COL-ISG-025). This process allows construction to proceed at risk while the change is being reviewed by the NRC and may improve efficiency regarding implementation of departures from Tier 1 information. If the change is ultimately approved, then the licensee avoids delays, and the NRC ensures that its safety finding remains valid.

The change process for Tier 1 information is premised on the fact that Tier 1 information is certified by rulemaking; the generic change process for this certified information, therefore, follows the rulemaking process. Amending the Tier 1 change process would entail complicated revisions to the regulations and a change to a longstanding policy established by the Commission. The NRC recognizes that some of

the change requests in Tier 1 addressed information that may not have been important to safety. Changes of an editorial nature can be grouped together and may be handled with some careful planning in licensing activities.

Accordingly, the NRC is not proposing any change to RG 1.237 or to its regulations to allow applicants to make changes to Tier 1 information without prior NRC approval, other than the proposed changes to the definitions of tiered information, as discussed in section III.H.3 of this document.

Comment Summary:

The NEI stated that the NRC significantly underestimated the benefits that would result from allowing licensees to make Tier 1 conforming changes (to align with Tier 2 changes to a COL holder’s licensing basis) without requesting both a license amendment and an exemption. The NEI supported amending the regulations to permit part 52 licensees as well as applicants to depart from Tier 1 and Tier 2 information in a certified design outside of the formal license amendment process as needed for alignment between Tier 1 and Tier 2 details. The NEI said that the benefits of being able to make such changes to the generic DCD far outweigh the estimated cost for COL holders referencing the existing part 52 certified design appendices to revise their internal procedures for processing Tier 2 changes. The NEI stated that the NRC had underestimated the potential benefits to COL holders by focusing on the construction phase and ignoring the continuing cost impacts to licensees after that phase.

The NEI suggested two alternatives the NRC should consider with respect to Tier 1 information: designate certain portions of the Tier 1 document as not requiring prior NRC approval for changes and remove the construction-specific designations of Tier 1 after completion of certain portions so that licensees can maintain portions of Tier 1 themselves following the § 52.103(g) finding.

NRC Response:

The NRC disagrees with the comment. As discussed in the responses to other comments regarding amendments to the change process for certified information (Tier 1), the NRC has concluded that it is premature to revise the process based on the experience for one certified design. As acknowledged by the NRC and industry, it would be complex to change a longstanding policy to resolve the issues identified by the comment. Further, it is not clear that these issues will be as important for other certified designs if the lessons learned from previous DCs are applied by the NRC and industry. The part 52 process is based on the intention of making limited changes after the design is certified to preserve the standardization of the certified design. The NRC has made significant progress in reducing the undesired impact on designs by refining the approach to identifying Tier 1 information and providing flexibilities for changing Tier 2 and Tier 2* information. While it is difficult to estimate the precise impact of minor editorial changes to certified designs, the NRC concludes it is not advisable to revise the change process at this point. As far as the comment on the cost-benefit analysis is concerned, the NRC finds that the regulatory analysis is correct because the NRC is not pursuing rulemaking with respect to changing Tier 1 information. Increasing the estimated benefit to industry will not change this approach.

<u>Approval Process for Changes While the Plant Is Being Constructed</u>

The NRC is proposing to change its regulations to make the process for review and approval of changes during construction more efficient. The proposed changes would align the implementation provisions in the departure process in the part 52 DC appendices with the implementation provision in the § 50.59 process. The various licensees subject to these different regulations would be subject to similar requirements for when a licensee can carry out a change proposed in an LAR.

The NRC proposes to modify section VIII.B.5 of each part 52 DC appendix to add a new paragraph to permit a licensee to make a change before the § 52.103(g) finding. The proposed new paragraph would permit a licensee to construct an SSC in accordance with a proposed departure from Tier 2 or Tier 2* information, excluding the Tier 2* departures covered under section VIII.B.6.b., without first obtaining a license amendment. The proposed new paragraph would contain three conditions. Permission to construct the SSC without first obtaining a license amendment would be permitted only if the licensee submits the LAR that is required to authorize the change to the facility or departure from Tier 2 of the PS-DCD within 45 days after the licensee begins construction of the SSCs subject to the change or departure; the change is within the restricted area defined in part 20, "Standards for Protection Against Radiation," and described in the FSAR; and, if the LAR is not approved, the licensee must construct the facility in accordance with the FSAR. The NRC intends that the proposed new paragraph would be consistent with existing guidance in RG 1.237.

The proposed change to the regulations would enable the licensee to continue construction while the change request is under NRC review. The proposed change would eliminate construction delays that are related to the NRC staff review of the LAR. The SSC under construction must be located within the restricted area defined in part 20 and must be described in the FSAR. These conditions would ensure that an NRC approval of the change would be the type of regulatory action described in § 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," and an NRC environmental review would not be necessary. Any changes carried out by the licensee before receiving NRC approval would be at the licensee's own risk, subject to reversal or modification if the requested change was not later approved by the NRC. In

the event of disapproval of a change under this process, the licensee would be required to return the facility to its approved licensing basis before completing construction.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI requested the NRC justify the provision in RG 1.237 that provides guidance for the schedule for submittal of the LAR. The guidance states that a licensee that proposes a change to the facility design during construction should submit the LAR to the NRC no later than 45 days after beginning construction of the SSCs subject to the change. The NEI recommended removing this additional administrative requirement if the NRC cannot link it to a safety benefit.

NRC Response:

The NRC disagrees with the comment. The NRC considers 45 days is sufficient time for the licensee to prepare an LAR and submit it, such that the NRC can perform its safety review and respond in a timely manner. As discussed in RG 1.237, submission of an LAR within 45 days after the licensee begins construction of the SSCs subject to the request would allow for sufficient time to process the LAR so that the ITAAC findings and fuel load would not be delayed. Additionally, the NRC is proposing to add this time period to the part 52 DC appendices as one of the conditions for allowing a licensee to construct an SSC without first obtaining a license amendment. Thus, the guidance would be restating a requirement. Accordingly, the NRC is not proposing any change to RG 1.237 in response to this comment.

Standard Design Approval Variance Process

In response to public comments on the regulatory basis for this proposed rule, the NRC is proposing to add regulations to part 52, subpart C, in new § 52.93(c) and to part 52, subpart E, in § 52.145(c) and (d) that would govern how variances can be taken from one or more SDAs that are referenced in an application for a CP, an OL, a COL, or an ML. Part 52 does not currently have a variance process for SDAs. Based on NRC experience, COL applicants referencing a certified design have taken multiple departures from the referenced certified design. The NRC anticipates that CP, OL, COL, and ML applicants likely would seek to depart from referenced SDAs, and adding regulations providing for SDA variances would create a framework for this.

To provide a process for applicants who wish to take variances from approved SDAs, the NRC is proposing a new § 52.145(d) that would allow license applicants to request variances from SDAs that are referenced in CP, OL, COL, or ML applications. The NRC determined that a license or permit applicant should identify in its application its request for variance from a portion of the referenced SDA to allow for evaluation of whether the referenced design with the variance will allow the staff to conclude that the findings it made in issuing the SDA remain applicable.

For the portion of the SDA not impacted by the variances, the new process would preserve finality as specified in § 52.145(a) and (b), which require that an approved design must be used and relied upon by the NRC staff and the ACRS in their reviews of any individual facility license application that incorporates by reference a standard design unless there exists significant new information that substantially affects the earlier determination or other good cause. Staff issuance of an SDA does not in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under 10 CFR part 2.

The NRC is proposing that when determining whether to grant the variance, the NRC staff must apply the same technically relevant criteria applicable to the variance as were applied to the original SDA. The NRC is proposing to add a new § 52.145(c) to provide that once a CP, an OL, a COL, or an ML that references an SDA is issued, the referenced SDA is subsumed into the CP, OL, COL, or ML. The proposed § 52.145(c) would clarify that the SDA variance process would not be used by CP, OL, COL, and ML holders that referenced an SDA in their license application. For an issued CP, OL, COL, or ML referencing an SDA, the existing change process for that license would be used. For example, the change process for COLs that reference an SDA would be in accordance with § 52.98(b). The NRC is proposing to add a new paragraph (c) in § 52.93, "Exemptions and variances," to provide conforming requirements for COL applications that reference SDAs with variances.

Generic Standard Design Approval Change Process

The NRC is proposing to amend regulations in §§ 2.100, "Scope of subpart," 2.101, "Filing of application," 2.110, "Filing and administrative action on submittals for standard design approval or early review of site suitability issues," and 52.3(b)(1) and add a new § 52.145(e) to allow SDA holders to make generic changes to SDAs. Part 52 does not currently have an amendment process for SDAs, in part due to § 52.147, "Duration of design approval," which specifies a 15-year duration for SDAs and no opportunity for renewal. As discussed in Section III.H.1 of this document, the NRC is proposing to remove the regulations in § 52.147, which would eliminate duration and expiration provisions for SDAs. With SDAs that do not expire, the NRC anticipates that SDA holders may desire to amend their SDAs. The NRC is proposing to add a new § 52.145(e) to allow an approved SDA to be amended. For the portion of the SDA not impacted by the amendment, the new process would preserve finality under § 52.145(a)

and (b), as explained in “Standard Design Approval Variance Process” in Section III.H.2 of this document.

The NRC is proposing to use language similar to § 50.90, “Application for amendment of license, construction permit, or early site permit” in proposed § 52.145(e). The proposed regulation would require applicants for the SDA amendment to fully describe the changes desired, following the form prescribed for original applications insofar as it applies.

Regarding the NRC’s evaluation of an SDA amendment request, the NRC is proposing to use language in proposed § 52.145(e) that is similar to § 50.92, “Issuance of amendment,” in that the NRC’s review of the amendment application will be guided by the applicable considerations governing the issuance of the initial approval. Finally, the NRC proposes to use the process set out in § 52.143, “Staff approval of design,” which provides requirements for the initial SDA approval, for SDA amendments. The NRC is proposing to amend § 52.3(b)(1) to clarify that applications for amendments to approvals may be submitted in addition to permits and licenses. The NRC is proposing to amend §§ 2.100, 2.101, and 2.110 to make these procedures applicable to SDA amendments. It is important to note that because an SDA is an NRC staff approval and is not an action described under section 189a. of the AEA, SDAs and SDA amendments do not confer an opportunity for a hearing.

The NRC considered an alternative approach. The NRC considered whether an SDA holder should be able to use a § 50.59-like process to make generic changes to SDAs. Section 50.59 allows licensees to make certain changes and conduct tests and experiments without prior NRC approval. Because an SDA is not a license, § 50.59 is not applicable to SDAs. One of the purposes of SDAs is to allow CP, OL, COL, or ML applications to incorporate by reference a standard design or major portion thereof that

has NRC staff and ACRS approvals, which are documented in an NRC report and published in the *Federal Register*. Allowing unreviewed and unapproved changes to SDAs contradicts this purpose of SDAs. Additionally, the introduction of a § 50.59-like process for SDAs would require new quality assurance, recordkeeping, and reporting requirements for SDA holders, notably for recording changes made using the § 50.59-like process and associated SDA FSAR changes. Therefore, the NRC concluded that a § 50.59-like process to allow SDA holders to make generic changes to SDAs would not provide a net benefit.

<u>Referencing Manufacturing Licenses and Standard Design Approvals while they are Under Review</u>

The NRC is proposing to amend regulations in § 52.173 to allow an applicant for a CP or a COL, at its own risk, to reference in its application a design for which an ML application has been docketed but not granted. The NRC also is proposing to update its guidance to clarify that an applicant for a COL, at its own risk, may reference in its application a design for which an SDA application has been docketed but not granted.

The regulations in §§ 52.26(c) and 52.55(c) allow an applicant for a CP or a COL, at its own risk, to reference in its application a site for which an ESP or a design for which a DC application, respectively, has been docketed but not granted. However, there are no such provisions in §§ 52.147 and 52.173 for SDAs and MLs, respectively. Based on its experience with VEGP 3&4 and the AP1000 part 52 appendix, the NRC anticipates that a future CP or COL applicant may want to reference an SDA or ML, at its own risk, while the SDA or ML is under review. The NRC has determined that, given the adjudicatory hearing finality considerations applicable to MLs, adding a provision to address referencing an ML "at risk," similar to that regarding ESPs and DCs, would add regulatory clarity. For an SDA, there are no adjudicatory hearing finality considerations

at stake because an SDA does not affect the authority of the Commission or the Atomic Safety and Licensing Board Panel. While the fact that a lesser degree of finality accompanies an SDA may limit the utility for referencing an SDA before it has been issued, a CP or COL applicant may nevertheless choose to do so. The NRC will propose guidance to clarify that a CP or COL applicant may reference an SDA still under review.

H.3. Design Scope and Standardization

Add Definitions of Tier 1, Tier 2, and Tier 2*

The NRC is proposing to change its regulations to add the definitions of tier information to § 52.1 and to make the definitions consistent with the principles in SECY-19-0034, "Improving Design Certification Content." In addition, the NRC proposes to amend § 52.47 to require DC applicants to identify Tier 1, Tier 2, and Tier 2* information in their applications.

The terms "Tier 1," "Tier 2," and "Tier 2*" are defined in section II, "Definitions," of each design certification in appendix A through F to part 52. A design certification applicant is free to define this information. For example, an application can define no tier information, include more than three tiers of information, or define tiers with definitions that are different than those in current part 52 DC appendices. This flexibility can lead to inconsistencies and increased burden for DC and COL applicants in preparing applications and increased burden to the NRC in reviewing the application.

Recent new reactor licensing experience has shown that some applications have included more information in Tier 1 than is necessary for the purpose of Tier 1. This resulted in the need for licensees to ask for NRC review and approval of Tier 1 departures of information which, because of its minimal safety significance, could more appropriately have been handled under a § 50.59- like change process.

To address these problems, the NRC is proposing to change its regulations to add a definition that contains two general principles for Tier 1 information content: (1) Tier 1 information should be described at a qualitative and functional level of detail, and (2) Tier 1 information should not include detail that could necessitate NRC approval for departures from the certified design that have minimal safety significance. The NRC proposes the same refinements to the definition of Tier 2* information because information should be designated as Tier 2* only if it qualifies for inclusion in Tier 1.

Public Comments Related to This Item

The NRC received two comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

NuScale and the NEI objected to the provision of the recommended rulemaking that would require tiering of information in FSARs for applications other than DC applications (i.e., COL, SDA, and ML applications), saying it was without basis; the NRC had not identified a regulatory issue the proposal would resolve; and the unique rationale for tiering of information for DCs, which act as regulations, does not apply to other application types. The NEI recommended the NRC clarify the regulatory basis to state that, while all COLs issued to date have referenced a DC, the NRC currently is reviewing a COL that does not reference a DC. The NEI recommended the NRC not extend tiering to COL and SDA applications and consider less burdensome alternatives for ML applications. NuScale recommended the NRC not apply tiering to COL, SDA, and ML applications and expressed particular concern about extending the requirement to SDA applications. NuScale stated that for DCs, the burden of tiering is justified by the benefit of issue resolution, but for SDAs, the same requirement would impose an undue burden not justified by safety or finality. NuScale referenced language regarding the finality of

MLs that appeared in the 2007 part 52 final rule and was quoted in the regulatory basis at page J-13, saying it showed the NRC intended for the degree of finality afforded by a licensing process to be correlated to the degree of standardization the process achieved, and requested that the NRC not reverse that intent without fully considering and justifying the purpose and results of the proposed change in approach.

The NEI stated its understanding of the approach to Tier 2* information as being that the NRC "only intends to use Tier 2* in situations when specifically requested by an applicant, but has reserved it for special exceptions." The NEI suggested that any definition of Tier 2* included in the regulations should make clear that it is not expected to be used apart from special exceptions when an applicant sees a benefit to the additional flexibility for making changes.

NRC Response:

The NRC agrees, in part, with these comments. The NRC agrees that the regulations in §§ 52.47, 52.79, 52.137, and 52.157 do not require tiering of information for license applicants. The NRC also agrees that the regulatory basis did not adequately explain the staff's basis for proposing to amend §§ 52.47, 52.79, 52.137, and 52.157 to require DC, COL, SDA, and ML applicants to identify Tier 1, Tier 2, and Tier 2* information in their FSARs. The NRC is not proposing to require COL, SDA, or ML applicants to identify Tier 1, Tier 2, and Tier 2* information in their applications. Accordingly, in response to these comments, the NRC is proposing to revise the language in § 52.47 to require only DC applicants to identify tiered information in their applications. With respect to Tier 2* information, the NRC will continue to reserve the option to use this designation in appropriate circumstances; maintaining this category of change control process may increase regulatory flexibility in the event it is required to support an NRC finding. With respect to correcting the statement in the regulatory basis

that all COLs issued to date have referenced a DC, the NRC is not re-issuing the regulatory basis, and the statement in question does not repeat in this proposed rule. As such, there is no opportunity or need to revise it.

Clarify the Phrase "Essentially Complete Design"

The NRC proposes to amend § 52.1 to add a definition of "Essentially complete nuclear power plant design," and amend § 52.41(b)(1) to provide clarity.

In general terms, a DC application should provide an essentially complete nuclear plant design, except for some site-specific design features. The term "essentially complete" is mentioned in § 52.41(b)(1) and 52.47(c)(1) and (2), but the term is not defined in those sections or in § 52.1 with other definitions of terms used in part 52. The NRC is proposing to revise its regulations to define the term "essentially complete nuclear power plant design" as a design that includes all structures, systems, and components that can affect safe operation of the plant except for site-specific elements such as the service water intake structure and the ultimate heat sink. This definition is consistent with the definition of "essentially complete nuclear power plant" provided in the preamble for the 1989 part 52 final rule.

Additionally, the NRC proposes to amend § 52.41(b)(1) by deleting the phrase "essentially complete." This change intends to clarify the regulations to ensure that future applicants would submit an "essentially complete" design for standard design certifications for a nuclear power plant design that is an evolutionary change from light water reactor designs of plants that have been licensed and in commercial operation before April 18, 1989, as well as for certifications for a nuclear power plant design that differs significantly from evolutionary designs or that uses simplified, inherent, passive, or other innovative means to accomplish its safety functions. Currently, § 52.41, "Scope of subpart," uses the term "essentially complete" when describing an evolutionary design

and omits the term when describing a design that differs significantly from evolutionary designs. This could lead to an interpretation that contradicts § 52.47(c)(2), which requires a design that differs significantly from evolutionary designs to provide an essentially complete design. Ultimately, the use of the term "essentially complete" is unnecessary in § 52.41 because § 52.47(c) already requires both § 52.41(b)(1) and § 52.41(b)(2) applicants to provide an essentially complete design. This proposed change would eliminate a potential conflict between § 52.41 and § 52.47(c), which specifies content requirements for particular applications, and provide clarification to ensure standard design certification applicants submit an essentially complete design. The NRC staff discussed this topic with the ACRS on March 2, 2022. In a letter to the Commission dated, March 23, 2022 (ADAMS Accession Number ML22069A269), the ACRS recommended that the staff should proceed with this rulemaking package.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

NuScale recommended that the NRC adopt Appendix H.3, Section 2.0, Alternative 2 (rulemaking) to clarify the scope and level of detail for DC applications as well as extend those same changes to SDA applications. NuScale wrote in agreement with a letter sent to the NRC by the NEI on September 24, 2020, in which the NEI provided suggestions on the clarification of "essentially complete." NuScale agreed with the NEI's recommendations in the letter that the NRC should:

- Clarify the phrase "can affect safe operation" in order for the clarification of "essentially complete" to be meaningful;

- Separately and clearly define the level of detail needed for a DC application, which should be graded and considered distinct from the scope of design that must be described to satisfy “essentially complete”;
- Revise § 52.47 to acknowledge that design information can be substituted for design and programmatic controls; and
- Make conforming changes for SDA applicants under part 52, subpart E.

NuScale added that § 52.135(a) should be amended to replace “the entire facility” with “an essentially complete facility” so that an SDA application is not required to go beyond the design scope of the DC application. NuScale wrote that these additional clarifications could save applicants more than the 200 hours of work estimated by the NRC as well as increase clarity and certainty in the regulatory process.

NRC Response:

The NRC agrees, in part, with the comment. In this proposed rule, the NRC is providing a definition for the phrase “essentially complete nuclear power plant design” under § 52.1 to clarify what an “essentially complete nuclear power plant design” means without being too restrictive or prescriptive for the applicants to prepare their DC applications. The NRC disagrees with NuScale’s suggestion to amend § 52.135(a) to replace “the entire facility” with “an essentially complete facility.” The scope of the rulemaking action in the regulatory basis, Appendix H.3, Section 2.0, was to clarify the term “essentially complete design,” as used in several places throughout part 52. Specifically, NuScale’s request for the NRC to make “conforming changes” for SDA applicants under § 52.135(a) is outside the scope of the recommended rulemaking because there is no mention of “essentially complete” in § 52.135(a). The purpose of the language in § 52.135(a) is to convey that an SDA applicant has the flexibility to

choose how much of its final design (i.e., a portion of the design or the entire facility) should be reviewed and approved by the NRC. Accordingly, the Commission did not change the NRC staff's recommendation in the regulatory basis in response to this comment.

Modify Restrictions on Changes to a DC or COL Referencing a DC for Reasons of Standardization

The NRC is proposing to amend its regulations to remove the requirement to consider standardization as a criterion to justify requested changes in a standard design. Specifically, the NRC proposes to revise § 52.63(b)(1) to remove the requirement to discuss standardization as a criterion to justify making changes to a standard design through applicant or licensee exemption requests.

Recent new reactor licensing experience with VEGP 3&4 has shown that the requirement for maintaining standardization as a criterion for allowing requested changes is often burdensome to a licensee without significant benefit.

With regard to changes imposed by the NRC, § 52.63(a)(1) and (4) set out criteria that must be met before the Commission modifies, rescinds, or imposes new requirements on certified information by rulemaking or plant-specific order. Sections 52.63(a)(1)(vii) and (a)(4)(ii) contain the criterion that the Commission must determine that the change contributes to increased standardization of the certification information. This criterion, which applies to the Commission, would remain in the NRC's regulations. The NRC recognizes that standardization remains a policy goal of part 52 and is advanced by retaining standardization as a consideration for changes initiated by NRC rulemaking in § 52.63(a)(1) and for changes initiated by plant-specific NRC order under § 52.63(a)(4). More broadly, the regulatory structure and change processes in part 52 will continue to support the policy goal of standardization.

With regard to changes proposed by licensees and applicants, § 52.63(b)(1) permits an applicant or licensee that references a DC rule to ask for an exemption from one or more elements of the certification information. Because § 52.7, “Specific exemptions,” also requires the applicant or licensee and the NRC to consider whether special circumstances exist, experience has shown that for all cases, this criterion outweighs any decrease in safety that may result from the reduction in standardization caused by the requested exemption. Therefore, the NRC is proposing to delete the requirement to justify, and the NRC to review the impact of the requested exemption on standardization because it does not serve the underlying purpose of the rule.

Experience has shown that it is challenging for an applicant or the NRC to evaluate whether any one change proposed in an LAR would decrease safety solely as a result of a reduction in standardization. The NRC recognizes that increased standardization remains a policy goal of part 52, and requirements supporting that goal should be maintained when there is an appropriate benefit to doing so.

For similar reasons, the NRC also is proposing to revise current § 52.93(c) (redesignated as proposed § 52.93(d)) and § 52.171(b)(2) to remove the requirement to discuss the impact of the change on standardization as a criterion for the justification for departures from ML information.

The proposed changes to the NRC’s regulations that remove the requirement for applicants to justify requested changes to the design based on the changes’ effects on standardization could eliminate unnecessary burden on applicants and licensees. The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

The NRC concludes that the provision in § 52.63(a)(1)(vii) offers more flexibility, rather than restriction, to a vendor that wishes to request an amendment to its certified

design in that if a vendor wishes to make a generic change to its certified design because the proposed change would increase standardization, the provision in § 52.63(a)(1)(vii) would provide the regulatory vehicle to the vendor to request that amendment. The NRC also concludes that the provision in § 52.63(a)(4)(ii) promotes both design finality and standardization because the NRC must evaluate the effect on standardization before imposing a plant-specific order. On that basis, the NRC is not proposing to remove § 52.63(a)(1)(vii) and (a)(4)(ii) from the regulations.

Relocate Requirements from DC Appendices Section IV to § 52.79(d)

The NRC is proposing to move to § 52.79(d) the requirements in sections IV.A.1 and IV.A.2.a through f of appendices A, D, E, and F to part 52 with one exception. For appendices A, D, and F, the NRC is proposing to remove sections IV.A.1 and IV.A.2 and renumber sections IV.A.3 and IV.A.4 as sections IV.A.1 and IV.A.2. For appendix E, the NRC is proposing to remove sections IV.A.1 and IV.A.2.a through f and renumber section IV.A.2.g and h as section IV.A.1.a and b and sections IV.A.3 and IV.A.4 as sections IV.A.2 and IV.A.3. As discussed in section III.H.1 of this document, the NRC is proposing to remove and reserve the expired DC appendices B and C.

Section 52.79(d) gives the requirements for the contents of applications for COLs that reference a standard DC. Section IV for each DC appendix to part 52 provides additional requirements for and restrictions on COL applicants who incorporate by reference that specific DC appendix. When the first DC rules were issued, it was not clear whether the requirements in sections IV.A.1 and IV.A.2.a through f of the DC appendices should be applicable to all DCs. Therefore, the NRC included them within each individual DC rule.

This rulemaking would remove and reserve those sections of each DC appendix and move those COL application requirements to a single location in § 52.79(d).

Because the NRC expects that future DC rules will have these same requirements and restrictions, the purpose of the proposed changes is to simplify the requirements for an application for a COL by consolidating some application content requirements into § 52.79. This proposed rule change is not intended to change any requirements for COLs that reference a DC rule.

The exception to moving to § 52.79(d) the requirements in sections IV.A.1 and IV.A.2.a through f of appendices A, D, E, and F to part 52 is that the NRC would not move to § 52.79(d) the requirements in section IV.A.2.d of appendices A and D. Current section IV.A.2.d of appendices A and D is different than section IV.A.2.d of appendices E and F, and the NRC proposes to move only section IV.A.2.d of appendices E and F to § 52.79(d).

Section 52.79(d)(1) requires a COL application to provide information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the design certification. Similarly, under § 51.50(c)(2), if a COL environmental report references the environmental assessment prepared by the NRC for a referenced DC, then the COL environmental report must include information to demonstrate that the site characteristics for the COL site fall within the site parameters in the design certification environmental assessment. Under section IV.A.2.d of appendices A and D, a COL applicant referencing the DC is required to include in its application information demonstrating compliance with the site parameters and interface requirements.

The NRC recognized that the requirement in appendices A and D describe the use of site parameters and site characteristics slightly differently than in §§ 51.50(c)(2) and 52.79(d)(1). As a result, the NRC wrote section IV.A.2.d in appendices E and F to part 52 to be consistent with the language in §§ 51.50(c)(2) and 52.79(d)(1). Specifically, section IV.A.2.d of appendices E and F states that applications include

information demonstrating that the site characteristics fall within the site parameters and that the interface requirements have been met. However, this conforming change was not made to appendices A and D.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Design Certification Rule Section IX

The NRC is proposing to change the regulations in appendix D of part 52. Specifically, the NRC proposes to remove and reserve section IX, “Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC),” in this appendix. Section IX contains requirements for COL applicants that reference the appendix. In the 2007 part 52 rulemaking, the NRC amended §§ 52.99, “Inspection during construction; ITAAC schedules and notifications; NRC notices,” and 52.103, “Operation under a combined license.” As a result of that rulemaking, §§ 52.99(b), 52.99(c), 52.99(d)(1), 52.99(e)(2), 52.103(g), and 52.103(h) contain the same requirements as section IX with respect to successful ITAAC completion and NRC verification before loading fuel.

The NRC had previously identified during rulemaking for the Economic Simplified Boiling Water Reactor (ESBWR) DC (October 15, 2014), that section IX of that draft DC (i.e., part 52, appendix E) would be redundant to §§ 52.99 and 52.103. In that rulemaking, the NRC stated its intent to remove section IX from appendices A through D of part 52 in future amendments to the regulations, separate from the ESBWR rulemaking.

As part of the “Advanced Boiling Water Reactor (ABWR) Design Certification Renewal” direct final rule (July 1, 2021), section IX of that appendix was removed from appendix A and reserved. In this proposed rule, the NRC is proposing to remove and

reserve expired appendices B and C. The NRC's proposed change would remove the redundant requirements in section IX of appendix D.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI recommended that the NRC reduce or eliminate the reporting requirement in § 52.99(a), which requires submittal of ITAAC schedules every six months at first, and then monthly starting one year before fuel load. The NEI stated that this requirement does not provide any public health or safety benefit and that inspection planning activities provide more useful information to the NRC.

NRC Response:

The NRC agrees, in part, with the comment. Similar comments related to ITAAC completion schedules were provided and are detailed in the part 52 final rule comment summary report, dated July 2007. The development of § 52.99(a) was, in part, a result of those final rule comments. The NRC reiterates that timely information related to a licensee's plan for completing ITAAC remains critical to ensuring the NRC meets its obligations regarding the review and closure of ITAAC issues prior to the licensee's scheduled fuel load date. The NRC notes that licensee engagement with the NRC regarding inspection planning and associated activities is not a requirement. The submittals required by § 52.99(a) ensure that the NRC has sufficient information to plan all the oversight activities necessary for the NRC to support the Commission's determination as to whether all the ITAAC have been met prior to initial operation.

The NRC recognizes that the dynamics of nuclear plant construction have resulted in inconsistent ITAAC completion and closure progress in keeping with an

evolving construction schedule, resulting in a significant portion of ITAAC completion being projected to occur within the final six months of construction. The NRC acknowledges that the requirements of § 52.99(a) should be amended to reflect the reality of ITAAC schedule and completion in an evolving construction environment.

Accordingly, the NRC is proposing to revise § 52.99(a) in response to this comment. Specifically, the requirement for ITAAC completion reports, which must be submitted every 30 days when within one year of fuel load in the current rule, would be replaced with a requirement to report on ITAAC completion every 60 days when within 6 months of fuel load. The existing 6 month reporting requirement would apply for periods prior to 6 months before fuel load.

H.4. References to Standard Design Approvals

The NRC is proposing to amend regulations in §§ 52.73(a), 52.79(c), 52.133(a), and 52.153(b) to clarify that more than one SDA may be referenced by COL, CP, or ML applicants, provided each referenced SDA is for different portions of the same reactor design. Section 52.79(c)(3) is added to clarify that the COL FSAR must demonstrate that interface requirements in a referenced SDA are satisfied consistent with § 52.137(a)(24) and similar requirements for COLs referencing a DC or ML in § 52.79(d)(2) and § 52.79(e)(2). Section 52.79(c)(4) is added to require that, for a COL application that references more than one SDA, the FSAR must demonstrate that the interfaces between each of the referenced SDAs conform to the descriptions, analyses, and evaluations stated in each referenced standard FSAR. This includes clarifying § 52.133(a) to make it consistent with § 52.153(b) (i.e., an ML application may reference an SDA) and with the changes the NRC is proposing to make to § 52.145 (i.e., an operating license application may reference an SDA). The current regulations do not specify whether only one or more than one SDA may be referenced in COL, CP, or ML

applications, although it is implicit that more than one SDA could cover the final design of major portions of an entire facility. Changing the regulations accordingly would resolve any such ambiguity for COL, CP, or ML applicants who plan to reference more than one SDA if each referenced SDA is for different portions of the same reactor design. The proposed changes would allow an applicant to incorporate by reference multiple SDAs for major portions of the design, provided the referenced SDAs are complementary, compatible with corresponding interfaces, and for different portions of the same reactor design (e.g., performance characteristics, power level, design basis, engineering safety features, etc.). The proposed changes would not allow conflicting or superseding SDAs to be referenced, such as multiple revisions of the same reactor design, due to conflicting interface requirements. In addition, staff's findings on any complete SDA for the entire facility are based on a complete design and consider all of the features and aspects in an integral fashion; therefore, interface requirements for major portions would not have been previously reviewed or approved by the staff. Instead of an applicant referencing conflicting or superseding SDAs, an applicant would reference one SDA or multiple compatible SDAs for major portions of the same reactor design.

<u>Public Comments Related to This Item</u>

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

H.5. Content of Applications

<u>Modify Requirements to Evaluate Conformance with the Standard Review Plan</u>

The NRC is proposing to remove and reserve §§ 50.34(h), 52.17(a)(1)(xii), 52.47(a)(9), 52.79(a)(41), 52.137(a)(9), and 52.157(f)(30). The NRC is proposing to remove these requirements, which apply to applications for light-water cooled nuclear

power plants, that require an applicant to include an evaluation of conformance with the SRP in effect 6 months before docketing of an application. The requirements for applications for ESPs in § 52.17(a)(1)(xii) are not technology specific so the requirements are also applicable to non-light-water cooled nuclear power plants. The purposes of the SRP are to ensure the quality and uniformity of the NRC's review and to improve the public's understanding of the NRC review process. In the "Rule to Require Applicants to Evaluate Differences from the Standard Review Plan" (March 18, 1982), the Commission originally codified the requirement for an applicant to include an evaluation of conformance with the SRP in § 50.34 in order to add a regulation that would serve to help the NRC find where in the application the applicant is proposing alternatives to the SRP acceptance criteria, and how these alternatives comply with the regulations. This information was intended to lead to improved efficiency and effectiveness of the NRC safety reviews.

Recent experience with new reactor licensing highlighted the fact that applicants expend significant resources to evaluate the differences between their applications and the SRP. Such an extensive evaluation was not necessary because the information in the body of the application described how the applicant's proposal met the regulations. In accordance with § 50.34(h)(2), an applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations. However, unless the SRP is up to date and customized for the specific application, its use as a guide for reviewing some applications could impact the efficiency and effectiveness of the licensing process for those applicants as well as the NRC.

In addition, the NRC developed the SRP guidance based on the operating fleet of large LWRs. The most recent applications have been for small modular reactors for which the NRC has developed additional staff review guidance beyond the SRP. The NRC expects the near-term prospective LWR applications also to be for small modular reactor designs and, thus, the potential benefit of a comparison to the SRP is expected to be limited for such applications. The removal of this regulatory requirement could have an adverse effect on the efficiency of the NRC acceptance review as it relates to the NRC's ability to quickly find where the design departs from the SRP guidance. This could increase the time needed for the NRC to assess the adequacy of the submittal before the application is docketed. However, there is no evidence that the NRC review of the applicant's evaluation of the applications' conformance with the SRP provided a corresponding increase in NRC efficiency sufficient to justify the burden expended by applicants to comply with this requirement.

The NRC is also proposing to revise RG 1.206 and SRP Section 1.0 to reflect removal of the regulations. The NRC is proposing edits to five other SRP sections with this proposed rule, each of which reflects in a first page footer the proposed removal of the regulations. In addition, the NRC will revise the footer of other SRP sections to reflect the removal of the regulations as each SRP section is revised in the future.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Align Requirements for Timely Completion of Construction

The NRC is proposing to amend § 50.100, "Revocation, suspension, modification of licenses, permits, and approvals for cause," to address an inconsistency with § 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses," on timely completion of construction requirements. Section

50.55 states that each combined license is subject to the terms and conditions in paragraphs (e), (f), and (i) of that section. The timely completion of construction requirements are in § 50.55(b) and are not applicable to combined licenses. However, § 50.100 states, in part, that failure to make timely completion of the proposed construction or alteration of a facility under a CP under part 50 or a combined license under part 52 shall be governed by the provisions of § 50.55(b). Thus, with respect to combined licenses, § 50.100 is inconsistent with § 50.55 regarding the applicability of requirements of § 50.55(b), including timely completion of construction requirements. In addition, in the 2007 part 52 final rule, the Commission stated that the requirements related to timely completion of construction did not apply to the CP portion of combined licenses in light of an amendment to section 185 of the AEA that was made by section 2801 of the Energy Policy Act of 1992 (Pub. L. No. 102-486, 106 Stat. 3120). The Energy Policy Act retained the timely completion of construction requirements for CPs while establishing the ITAAC process for combined licenses. Therefore, the NRC is proposing to remove from § 50.100 the phrase about the applicability of provisions of § 50.55(b) to combined licenses.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Clarify Applicable Regulatory Parts for Certified Designs

The NRC is proposing to amend section V.A of the design certification rules in appendices D and E of part 52. This section lists the applicable regulatory parts for the reactor designs the NRC certified by rule in appendices D and E. Although part 52 includes technically relevant regulations applicable to the designs certified in appendices D and E, section V.A of these two design certification rules omitted inclusion of part 52 from the list of applicable regulations. Section V.A of appendix A includes part 52 in the

list of applicable regulations, so no change is proposed for appendix A. In this proposed rule, the NRC is proposing to remove and reserve the expired appendices B and C. Section V.A of appendix F includes part 52 in the list of applicable regulations. Including this reference in section V.A of appendices D and E would provide greater regulatory clarity and consistency between the design certification appendices in part 52.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Clarify the Requirements for Environmental Qualification Program for Manufacturing Licenses

The NRC is proposing to amend § 52.157(f)(6) to address an inconsistency with § 50.49(a). Section 50.49(a) requires a part 52 ML applicant to include a § 50.49(b) program for environmental qualification (EQ) of electric equipment in its final safety analysis report but § 52.157(f)(6) omits this requirement. In the 2007 part 52 final rule, the Commission revised § 50.49(a) to clarify that EQ programmatic requirements apply to COLs and MLs under part 52. The 2007 part 52 final rule also revised § 52.79(a)(10) to require a description of the program and its implementation, required by § 50.49(a), for the EQ of electric equipment important to safety, but a corresponding revision was not made to § 52.157(f)(6). Because MLs authorize the holder to procure certain electric equipment subject to § 50.49, the ML applicant should be required to have a verified § 50.49(b) EQ program like a COL applicant to ensure the equipment that can be procured will function as intended. Therefore, the NRC is proposing to amend § 52.157(f)(6) to require a description of a § 50.49(b) EQ program.

This item was not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

I. Environmental

The NRC is proposing to amend § 51.50(a), "Construction permit stage," to clarify that an applicant for a CP can incorporate by reference an environmental document prepared by the NRC staff for a different approval. This proposed change would make § 51.50(a) consistent with § 51.50(c), "Combined license stage," which affirmatively states that a COL applicant may reference in its environmental report information contained in a final environmental document prepared by the NRC (e.g., an EA in the case of an application referencing a DC). Current § 51.50(a) does not specify whether a CP applicant may reference such a document. Although § 51.50(a) does not explicitly forbid CP applicants from referencing final NRC environmental documents, the differing language raises the question of whether the NRC intended for different reference requirements to apply to CP and COL applicants. The proposed change would clarify the NRC's regulations. As an example, a CP applicant that references a DC would more clearly be able to incorporate by reference the DC EA, and the CP applicant would no longer have to prepare and submit a severe accident mitigation design alternative analysis identical to that presented in the DC EA.

The NRC is also proposing to expand § 51.50(a) to state the additional information applicants must provide when referencing previous environmental analyses in environmental reports for construction permits.

Public Comments Related to This Item

The NRC received two comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

The NEI agreed with the recommended rulemaking for § 51.50(a) and asked the NRC to consider also revising part 50 to allow CP applicants to reference previous environmental analyses that are available to COL applicants (e.g., ESP).

NRC Response:

The NRC agrees with the comment. The regulatory basis recommended changing § 51.50(a) to permit a CP applicant to reference an EA for a DC referenced in the CP application. The NRC agrees that CP applicants should have the same flexibility as COL applicants, who can reference the final EA of any NRC approval under § 51.50(c). Therefore, in response to this comment, the NRC revised § 51.50(a) to state that the environmental report for a CP application may incorporate by reference information contained in a final environmental document previously prepared by the NRC staff.

Comment Summary:

The NEI suggested two editorial corrections related to Appendix I of the regulatory basis: in the first sentence of Section 2.3.2.2, change the citation from "51.51(a)" to "51.50(a)," and in Section 2.4, change "an applicant" to "a CP applicant."

NRC Response:

The NRC agrees, in part, with the comment. The regulatory basis did incorrectly refer to "paragraph 51.51(a)" instead of "paragraph 51.50(a)" in the first sentence of Section 2.3.2.2 of Appendix I to the regulatory basis. However, the NRC is not re-issuing the regulatory basis, and the statements in question do not repeat in this proposed rule. As such, there is no opportunity or need to revise them. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

J. Applicability of Other Processes to the Part 52 Process

J.1. Definition of Contested Proceeding in § 2.4

The NRC is proposing to amend the definition of "contested proceeding" in § 2.4, "Definitions," to explicitly incorporate hearings on a licensee's compliance with the

acceptance criteria that are a part of the ITAAC included in a COL. Although an ITAAC hearing is expressly treated as a contested proceeding under some regulations (e.g., § 2.340 is titled, in part, "Initial decision in certain contested proceedings," and § 2.340(c) refers to initial decisions on findings in ITAAC hearings under § 52.103), the current definition of "contested proceeding" in § 2.4 does not include ITAAC hearings.

The NRC's regulations and ITAAC hearing procedures allow for two types of ITAAC hearings. Section 52.103(a) gives the public an opportunity to ask for a hearing on compliance with the acceptance criteria in the COL. Section 52.103(b) states that this hearing request must show, *prima facie*, that one or more of the acceptance criteria of the ITAAC have not been, or will not be, met and the specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of public health and safety. Additionally, the NRC's ITAAC hearing procedures allow a licensee to ask for a hearing to challenge an NRC staff determination that ITAAC have not been successfully completed. In either case—whether a hearing challenges if an acceptance criterion has or has not been met—ITAAC hearings are limited to the question of whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the combined license.

The proposed inclusion of ITAAC hearings within the § 2.4 definition of "contested hearing" would apply both to hearings under § 52.103(a) where the claim is that one or more acceptance criteria have not been met and to licensee-requested hearings under the NRC's ITAAC hearing procedures where the claim is to challenge an NRC staff determination that one or more acceptance criteria have not been met. Inclusion of these ITAAC hearings in the definition of "contested hearing" would provide

for greater consistency between regulations and limit potential ambiguity with respect to the applicable hearing processes.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

J.2. Maintenance of Records for COL Holders

The NRC is proposing to amend § 50.71(e)(3)(iii), which requires annual updates to the FSAR following the docketing of an application for a COL until the Commission finds that the acceptance criteria in the COL are met under § 52.103(g). Changes to § 50.71(e)(3)(iii) would make annual updates to an FSAR applicable to those COL applicants who are actively pursuing a COL and to COL holders actively pursuing construction. A COL applicant that has requested the NRC to suspend its review of the application or a COL holder that has notified the NRC that the COL holder is not pursuing construction would no longer be required to provide annual updates to the FSAR for new information or reevaluated conditions. Additionally, the proposed rule language in § 50.71(e)(3)(iii) would require COL applicants who request the NRC to resume its review of the COL application or COL holders who notify the NRC that they plan to commence or resume construction activities to submit an updated FSAR to the NRC within 90 days of submitting their requests or notifications, as applicable.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

J.3. Backfitting and Issue Finality

The NRC is proposing to amend § 50.109, "Backfitting," to clarify how backfitting and issue finality apply to NRC, applicant, or licensee actions that could affect SDAs, ESPs, and MLs. Certain provisions of § 50.109 address SDAs, ESPs, and MLs. Section § 52.145 contains issue finality regulations for SDAs. Section § 52.39, "Finality

of early site permit determinations," contains issue finality regulations for ESPs. Section § 52.171, "Finality of manufacturing licenses; information requests," contains issue finality regulations for MLs. These requirements overlap in some areas and create inconsistencies that may lead to confusion about the applicable criteria for making changes to SDAs, ESPs, and MLs. This proposed rule would correct these inconsistencies and provide clarity on the backfitting and issue finality requirements that govern changes to SDAs, ESPs, and MLs.

Specifically, the NRC is proposing to delete the sentence in § 50.109(a)(1)(vii) that states that, for a combined license referencing an SDA, § 52.145 applies to the design matters resolved in that SDA. The NRC proposes to remove this text because §§ 52.145 and 52.98 and the associated discussions in the preamble for the 2007 part 52 final rule do not support the application of § 52.145 to the design matters resolved in an SDA referenced in a COL. Issue finality under § 52.145 applies only when the NRC and ACRS are reviewing an individual facility license application incorporating an SDA. In the 2007 part 52 final rule preamble, the Commission stated the following:

> The Commission, Atomic Safety Licensing Board Panel, or presiding officers are not bound by NRC staff determinations in the [final design approval] or [final safety evaluation report] for the standard plant design. Therefore, there is no issue preclusion in the mandatory hearing for a combined license that references an SDA. Generic changes to the standard design can be made as a compliance backfit or under the backfit process in 10 CFR 50.109.

Because generic changes to an SDA are made under § 50.109, § 50.109(a)(1) includes design approvals within the definition of "backfitting" and § 50.109(a)(1)(iv) establishes the date when an SDA holder is included within the scope of the backfitting provisions of § 50.109.

In addition, the language in § 50.109(a)(1)(vii) that § 52.145 applies to the design matters resolved in that SDA conflicts with the finality requirements for COLs referencing

SDAs in § 52.98. That provision states, in relevant part, that after issuance of a COL, the Commission may not change any term or condition of the COL, the design of the facility, or the ITAAC that are not derived from a referenced standard design certification or manufacturing license. This point is reinforced by the Commission's preamble discussion for § 52.98 in the 2007 part 52 final rule: "The change processes in 10 CFR part 50 apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license." Thus, § 52.145 does not apply to an issued COL that references an SDA .

The NRC proposes to delete the sentence in § 50.109(a)(1)(vii) that states that, for a combined license referencing an ESP, § 52.39 applies to the site characteristics, design parameters, and terms and conditions specified in the ESP once the COL is issued. The NRC proposes to remove this text because it is incorrect. Section 52.26(d) explains that the ESP is subsumed, to the extent referenced by the COL, into the issued COL. Therefore, an ESP is no longer operative once the COL is issued, so § 52.39 cannot apply to an issued COL that references an ESP.

The NRC also proposes to remove the words "or manufacturing license" from the definition of "backfitting" in § 50.109(a)(1) and to remove and reserve § 50.109(a)(1)(v), which establishes the date when an ML holder is included within the scope of the backfitting provisions of § 50.109. These changes would remove MLs from the scope of backfitting. As a result, changes to MLs would be governed by the provisions in § 52.171. This result would be consistent with the sentence in § 50.109(a)(1)(vii) concerning COLs that use a reactor manufactured under an ML and with § 52.98(a) and (d), because the sentence in § 50.109(a)(1)(vii), like § 52.98(d), explains that § 52.171 is the controlling provision for changes to MLs that are referenced by a COL. Furthermore, § 50.109(a)(1) currently reads that CP and OL applicants that reference MLs are within

the scope of the backfitting provisions, but this conflicts with § 52.171(a)(3), which provides issue finality for CPs and OLs that reference MLs. Removing the words “or manufacturing license” from the definition of “backfitting” in § 50.109(a)(1) and deleting § 50.109(a)(1)(v) would eliminate these inconsistencies.

To ensure consistency between the application of § 50.109 to NRC actions that could affect CP, OL, and COL holders that reference DCs and MLs, the NRC is also proposing to clarify that, for a CP or OL holder that references a DC or an ML, the backfitting provisions in § 50.109 generally do not apply to changes to the referenced DC or ML. This clarification would be accomplished by amending § 50.109(a)(1)(i) for CP holders and § 50.109(a)(1)(iii) for OL holders to include language identical to that found in § 50.109(a)(1)(vii) for COLs that reference a DC or an ML. This language explains that § 52.63 generally applies with respect to the design matters resolved in the referenced DC and § 52.171 applies with respect to matters resolved in the referenced ML.

The NRC also proposes to amend § 52.171 because § 52.171(a)(1) is unclear as to the applicability of that provision to Commission-imposed plant-specific and generic changes to an ML. Section 52.171(a)(1) restricts the ability of the Commission to impose changes to the design of the reactor “being manufactured.” However, in the preamble for the 2007 part 52 final rule, the Commission explained that this restriction also applies in license proceedings that reference the use of the “manufactured license,” enforcement proceedings, and rulemakings that propose to apply new or changed requirements to reactors that have already been manufactured. The NRC proposes to amend § 52.171 to clarify that the restriction on making changes would apply to the design of a nuclear power reactor manufactured or being manufactured under an ML

and the requirements for the manufacture of a nuclear power reactor manufactured or being manufactured under an ML.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

NuScale recommended that the NRC adopt the rulemaking alternative in its regulatory basis to clarify the backfitting and issue finality provisions, with some changes. NuScale suggested clarifying the regulatory issue as it relates to SDAs, stating that under the current rules, the parts of a COL that derive from an SDA are afforded less finality than the parts that do not, meaning a custom COL that does not reference an SDA would have backfit protection for its full scope under § 50.109, while one that does reference an SDA would not have backfit protection for the scope of design that derives from the SDA. NuScale agreed that deleting the sentence in § 50.109(a)(1)(vii) regarding how § 52.145 applies to a COL referencing an SDA would resolve this issue.

NuScale also agreed with deleting § 50.109(a)(1)(v), saying it seems to conflict with § 52.171 in a way that could decrease the level of finality associated with an ML. However, NuScale did not agree with deleting the sentence in § 50.109(a)(1)(vii) regarding how § 52.171 applies to a COL using a reactor manufactured under an ML. NuScale stated that the revised text could be misinterpreted as meaning that the only backfit provisions applicable to a COL using a reactor manufactured under an ML were the remaining portions of § 50.109 because the “stronger” backfit protections of § 52.171 would no longer apply. NuScale suggested instead making a conforming change to § 52.171 to clarify that § 52.171(a)(1) is not limited to the term of the ML or the reactor

while being manufactured but rather applies for the term of the operating license to the operating reactor that was originally licensed and manufactured under an ML.

NRC Response:

The NRC agrees, in part, with the comment. The NRC agrees that it should propose to delete the sentence in § 50.109(a)(1)(vii) that states that, for a combined license referencing an SDA, § 52.145 applies to the design matters resolved in that SDA. However, the NRC finds that the background information provided in the regulatory basis adequately justifies this proposed change. Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

The NRC agrees that removing the sentence in § 50.109(a)(1)(vii) regarding a COL using a reactor manufactured under an ML would create an unintended result. The removal of the sentence would create a conflict between § 50.109 and § 52.98(a) and 52.98(d) regarding finality for a COL. Removal of the sentence could be read to mean that a COL referencing an ML would be subject to § 50.109, whereas § 52.98(a) and (d) state that a COL referencing an ML is subject to the issue finality provisions in § 52.171. So, the NRC is not removing that sentence. However, the NRC is proposing other edits to § 50.109 to remove MLs from the scope of backfitting so that § 52.171 is the controlling provision for changes to MLs. As a result of this comment, the Commission did not delete the sentence in § 50.109(a)(1)(vii) that, for a combined license referencing an ML, § 52.171 applies with respect to matters resolved in the referenced ML.

The NRC agrees that § 52.171(a)(1) needs clarification regarding the restriction on the Commission to modify reactors manufactured under an ML. Accordingly, the NRC is proposing changes to § 52.171(a)(1) as a result of this comment.

J.4. Remove and Reserve Subpart E of Part 2

The NRC is proposing to delete the content of subpart E of part 2 (i.e., §§ 2.500, “Scope of subpart,” and 2.501, “Notice of hearing on application under subpart F of 10 CFR part 52 for a license to manufacture nuclear power reactors”) and keep subpart E as reserved. This change corrects an error in the 2007 part 52 rule in which the Commission’s decision not to hold mandatory hearings for MLs is not fully reflected in the NRC’s regulations.

There are two types of basic hearing-related notices for license applications under part 2. Section 2.104 requires a “notice of hearing” and governs applications for which a hearing is required by the AEA, NRC regulations, or Commission discretion. This section governs, among other licenses and permits, COLs, CPs, and ESPs, for which a mandatory hearing is required. Section 2.105 requires a “notice of proposed action” and governs applications for which an opportunity to ask for a hearing is provided but there is no mandatory hearing, such as OLs and reactor license amendments.

In the 2006 proposed revisions to part 52 (March 13, 2006), the Commission proposed requiring a mandatory hearing for MLs as a matter of discretion. The proposed rule contained provisions for the mandatory hearing in § 2.104(f), and proposed § 52.163 stated that a notice of hearing under § 2.104 would be issued. In the 2007 part 52 final rule, however, the Commission explicitly decided not to hold a mandatory hearing for ML applications. The final rule did not include a notice of hearing provision in § 2.104 for MLs. Instead, § 2.105(a)(13) was added so that a notice of proposed action would be issued for MLs. Also, § 52.163 was revised to refer to a notice of proposed action under § 2.105. However, the changes to § 2.501 that were in the proposed rule were erroneously repeated in the final rule. Thus, § 2.501 currently states that a notice of hearing will be issued for an ML application and references § 2.104(f) for the contents of that notice. But § 2.104(f) does not exist, and § 2.501 is

otherwise contrary to the explicit decision the Commission made in the 2007 part 52 final rule, as well as to current §§ 2.105 and 52.163. Finally, with the removal of § 2.501, § 2.500 becomes unnecessary since its purpose is to describe the scope of subpart E, and, therefore, it also should be removed.

This item was not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

*J.5.	Amend Section VIII.C.5 of the Design Certification Rules Addressing Contention Requirements for Certain Challenges to Operational Requirements*

The NRC is proposing to amend section VIII.C.5 of the design certification rules in appendices A, D, E, and F of part 52. Among other things, this section sets out the requirements that apply to a petition to admit a contention in an adjudicatory proceeding for the issuance, amendment, or renewal of a license, or for operation under § 52.103(a), asserting that an operational requirement approved in the DCD or a technical specification (TS) derived from the generic TS must be changed. The second sentence of section VIII.C.5 provides that such a petition must comply with the general requirements of § 2.309, “Hearing requests, petitions to intervene, requirements for standing, and contentions.” and also must demonstrate either that special circumstances as defined in § 2.335. “Consideration of Commission rules and regulations in adjudicatory proceedings,” are present or that the change sought by the petitioner is necessary for compliance with the NRC regulations in effect at the time the design certification rulemaking was approved. However, the current language in this sentence omits several words, leading to a lack of clarity on the nature of the requirement on showing compliance with NRC regulations in effect at the time the design certification rulemaking was approved. Revising this section to clearly set out the requirements that apply to a petition seeking to admit a contention that an operational requirement

approved in the DCD or a TS derived from the generic TS must be changed will improve the regulatory clarity of section VIII.C.5 of the design certification appendices.

This item was not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

K. Miscellaneous Topics

K.1. Notice of Issuance in § 2.106(b)(2)(ii)

The NRC is proposing to amend § 2.106(b)(2)(ii) to clarify what information is required to be included in a notice of issuance in the case of a finding under § 52.103(g) that the acceptance criteria in the ITAAC for a COL are met. The language of § 52.103(g) states that the licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under § 52.97(a)(2). Section 2.106(b)(2)(ii), however, requires a notice of issuance of a § 52.103(g) finding to include additional information beyond the scope of the finding required by § 52.103(g)—specifically, a finding that the license complies with the requirements of the AEA and NRC regulations. However, that finding was already made upon issuance of the COL and need not be made again during the § 52.103(g) ITAAC verification process. Thus, the inclusion in the notice of a finding that the license complies with the requirements of the AEA and the entirety of the NRC's regulations is not only unnecessary but also could be misinterpreted to require the NRC to make additional findings beyond those required by § 52.103(g).

The proper information to be included in a notice of issuance under § 2.106(b)(2) should be determined by the scope of § 52.103(g). Removing from § 2.106(b)(2)(ii) the language that goes beyond the scope of the finding required under § 52.103(g) would

provide regulatory clarity and consistency between these two regulations and may avoid confusion on the scope of the ITAAC hearing process.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.2. Definitions in § 21.3

The NRC proposes to amend the definitions of certain terms.

The regulations in part 21 apply to individuals, corporations, partnerships, or other entities that supply basic components for a facility or activity licensed under NRC regulations. The regulations also apply to the director or responsible officer of such an organization. As defined by § 21.3, a basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design, design certification, design approval, or information in support of CPs issued under part 50 and ESPs, COLs, and MLs issued under part 52, whether these services are done by the component supplier or others. The regulations in § 21.3 define the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” for applicability in part 21 and other parts of the regulations. However, unlike other definitions in this section that apply to part 52 licensees, these terms do not explicitly state their applicability to part 52 licensees. Relatedly, § 50.55 contains conditions of CPs, ESPs, COLs, and MLs, and § 50.55(e)(1), “Definitions,” states that, for purposes of § 50.55(e), the definitions in § 21.3 apply.

During the revision of part 21 to address the applicability of part 21 to part 52 licensees in the 2007 part 52 final rule, the NRC unintentionally omitted “10 CFR part 52,” from the definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” in § 21.3. This omission created inconsistencies

with other definitions in § 21.3 that apply to part 52 licensees. The inconsistencies may result in confusion and expenditure of unnecessary resources to address the applicability of these terms for an ESP, a COL, and an ML.

The NRC proposes to amend the regulations in § 21.3 to add part 52 to the definitions of "Commercial grade item," "Critical characteristics," "Dedicating entity," and "Dedication." These amendments would address the inconsistencies in the regulations by clearly identifying the applicability of the terms to part 52 licensees. These amendments would reduce confusion and resources expended to address the existing inconsistencies in the regulations, including § 50.55, which references these definitions in § 21.3.

The NRC does not plan to develop new regulatory guidance as part of the actions for resolving the issue. The 2018 issuance of RG 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under Part 21," endorses the NEI document NEI 14-09, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance." A section in NEI 14-09 entitled "Clarification of Dedication for Part 52" states as follows:

> Although 10 CFR 21.3 does not explicitly identify the manner in which to define "dedication" for nuclear power plants licensed under 10 CFR part 52, the definition should be interpreted and implemented as defined for nuclear power plants licensed under 10 CFR part 50. Thus for 10 CFR part 52 COL applicants or COL holders, "dedication" is interpreted and implemented as the term is defined in 10 CFR 21.3. Similarly, the definitions of commercial grade item, critical characteristics, and dedicating entity should be interpreted and implemented for part 52 nuclear power plants as they are defined in 10 CFR 21.3 for 10 CFR part 50 reactor licensees.

Thus, the revised regulations would be aligned with the existing guidance in RG 1.234 and NEI 14-09.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.3. Requirement for a Safety Parameter Display System Console in § 50.34(f)(2)(iv)

The NRC proposes to amend § 50.34(f)(2)(iv) to remove the requirement for a stand-alone console to display important plant parameters and trends.

After the 1979 accident at TMI, Unit 2, the NRC issued NUREG-0660, Volume 1, "NRC Action Plan Developed as a Result of the TMI-2 Accident." Action Item I.D.2 in this NUREG called for operating reactors and plants under construction to have a plant safety parameter display console. To conform to the Action Plan, licensees operating facilities subject to the Action Plan retrofitted their existing control rooms with a stand-alone, console-based, safety parameter display system. Subsequently, the NRC amended its regulations to include Action Item I.D.2 as § 50.34(f)(2)(iv). The purpose of the safety parameter display system is to present information to operators that they can use to determine the safety status of a nuclear power plant during normal, abnormal, and emergency conditions, including severe accidents, and to determine whether conditions warrant corrective actions to avoid or mitigate a degraded core. The system must be capable of displaying a full range of important plant parameters and data trends on demand and indicating when process limits are being approached or exceeded.

Considering advances in human-system interface technology that have resulted in effective alternatives to stand-alone consoles for displaying important plant parameters and trends (e.g., integrated digital displays), the NRC proposes to amend § 50.34(f)(2)(iv) to require the display of such parameters instead of requiring a stand-alone "console" to perform this function. Revising the regulation to remove the term "console" would better convey that the purpose of the safety parameter display console requirements is functional and not necessarily focused on whether there is a dedicated

console. Multiple DC applicants have previously requested and been granted exemptions from the console requirement, and the APR1400 DC proceeding (May 22, 2019) was the first application review—outside the context of an exemption request—in which the NRC found a safety parameter display system design without a stand-alone console to be acceptable.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

NuScale supported rulemaking to resolve ambiguity around the requirement for a “console,” adding that that this change could be addressed as part of the “complete and holistic” review of the TMI requirements it recommended elsewhere in its comments.

NRC Response:

The NRC agrees, in part, with the comment. The comment supports the rulemaking and suggests no changes to the staff’s recommendations. However, as discussed in Section III.C. of this document, the NRC proposes to make additional changes to the regulations related to the TMI requirements but not as NuScale recommends. Accordingly, the Commission did not change the NRC staff’s recommendations in the regulatory basis in response to this comment.

K.4. Requirements for Reporting Errors and Changes in Emergency Core Cooling System Models

The NRC proposes to amend § 50.46(a)(3)(i) and (iii) to relax certain reporting requirements related to those SDAs and DCs that are not referenced in any application for the construction or operation of a reactor. The specific reporting requirements are in § 50.46, “Acceptance criteria for emergency core cooling systems for light-water nuclear

power reactors." They address changes and errors affecting emergency core cooling system evaluation models associated with the SDA or DC.

Currently, § 50.46(a)(3)(i) requires applicants for or holders of SDAs and applicants for DCs (including an applicant after the Commission has adopted a final DC rule), among others, to estimate the impacts of changes and errors associated with an acceptable emergency core cooling system evaluation model to determine if the change is significant. A significant change or error is defined in § 50.46(a)(3)(i) as a change or error, or cumulation of changes and errors, that results in the peak cladding temperature for the limiting transient differing by more than 50°F from the last acceptable model. In addition, § 50.46(a)(3)(iii) requires that applicants or holders of SDAs and applicants for DCs report, at least annually, the nature of each change or error to an acceptable evaluation model and its estimated effect on the limiting emergency core cooling system analysis. The report must be provided to both the Commission and any applicant or licensee referencing the SDA or DC. Section 50.46(a)(3)(iii) requires that reports of significant changes or errors be provided within 30 days and include a proposed schedule for reanalysis or other actions necessary to show compliance with requirements in § 50.46. Section 50.46(a)(3)(iii) also requires that, as necessary, affected applicants or holders propose immediate steps to demonstrate compliance or bring the plant design into compliance with requirements in § 50.46.

Under § 50.46(a)(3)(iii), applicants for or holders of SDAs and applicants for DCs are required to report changes and errors to the emergency core cooling system evaluation model before an applicant for the construction or operation of a reactor has submitted to the NRC an application that references the SDA or DC. Reporting such changes and errors to the NRC before the design is referenced in an application for a CP, an OL, a COL, or an ML does not produce a tangible public health and safety

benefit, provided that the changes or errors do not create the potential for the SDA or DC to become noncompliant with NRC requirements. There is no public health and safety benefit because the change or error does not impact the operation of an operating reactor or even the NRC's safety review of an application. The NRC proposes to eliminate reporting requirements for changes or errors that do not result in an inability to assure compliance with § 50.46 until an SDA or a DC is referenced in an application for a CP, OL, COL, or ML. Instead of the applicant for or holder of an SDA or applicant for a DC reporting this information to the NRC, the CP, OL, COL, or ML applicant would be responsible for providing an acceptable analysis of the emergency core cooling system in its application submitted to the NRC. That is the point in time when the changes or errors become relevant to public health and safety and would receive due consideration. Consistent with § 50.46(a)(3)(ii), the CP, OL, COL, or ML applicant could, for example, include in its application a description of the nature of the changes or errors in the emergency core cooling system evaluation model along with an estimate of their impact on the original analysis, or provide a reanalysis using an updated evaluation model that directly incorporates the changes or error corrections.

The NRC also would eliminate the requirement in § 50.46(a)(3)(iii) for applicants or holders of SDAs and applicants for DCs to report changes or errors to a licensee referencing the SDA or DC. However, under § 50.46(a)(3)(ii), the holder of the CP, OL, COL, or ML retains responsibility for reporting and addressing changes and errors associated with the emergency core cooling system evaluation model for its licensed facility. This responsibility begins at the time of initial application and continues for the duration of the approved license. The requirements in § 50.46(a)(3)(ii) generally parallel those in current § 50.46(a)(3)(iii), addressing in a similar manner the reporting of changes and errors, reanalysis schedules, and, if necessary, required actions to restore

compliance with requirements in § 50.46(b). Although communication from applicants for or holders of SDAs and applicants for DCs may support licensees referencing the associated reactor designs in complying with reporting requirements in § 50.46(a)(3), elimination of explicit requirements concerning information transfer between these parties is justified based upon ample experience with the efficacy of change and error reporting for operating reactors. Operating reactor licensees, whose emergency core cooling system evaluation models are typically maintained by third-party fuel vendors, are responsible for satisfying reporting requirements in § 50.46(a)(3) without explicit requirements in § 50.46 concerning the transfer of information from fuel vendors to operating reactor licensees.

Proposed § 50.46(a)(3)(iii) still would require SDA holders and applicants and DC applicants to internally document the nature and estimated effect of all changes and errors affecting emergency core cooling system evaluation models. This documentation would be subject to NRC inspection. Also, if the cumulative effect of changes or errors results in an inability to ensure compliance with § 50.46(b), then proposed § 50.46(a)(3)(iii) would continue to require NRC notification of the underlying changes or errors and associated corrective actions so that the NRC may evaluate the potential for impacts to the affected SDA or DC. The NRC also would move from § 50.46(a)(3)(i) to § 50.46(a)(3)(iii) the requirement that applicants for or holders of SDAs and applicants for DCs estimate the impacts of changes and errors associated with an acceptable emergency core cooling system evaluation model to determine if the change is significant.

The proposed revision of these reporting requirements would not relieve applicants for or holders of SDAs or applicants for DCs of their responsibilities under § 52.6 to provide complete and accurate information to the NRC or to notify the Commission of

information identified by the applicant as having a significant implication for public health and safety or common defense and security. Moreover, the quality assurance requirements for nuclear power plants specified in appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to part 50 remain applicable to both SDAs and DCs and require, among other things, prompt corrective actions to address conditions adverse to quality.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.5. Notification to the NRC of Significant Information

The NRC is proposing to amend § 52.6(b), which requires each license applicant or licensee under part 52, each applicant for or holder of a part 52 SDA, and each applicant for a part 52 DC following Commission adoption of a final DC regulation to notify the Commission of information having a significant implication for public health and safety or common defense and security. Currently, this notification must be made to the Administrator of the appropriate Regional Office within 2 working days of finding the information. The Regional Administrator, however, is not involved in the issuance of either SDAs or DCs, nor is the Regional Administrator responsible for the receipt or review of applications for part 52 permits, certifications, or licenses. Therefore, there may be a delay in assessing and acting upon the information because the cognizant and responsible organization for these applications and approvals has not been notified. As described in § 1.43(a), the Office of Nuclear Reactor Regulation is responsible for developing, issuing, and implementing regulations, policies, programs, and procedures for all aspects of licensing, inspection, and safeguarding of manufacturing, production, or utilization facilities. Therefore, the NRC is proposing to replace the requirement in

§ 52.6(b) to notify the Regional Administrator with a requirement to notify the Director of the Office of the Nuclear Reactor Regulation.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.6. Discontinue Use of Priority Ranking Model for Generic Issues

Section 52.47(a)(21) requires an applicant for a DC to include in its application the technical resolution of the relevant unresolved safety issues (USI) and medium- and high-priority generic safety issues (GSI) identified in the version of NUREG-0933, "Resolution of Generic Safety Issues," that is current on the date up to 6 months before the docket date of the application. Similarly, § 52.79(a)(20) requires the same information in the FSAR for COL applicants, § 52.137(a)(21) requires the same information from an applicant for an SDA, and § 52.157(f)(28) requires the same information from an applicant for an ML.

For the convenience of the applicants and licensees, the NRC maintains NUREG-0933 on its website at https://www.nrc.gov/sr0933/index.html. This NUREG contains a summary of the results of the NRC's evaluation of GSIs. The NRC routinely updates the version of NUREG-0933. The web-based NUREG-0933 is a suitable reference for applicants and licensees to use for their submittals to the NRC. Appendix B of NUREG-0933 contains a list of the GSIs that apply to operating and future reactor plants, including issues that have been resolved with requirements and issues that are in progress for resolution. The priority designations for all issues are consistent with those listed in Table II of the Introduction to NUREG-0933.

On July 21, 1999, the NRC revised Management Directive 6.4, "Generic Issues Program," to no longer direct NRC staff to prioritize GSIs as "high," "medium," "low," or "drop." Instead, the NRC started to use a risk-informed method to identify significant

GSIs. The revised screening process directed the NRC staff to identify an issue as a true Generic Issue (GI) or reject it from the program. Hence, for the purposes of §§ 52.47(a)(21), 52.79(a)(20), 52.137(a)(21), and 52.157(f)(28), any GI that passes the revised screening and assessment process is considered equivalent to a "high-priority" GI.

The screening and assessment processes use an evaluation of risk to screen out issues that would not have a significant impact on facilities. The screening criteria are based on the same technical basis that is used for determining whether the risk associated with a specific facility design change is acceptable. For specific facility changes, the NRC uses risk criteria illustrated in Figure 4 of RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." Licensees use these criteria to determine whether a proposed facility change has too high of a risk to be carried out. Similarly, the NRC uses these same criteria to determine whether an issue is significant enough to be considered a GI. If the NRC determines that an issue has a significant risk impact on facilities, then the NRC identifies it as a GI in the GI Program and adds it to NUREG-0933 for applicants to consider in their license applications.

The NRC proposes to amend §§ 52.47(a)(21), 52.79(a)(20), 52.137(a)(21), and 52.157(f)(28) to reflect that the NRC has discontinued the use of the priority ranking model to identify significant generic issues and instead uses a risk-informed method to identify significant GIs that an applicant should address in its submittal to the NRC. Specifically, the NRC would require an applicant for a DC, a COL, an SDA, or an ML to propose technical resolutions of all generic issues identified since July 21, 1999; unresolved safety issues; and medium- and high-priority generic safety issues identified before July 21, 1999, that are relevant to the applicant's design. The identification of

these issues would be based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application.

Public Comments Related to This Item

The NRC received one comment on this item as it was discussed in the regulatory basis associated with this proposed rule.

Comment Summary:

NuScale generally agreed with the rulemaking alternative but wrote that new guidance for applicants and licensees is needed to implement it. NuScale stated that part 52 applicants cannot risk-inform the resolution of GSIs using RG 1.174 because either the applicant's PRA would be deemed technically inadequate, or the applicant would need to justify significant departures from RG 1.174. NuScale said that part 52 applicants should not need to satisfy the expectations of RG 1.174 because risk information in a part 52 application is used to allow the NRC to conclude there is a reasonable assurance of adequate protection, not to make changes to a previously approved design or licensing basis.

NRC Response:

The NRC disagrees with the comment. The referenced risk-informed review of potential GIs is performed by the NRC staff, not by applicants or licensees, so new or revised guidance for applicants and licensees would not be necessary to implement the proposed changes. The NRC finds that RG 1.174 provides sufficient information about a risk-informed decision-making framework for applicants to address applications beyond licensing basis changes, including the disposition of USIs, GSIs, and GIs in their applications.

Regulatory Guide 1.174 provides an adequate framework through five principles for undertaking risk-informed decision making. Among the five principles is one for the

user to ensure any increase in risk is small. If the applicant cannot disposition the GI by considerations in design or construction, then the applicant may show that the risk increase associated with the issue is small. In addition to probabilistic methods, the applicant can use elements of risk assessment such as the initiating frequency or the potential consequences of the issue to evaluate the risk impact.

The NRC does not rely on PRA information alone to make adequate protection findings. The NRC's evaluation of whether and how adequate protection is assured is not based on PRA or other risk information so much as it is focused through the consideration of risk.

Accordingly, the Commission did not change the NRC staff's recommendations in the regulatory basis in response to this comment.

K.7. Status of ITAAC Completion

The NRC proposes to change § 52.97(a)(2). This paragraph states that the Commission may find, at the time it issues a COL, that certain acceptance criteria in one or more of the ITAAC in a referenced ESP or standard DC "have been" met. The proposed change will revise the language in § 52.97(a)(2) from "have been met" to "are met." This change is needed to be consistent with the requirements in section 185b. of the AEA and § 52.103(g), which state that the acceptance criteria in the COL "are met." Section 185b. of the AEA requires the Commission to make a finding that the acceptance criteria in a COL "are met" before a licensee can commence operation of its facility. Similarly, the regulation in § 52.103(g) requires, in part, that the licensee may not operates the facility until the Commission makes a finding that the acceptance criteria in the COL "are met." The proposed change to § 52.97(a)(2) would eliminate ambiguity in the context of acceptance criteria that were met at some earlier time during

the construction phase, where the criteria may not have been maintained, and are no longer met at the time of the § 52.97(a)(2) finding.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.8. Reporting Requirements at Completion of Power Ascension Testing – Start of Assessment of Annual Fees

The NRC proposes to add § 50.71(i) to require that all future part 50 power reactor licensees and part 52 COL holders promptly notify the NRC of the successful completion of power ascension testing.

On June 19, 2020, the NRC published in the *Federal Register* the final rule "Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020," which, among other things, modified the timing of the start of assessment of annual fees for holders of an OL issued under part 50 and holders of COLs issued under part 52. Specifically, the final rule amended § 171.15(a) to state that the NRC starts to assess annual fees for a part 50 power reactor licensee and a part 52 COL holder beginning on the date when the licensee or COL holder provides notification to the NRC that the power ascension testing has been completed. Part 171, "Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC," does not contain any notification or reporting requirements. Also, parts 50 and 52 do not contain any provisions requiring licensees to notify the NRC of the completion of power ascension testing. Only current part 52 COLs contain a standard license condition that requires written notification to be submitted to the NRC upon successful completion of power ascension testing. The NRC is proposing to add § 50.71(i) to require all future part 50 power reactor licensees and part 52 COL holders

to notify the NRC of the completion of power ascension testing. This would ensure that the licensee promptly submits a notification of successful completion of power ascension testing so the NRC can begin assessing part 171 fees.

The NRC did not receive any public comments on this item as it was discussed in the regulatory basis associated with this proposed rule.

K.9. Conditions of Licenses

The NRC proposes to amend § 50.54, “Conditions of licenses,” to clarify the applicability of conditions of operating licenses for non-power production and utilization facilities. In the 2007 part 52 final rule, the NRC amended its regulations to clarify the applicability of and relationship between various requirements in parts 50 and 52 for nuclear power plants. Section 50.54 sets forth various provisions that are deemed to be conditions in every operating or combined license issued for nuclear power plants as well as production and utilization facilities other than nuclear power plants. As part of the 2007 part 52 final rule, the NRC revised the introductory text of § 50.54 to explicitly refer to operating licenses and combined licenses for nuclear power plants, and to indicate which provisions are applicable only after the Commission makes its finding under § 52.103(g). However, by only referring to nuclear power reactor licenses, this revision to the introductory text introduced uncertainty in the applicability of certain paragraphs of § 50.54 to production and utilization facilities other than nuclear power plants. This proposed rule would amend the NRC’s regulations to ensure applicants and licensees clearly understand which provisions of § 50.54 apply to non-power production and utilization facilities.

The NRC proposes to amend the introductory text of § 50.54 to clarify that those paragraphs not explicitly limited in their applicability to nuclear power plants are applicable to non-power production and utilization facilities.

The NRC proposes to amend §§ 50.54(j), (k), and (m)(1) to clarify that the requirements of part 55 apply to all utilization facilities.

The NRC proposes to amend §§ 50.54(n), (s)(2)(ii), and (ee)(1) to clarify the applicability of the current generic language to all production and utilization facilities, including nuclear power plants and non-power production and utilization facilities.

The NRC proposes to amend § 50.54(z) to clarify that the requirements of § 50.72 apply only to nuclear power reactors. These proposed changes to § 50.54 were not discussed in the regulatory basis. Therefore, the NRC has not previously received any public comments on this item.

IV. Specific Requests for Comments

The NRC is seeking advice and recommendations from the public on this proposed rule. We are particularly interested in comments and supporting rationale from the public on the following:

Considerations for Human Factors Principles in Design

Section 50.34(f)(2)(iii) requires that applicants subject to § 50.34(f) provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication of control room panels and layouts. The NRC anticipates that future applications submitted under part 50 may include applications pertaining to advanced reactor designs, some of which may not include a main control room (MCR) or may rely on the performance of important human actions at locations outside the MCR. For such applications, the requirement may be overly prescriptive and may not assure that locations from which important human actions are performed reflect state-of-the-art human factor principles.

The NRC also notes that § 50.34(f)(2)(iii) requires that the applicant submit a design prior to committing to fabrication or modification of control room panels and layouts. This requirement may, in some cases, be overly prescriptive and unnecessary. As written, this requirement precludes an applicant proceeding at risk that the NRC might not approve the application or modification. However, this requirement may not be necessary because the NRC reviews the application prior to implementation. This review occurs regardless of when the applicant commits to fabrication of the panels. For applications pertaining to the revision of panels and layouts (e.g., control room modifications), § 50.59 provides assurance of appropriate regulatory review for such instances.

For these reasons, the NRC is considering amending § 50.34(f)(2)(iii) to require applicants to submit a facility design that reflects state-of-the-art human factors principles for safe and reliable performance in all locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions. The NRC is seeking comment on whether and how the NRC should amend § 50.34(f)(2)(iii). Please provide a basis with your response.

Content of Application Requirements for CP and ML Applicants Referencing an SDA

Section 52.79(c) provides content of application requirements for COL applicants referencing an SDA. The NRC is considering amending § 50.34 and § 52.157 to provide content of application requirements for CP and ML applicants that reference an SDA to be consistent with the requirements provided in § 52.79(c). The NRC is seeking comment on whether and how the NRC should amend § 50.34 and § 52.157. Please provide a basis with your response.

Application for Renewal and Criteria for Renewal Requirements for MLs

Sections 52.177 and 52.179 provide application for renewal and criteria for renewal requirements for MLs, respectively. The proposed rule would extend the maximum duration of new and renewed MLs to 40 years. The NRC received comments on the regulatory basis to eliminate the duration and renewal requirements for MLs. Because the AEA requires licenses to have a duration, the NRC is retaining the ML renewal requirements. The NRC is seeking comment on whether and how the NRC should amend §§ 52.177 and 52.179. Please provide a basis with your response.

Escorting Requirements

Individuals at reactor construction sites and FFD personnel who require the types of access or perform any of the activities described in § 26.4(e), (f), and (g) must be subject to an FFD program. The proposed rule would revise § 26.4(f) to allow any individual who is constructing or directing the construction of safety- or security-related SSCs to be escorted instead of subjecting the individual to an FFD program. The proposed rule would add a requirement in § 26.4(e) that the escort be subject to all FFD program requirements, except those in subparts I and K. The requirements in § 26.403(a) and (b) would also be revised to require the licensee or other entity to develop, implement, and maintain written procedures for the processing, escorting, and control of individuals under escort and the duties and responsibilities of the escort. The NRC is seeking comment on whether licensees or other entities should also be allowed to escort individuals who require the types of access or perform any of the activities described in § 26.4(e) and (g) instead of subjecting the individuals to an FFD program. Please provide a basis with your response.

V. Section-by-Section Analysis

The following paragraphs describe the specific changes proposed by this rulemaking.

Section 2.4 Definitions

This proposed rule would revise the definition for "Contested proceeding" to include inspections, tests, analyses, and acceptance criteria (ITAAC) hearings.

Section 2.100 Scope of subpart

This proposed rule would revise this section to reflect that standard design approval (SDA) holders may request amendments to SDAs.

Section 2.101 Filing of application

This proposed rule would revise paragraph (a)(1) to reflect that SDA holders may request amendments to SDAs.

Section 2.106 Notice of issuance

This proposed rule would revise paragraph (b)(2)(ii) to conform to the language in § 52.103(g) with respect to the necessary regulatory findings.

Section 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues

This proposed rule would revise paragraphs (a)(1), (b), and (c)(1) to reflect that SDA holders may request amendments to SDAs. This proposed rule would make administrative corrections to paragraphs (a)(2) and (c)(2).

Subpart E of 10 CFR Part 2

This proposed rule would remove and reserve subpart E so that the regulations fully reflect the Commission's prior decision not to hold mandatory hearings for manufacturing license applications.

Section 21.3 Definitions

This proposed rule would revise the definitions for *Commercial grade item*, *Critical characteristics*, *Dedicating entity*, and *Dedication* to clarify their applicability to part 52 licensees.

Section 26.3 Scope

This proposed rule would revise paragraph (a) and paragraph (c) introductory text to clarify regulatory requirements regarding the implementation schedule for a fitness for duty program.

Section 26.4 FFD program applicability to categories of individuals

This proposed rule would revise paragraph (e)(1) to clarify regulatory requirements. This proposed rule also would add paragraph (e)(7) to add "escorts" to the list of activities and revise paragraph (f) to include individuals who are escorted.

Section 26.5 Definitions

This proposed rule would add a definition for *Escort* and revise the definition for *Reviewing official*.

Section 26.401 General

This proposed rule would revise paragraph (b) to include licensees and other entities.

Section 26.403 Written policy and procedures

This proposed rule would revise paragraph (a) to include individuals who are escorted. This proposed rule also would add a new paragraph (b)(4) to include the processing, escorting, and control of individuals and the duties and responsibilities of the escorts.

Section 26.405 Drug and alcohol testing

This proposed rule would revise paragraph (g) for clarity.

Section 26.419 Suitability and fitness evaluations

This proposed rule would revise § 26.419 to include the individual determined by the licensee or other entity as someone who can determine suitability and fitness.

Section 50.34 Contents of applications; technical information

This proposed rule would amend paragraph (a)(3)(iii) by replacing the period with a semicolon and adding a new paragraph (a)(3)(iv) to clarify the information regarding fire protection that an applicant under part 50 would submit for a construction permit. This proposed rule also would revise the last sentence of paragraph (a)(4) to clarify applicability. This proposed rule also would add new paragraphs (a)(14) through (16) to add the requirements to submit a description of a plant-specific probabilistic risk assessment, a description of design features for prevention and mitigation of severe

accidents, and a discussion on proposed technical resolutions of safety issues relevant to the design, respectively.

This proposed rule would revise the second sentence of paragraph (b)(4) to clarify applicability. This proposed rule also would add a new paragraph (b)(6)(viii) to clarify the information regarding fire protection that an applicant under part 50 would submit for an operating license. This proposed rule also would revise paragraph (b)(9) to clarify applicability. This proposed rule also would add new paragraphs (b)(13) through (15) to add the requirements to submit a description of design features for prevention and mitigation of severe accidents, a description of a plant-specific probabilistic risk assessment, and a discussion on proposed technical resolutions of safety issues relevant to the design, respectively.

This proposed rule would amend paragraph (f) by revising paragraph (f) introductory text, removing and reserving paragraph (f)(1), revising paragraph (f)(2) introductory text, removing and reserving paragraph (f)(2)(i), revising paragraphs (f)(2)(ii) through (v), (vii), (viii), (x) through (xv), (xvii) through (xxi), and (xxvi) through (xxviii), and removing and reserving paragraphs (f)(2)(vi), (ix), (xvi), and (xxii) through (xxv) so that it would apply to new power reactor applications submitted under part 50. This proposed rule would amend paragraph (f) by revising paragraphs (f)(3)(i) through (iv) and (vii) and removing and reserving paragraphs (f)(3)(v) and (vi) so that it would apply to new power reactor applications submitted under part 50.

This proposed rule would remove and reserve paragraph (h) to remove the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application.

Section 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors

This proposed rule would revise paragraphs (a)(3)(i) and (iii) to revise the reporting requirements for applicants for design certifications or applicants for, or holders of, standard design approvals.

Section 50.54 Conditions of licenses

This proposed rule would amend the introductory text of § 50.54 to add paragraph (q)(2) to the list of paragraphs that are not applicable until after the Commission's § 52.103(g) finding.

This proposed rule also would amend the introductory text of § 50.54 to clarify that those paragraphs not explicitly limited in their applicability to nuclear power plants are applicable to non-power production and utilization facilities.

This proposed rule also would amend paragraphs (q)(4) and (q)(5).

The proposed rule also would amend paragraphs (j), (k), and (m)(1) to clarify that the requirements of part 55 apply to all utilization facilities; paragraph (n), (s)(2)(ii), and (ee)(1) to clarify the applicability of the current generic language to all production and utilization facilities, including nuclear power plants and non-power production and utilization facilities; and paragraph (z) to clarify that the requirements of § 50.72 apply only to nuclear power reactors.

Section 50.59 Changes, tests, and experiments

This proposed rule would add paragraphs (c)(2)(ix) and (x) to require prior NRC review of changes to design features for ex-vessel severe accidents.

Section 50.69 Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors

This proposed rule would revise the introductory text of paragraph (b)(1) to allow construction permit holders, combined license holders, and design certification applicants to implement risk-informed classification of structures, systems, and components.

Section 50.71 Maintenance of records, making of reports

This proposed rule would revise paragraph (e)(3)(iii) to eliminate its applicability to, and reduce the burden for, a COL applicant that has requested suspension of the NRC review of its application or for a COL holder that has decided to delay or suspend construction of the facility.

This proposed rule also would revise paragraph (h) to require an operating license holder to periodically update the description and results of the plant-specific PRA.

This proposed rule would add a new paragraph (i) to add a requirement for a future part 50 power reactor licensee or part 52 COL holder to provide a written notification to the NRC of the successful completion of power ascension testing or startup testing, as applicable.

Section 50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause

This proposed rule would amend § 50.100 to remove the provision implying that the NRC has the ability to revoke, suspend, or modify, in whole or in part, a COL upon

failure to achieve timely completion of the proposed construction or alteration of the facility.

Section 50.109 Backfitting

This proposed rule would revise paragraph (a)(1) introductory text and paragraphs (a)(1)(i) and (iii), remove and reserve paragraph (a)(1)(v), and revise paragraph (a)(1)(vii) to clarify how backfitting and issue finality apply to certain NRC, applicant, or licensee actions.

Appendix E to 10 CFR Part 50, Emergency Planning and Preparedness for Production and Utilization Facilities

This proposed rule would revise paragraphs IV.F.2.a.(i) and (ii) and j to align the requirements for part 52 licensees with the requirements for part 50 licensees and make minor editorial changes.

This proposed rule would revise paragraph IV.F.2.a.(iii) to allow a COL applicant to forgo EP exercises for a new reactor constructed on a site with an identical operating reactor if it can show in its application that additional exercises are not required.

Section 51.50 Environmental report - construction permit, early site permit, or combined license stage

This proposed rule would revise paragraph (a) to clarify that an applicant for a construction permit can incorporate by reference a final environmental document previously prepared by the NRC staff and to state the additional information applicants must provide when referencing previous environmental analyses in environmental reports for construction permits.

Section 52.1 Definitions

This proposed rule would revise § 52.1 to add the definitions for *Essentially complete nuclear power plant design*, *Tier 1*, *Tier 2*, and *Tier 2** in alphabetical order.

Section 52.3 Written communications

This proposed rule would amend the heading for paragraph (b)(1) to reflect that SDA holders may request amendments to SDAs. This proposed rule would amend paragraph (b)(1) to make an administrative correction.

Section 52.6 Completeness and accuracy of information

This proposed rule would amend paragraph (b) to require the applicable applicants or licensees to notify the Director of the Office of Nuclear Reactor Regulation of information that has a significant implication for public health and safety or common defense and security for those part 52 applications or approvals that are not the responsibility of a Regional Administrator.

Section 52.11 Information collection requirements: OMB approval

This proposed rule would remove and reserve § 52.57 to remove the DC renewal requirements. This proposed rule also would remove and reserve appendices B and C to part 52 to clarify the NRC's regulations by removing expired content. Therefore, this proposed rule would also amend § 52.11(b) to make a conforming change to remove § 52.57 and appendices B and C from the list of sections in part 52 that contain approved information collection requirements.

Section 52.17 Contents of applications; technical information

This proposed rule would remove paragraph (a)(1)(xii) to remove the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application.

This proposed rule also would revise paragraph (b)(4) to properly differentiate when and to what extent descriptions of contacts and arrangements with Federal, State, and local governmental agencies are required and when certifications (including compensatory utility plans as necessary) are required.

Section 52.18 Standards for review of applications

This proposed rule would amend § 52.18 to clarify NRC review of the information submitted under § 52.17(b)(1).

Section 52.41 Scope of subpart

This proposed rule would amend paragraph (b)(1) to clarify a conflict in terminology between this paragraph and § 52.47(c)(1) regarding the phrase "essentially complete."

Section 52.47 Contents of applications; technical information

This proposed rule would amend paragraph (a) introductory text and add paragraph (a)(2)(v) to require each applicant to identify Tier 1, Tier 2, and Tier 2* information in their FSAR; amend paragraph (a)(4) to clarify applicability; amend paragraph (a)(8) to remove references to provisions in § 50.34(f) proposed for removal; remove and reserve paragraph (a)(9) to remove the requirements for an evaluation against the SRP in effect six months prior to docketing of an application; amend

paragraphs (a)(14) through (16) to clarify applicability; and revise paragraph (a)(21) to identify risk-significant generic safety issues that are required to be addressed by DC, COL, SDA, and ML applicants.

Section 52.55 Duration of certification

This proposed rule would revise the section heading and remove and reserve paragraphs (a) and (b) to remove the 15-year duration for DCs.

Section 52.57 Application for renewal

This proposed rule would remove and reserve § 52.57 to remove the DC renewal requirements.

Section 52.59 Criteria for renewal

This proposed rule would remove and reserve § 52.59 to remove the DC renewal requirements.

Section 52.61 Duration of renewal

This proposed rule would remove and reserve § 52.61 to remove the DC renewal requirements.

Section 52.63 Finality of standard design certifications

This proposed rule would amend paragraphs (a)(1) and (4) introductory text by removing a conditional phrase and amend paragraph (b)(1) to remove consideration of standardization from the criteria for making requested changes in the design.

Section 52.73 Relationship to other subparts

This proposed rule would revise the first sentence of paragraph (a) to clarify that more than one SDA may be referenced by applicants for a COL, a CP, or an ML if each referenced SDA is for different portions of the same reactor design.

Section 52.79 Contents of applications; technical information in final safety analysis report

This proposed rule would amend paragraphs (a)(5), (7), (9), (12), (13), (16)(ii), and (42) to clarify applicability; amend paragraph (a)(17) to remove references to provisions in § 50.34(f) proposed for removal; revise paragraph (a)(20) to identify risk-significant generic safety issues required to be addressed by DC, COL, SDA, and ML applicants; and remove and reserve paragraph (a)(41) to remove the requirements for an evaluation against the SRP in effect six months prior to docketing of an application.

This proposed rule would revise paragraph (c) to clarify that more than one SDA may be referenced by applicants for a COL, a CP, or an ML if each referenced SDA represents a major portion of the same reactor design.

This proposed rule also would add paragraphs (d)(4) and (5) to incorporate requirements currently found in sections IV.A.1 and IV.A.2.a through f of each DC appendix to part 52.

Section 52.93 Exemptions and variances

This proposed rule would add a new paragraph (c) to provide conforming requirements for COL applications that reference SDAs with variances; redesignate current paragraphs 52.93(c) and (d) as paragraphs 52.93(d) and (e); amend paragraph

(d) to remove consideration of standardization from the criteria for making changes in the design; and update references in paragraph (e).

Section 52.97 Issuance of combined licenses

This proposed rule would amend paragraph (a)(2) to be consistent with the requirements in section 185b. of the AEA and § 52.103(g).

Section 52.99 Inspection during construction; ITAAC schedules and notifications; NRC notices

This proposed rule would amend the second sentence of paragraph (a) to modify the timing of the reporting requirement.

Section 52.133 Relationship to other subparts

This proposed rule would revise paragraph (a) so that more than one standard design approval may be referenced in a construction permit, combined license, or manufacturing license application if each referenced standard design approval is for different portions of the same reactor design.

Section 52.137 Contents of applications; technical information

This proposed rule would amend paragraphs (a)(4) and (a)(14) through (16) to clarify applicability; amend paragraph (a)(8) to remove references to provisions in § 50.34(f) proposed for removal; remove and reserve paragraph (a)(9) to remove the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application; and revise paragraph (a)(21) to identify risk-significant generic safety issues required to be addressed by DC, COL, SDA, and ML applicants.

Section 52.145 Finality of standard design approvals; information requests

This proposed rule would add a new paragraph (c) to state that upon issuance of a CP, an OL, a COL, or an ML, a referenced SDA is subsumed into the CP, OL, COL, or ML; add a new paragraph (d) to allow an applicant for a CP, an OL, a COL, or an ML referencing an SDA to include a request for a variance from one or more provisions of the SDA; add a new paragraph (e) to prohibit a holder of an SDA from making changes to the design without prior NRC staff approval; and redesignate current paragraph (c) as paragraph (f).

Section 52.147 Duration of design approval

This proposed rule would remove and reserve § 52.147 to eliminate the duration and expiration provisions for SDAs.

Section 52.153 Relationship to other subparts

This proposed rule would revise paragraph (b) to clarify that more than one SDA may be referenced by applicants for a COL, a CP, or an ML if each referenced SDA is for different portions of the same reactor design.

Section 52.157 Contents of applications; technical information in final safety analysis report

This proposed rule would revise paragraph (f)(6) to address an inconsistency with § 50.49(a); amend paragraph (f)(12) to remove references to provisions in § 50.34(f) proposed for removal; revise paragraph (f)(28) to identify risk-significant generic safety issues required to be addressed by DC, COL, SDA, and ML applicants;

and remove and reserve paragraph (f)(30) to remove the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application.

Section 52.171 Finality of manufacturing licenses; information requests

This proposed rule would revise paragraph (a)(1) to clarify the applicability of that provision to Commission-imposed plant-specific and generic changes to an ML and amend paragraph (b)(2) to remove consideration of standardization from the criteria for making changes in the design.

Section 52.173 Duration of manufacturing license

This proposed rule would revise the maximum duration for manufacturing licenses from 15 years to 40 years and allow an applicant for a construction permit or a combined license to reference in its application a design for which a manufacturing license application has been docketed but not granted.

Section 52.181 Duration of renewal

This proposed rule would revise the maximum duration for renewed manufacturing licenses from 15 years to 40 years.

Section 52.303 Criminal penalties

This proposed rule would amend paragraph (b) by removing §§ 52.57, 52.59, 52.61, 52.147, 52.179, and 52.181 from the list of regulations that are not issued under one or more of sections 161b, 161i, or 160o of the Atomic Energy Act of 1954, as amended.

Appendix A to 10 CFR Part 52, Design Certification Rule for the U.S. Advanced Boiling Water Reactor

This proposed rule would remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively; remove and reserve paragraph VII; amend paragraph VIII.B.3 introductory text by removing a conditional phrase; revise paragraph VIII.B.5.a to add language similar to § 50.59(c)(4); add a new paragraph VIII.B.5.h; and revise the second sentence of paragraph VIII.C.5.

Appendix B to Part 52 - Design Certification Rule for the System 80 + Design

This proposed rule would remove and reserve appendix B to part 52 to clarify the NRC's regulations by removing expired content.

Appendix C to Part 52 - Design Certification Rule for the AP600 Design

This proposed rule would remove and reserve appendix C to part 52 to clarify the NRC's regulations by removing expired content.

Appendix D to Part 52 - Design Certification Rule for the AP1000 Design

This proposed rule would remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively; amend paragraph V.A.1 by adding the number "52" in numerical order; remove and reserve paragraph VII; amend paragraph VIII.B.3 introductory text by removing a conditional phrase; revise paragraph VIII.B.5.a to add language similar to § 50.59(c)(4); add a new paragraph VIII.B.5.h; revise the second sentence of paragraph VIII.C.5; and remove and reserve paragraph IX.

Appendix E to Part 52 - Design Certification Rule for the ESBWR Design

This proposed rule would remove paragraphs IV.A.1 and 2.a through f; redesignate paragraph IV.A.2 as IV.A.1; redesignate paragraph IV.A.2.g and h as paragraphs IV.A.1.a and b, respectively; redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.2 and 3, respectively; amend paragraph V.A by adding the number “52” in numerical order; remove and reserve paragraph VII; amend paragraph VIII.B.3 introductory text by removing a conditional phrase; revise paragraph VIII.B.5.a to add language similar to § 50.59(c)(4); add a new paragraph VIII.B.5.h; and revise the second sentence of paragraph VIII.C.5.

Appendix F to Part 52 - Design Certification Rule for the APR1400 Design

This proposed rule would remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively; remove and reserve paragraph VII; amend paragraph VIII.B.3 introductory text by removing a conditional phrase; revise paragraph VIII.B.5.a to add language similar to § 50.59(c)(4); add a new paragraph VIII.B.5.h; and revise the second sentence of paragraph VIII.C.5.

Section 55.4 Definitions

This proposed rule would amend § 55.4 by revising the definition for *plant-referenced simulator* to clarify that for a cold plant, a plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator will interface in the as-built control room. This proposed rule also would revise the definition for *reference plant* to clarify that it is not necessary for the reference plant to be actually constructed.

Section 55.31 How to apply

This proposed rule would redesignate paragraph (a)(4) as paragraph (a)(4)(i) and add a new paragraph (a)(4)(ii) to require facility licensees of new reactors under construction to provide information on NRC Form 398 to explain how the knowledge, skills, and abilities of applicants for an operator license would be maintained when the facility licensee requests an NRC examination to be administered well before the applicants would be expected to complete all requirements to receive operator licenses.

Section 55.45 Operating tests

This proposed rule would revise paragraph (b) to provide facility licensees of new reactors under construction the option of developing plant walkthrough test items (e.g., job performance measurements used for the in-plant portion of the operating test), using suitable alternatives to in-plant testing while the facility is under construction.

Section 55.46 Simulation facilities

This proposed rule would revise paragraph (c)(2)(i) to allow applicants for operator licenses to perform the control manipulations required by § 55.31(a)(5) on a simulation facility that uses a suitable alternative to “models relating to nuclear and thermal-hydraulic characteristics that replicate the most recent core load,” such as by using models related to nuclear and thermal-hydraulic characteristics that replicate the intended first core load for the plant.

Section 55.47 Waiver of examination and test requirements

This proposed rule would revise paragraph (a)(1) to include current paragraphs (a)(2) and (3), redesignate paragraphs (b) and (c) as paragraphs (a)(2) and (3), and add

a new paragraph (b) to include provisions for licensing of operators at subsequent new units at multiunit sites.

Section 70.22 Contents of applications

This proposed rule would amend paragraph (k) to clarify the applicability of the security requirements in § 73.67 to both part 50 and 52 licensees when the SNM is protected in accordance with the appropriate security requirements in § 73.55.

Section 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage

This proposed rule would amend paragraph (a)(4) to replace the current rule language “before fuel is allowed onsite (protected area)” with new rule language “before initial fuel load into the reactor.”

Section 73.56 Personnel access authorization requirements for nuclear power plants

This proposed rule would amend paragraph (a)(3) to replace the current rule language “before fuel is allowed onsite (protected area)” with new rule language “before initial fuel load into the reactor.”

Section 73.67 Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance

This proposed rule would amend the introductory text of paragraphs (d) and (f) to clarify that the existing exception applies to both part 50 and 52 licensees when the SNM is protected in accordance with the appropriate security requirements in § 73.55.

VI. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980 (RFA), as amended at 5 U.S.C. 601 et seq, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

In accordance with the Small Business Administration's (SBA) regulation at 13 CFR 121.903(c), the NRC has developed its own size standards for performing an RFA analysis and has verified with the SBA Office of Advocacy that its size standards are appropriate for NRC analyses. The NRC size standards at § 2.810, "NRC size standards," are used to determine whether an applicant or licensee qualifies as a small entity in the NRC's regulatory programs. Section 2.810 defines four types of small entities. A *small business* is a for-profit concern and is a 1) concern that provides a service or a concern not engaged in manufacturing with average gross receipts of $8.0 million or less over its last 5 completed fiscal years; or 2) manufacturing concern with an average number of 500 or fewer employees based upon employment during each pay period for the preceding 12 calendar months. A *small organization* is a not-for-profit organization that is independently owned and operated and has annual gross receipts of $8.0 million or less. A *small governmental jurisdiction* is a government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. A *small educational institution* is one that is 1) supported by a qualifying small governmental jurisdiction, or 2) not State or publicly supported and has 500 or fewer employees.

Number of Small Entities Affected

The NRC is currently aware of no known small entities that develop the reactor designs and that may seek a design certification or standard design approval, nor any entities that own or operate the facilities that would be affected by this proposed rule that fall within the scope of the definition of "small entities" set forth in the RFA or the size standards established by the NRC in § 2.810. Based on this finding, the NRC has preliminarily determined that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Economic Impact on Small Entities

Depending on how the ownership and/or operating responsibilities for such an enterprise were structured, applicants for an advanced nuclear reactor rated 8 MWe or less could conceivably meet the definition of small entities as defined by § 2.810. Owners that operate power reactors rated greater than 8 MWe could generate sufficient electricity revenue that exceeds the gross annual receipts limit of $8 million, assuming a 90-percent capacity factor, and the October 2021 U.S. Department of Energy's Energy Information Administration U.S. average price of electricity to the ultimate customer for all sectors of 11.32 cents per kilowatt hour.

Although the NRC is not aware of any small entities that would be affected by the proposed rule, there is a possibility that future applications for an advanced nuclear reactor permit or license could be submitted by small entities who plan to own and operate an advanced nuclear reactor rated 8 MWe or less. Advanced nuclear reactors that are rated 8 MWe or less would most likely be used to support electrical demand for military bases, small remote towns, and process heat and would not directly compete

with larger advanced nuclear reactors that typically produce electricity for the grid. As a result of these differing purposes, the NRC would expect that small and large entities would not be in direct competition with each other.

The NRC's regulations at § 171.16(c) allow for certain NRC licensees to pay reduced annual fees if they qualify as small entities, although these regulations do not include licensees authorized to conduct activities under either 10 CFR part 50 or 10 CFR part 52. However, should a small entity apply for an advanced nuclear reactor license or permit, the small entity could request a one-time fee exemption. In subsequent years, the NRC licensee could submit a new request for a fee exemption for each fiscal year for which it desires an exemption. Additionally, after the small entity receives an operating license under 10 CFR part 50 or under 10 CFR part 52 and has completed power ascension testing, the small entity would be eligible for a reduced annual fee under § 171.15, "Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses," based on the cumulative licensed thermal power rating of the reactor. The fiscal year 2021 annual fee for each large operating power reactor is $4,749,000.

Therefore, the NRC preliminarily concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities.

Request for Comments

The NRC is seeking comments on both its initial RFA analysis and on its preliminary conclusion that this proposed rule would not have a significant economic impact on a substantial number of small entities because of the likelihood that most expected applicants would not qualify as a small entity. Additionally, the NRC is seeking

comments on its preliminary conclusion that if a small entity were to submit an advanced nuclear reactor application, the small entity would not incur a significant economic impact as it would most likely not be in competition with a large entity. Any small entity that could be subject to this regulation that determines, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this opinion in a comment that indicates—

1) The applicant's size and how the proposed regulation would impose a significant economic burden on the applicant as compared to the economic burden on a larger applicant;

2) How the proposed regulations could be modified to take into account the applicant's differing needs or capabilities;

3) The benefits that would accrue or the detriments that would be avoided if the proposed regulations were modified as suggested by the applicant;

4) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group; and

5) How the proposed regulation, as modified, would still promote common defense and security and adequately protect public health and safety.

Comments may be submitted as indicated under the ADDRESSES section of this document.

VII. Regulatory Analysis

The NRC prepared a draft regulatory analysis to assess regulatory alternatives and determine the expected quantitative costs and benefits of this proposed rule and associated guidance as well as qualitative factors to be considered in the NRC's

rulemaking decision. The conclusion from the analysis is that this proposed rule and associated guidance would result in net averted costs to industry and the NRC ranging from $16.1 million using a 7-percent discount rate to $25.4 million using a 3-percent discount rate.

The draft regulatory analysis also assessed qualitative aspects, such as greater clarity, regulatory certainty, and efficiency. These benefits would result from enhanced alignment between the reactor licensing processes in parts 50 and 52, including implementation of the policy decisions described in Appendices A through D of the draft regulatory analysis. These recommended changes would help ensure consistent safety standards are applied, regardless of the process used to license a new reactor. In addition, updating parts 50 and 52 to address lessons learned from recent new reactor license reviews, as described in Appendices E through K of the draft regulatory analysis, will improve clarity and reduce unnecessary burden on applicants and the NRC. Another qualitative consideration is increased public confidence in the NRC's ability to improve its regulations, adapt to regulatory needs identified by stakeholders, provide opportunities for stakeholders to provide input on the changes to the new reactor licensing process, and maintain its role as an effective industry regulator.

The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as stated in the "Availability of Documents" section of this document. Comments on the draft regulatory analysis may be submitted to the NRC as stated under the ADDRESSES caption of this document.

VIII. Backfitting and Issue Finality

The Commission has completed a backfitting and issue finality assessment for this proposed rule under §§ 50.109, "Backfitting"; 52.39, "Finality of early site permit

determinations”; 52.63, “Finality of standard design certifications”; 52.83, “Finality of referenced NRC approvals; partial initial decision on site suitability”; 52.98, “Finality of combined licenses; information requests”; 52.145, “Finality of standard design approvals; information requests”; and 52.171, “Finality of manufacturing licenses; information requests.” The assessment is available as indicated in the “Availability of Documents” section of this document.

One set of changes in this proposed rule would constitute backfitting, as that term is defined in § 50.109 and described in NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.” The proposed changes to §§ 70.22(k), 73.67(d), and 73.67(f) to clarify the appropriate security requirements for Category II and III quantities of SNM stored within the owner-controlled area but outside the protected area at 10 CFR part 50 nuclear power reactors could impose a change to those licensees’ required physical security programs, thereby meeting the definition of “backfitting” in § 50.109(a)(1). These proposed backfits would be justified on the basis that the proposed changes are necessary to ensure that these facilities provide adequate protection to the health and safety of the public and are in accord with the common defense and security.

The NRC is issuing seven draft regulatory guides (DGs) that, if finalized, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. As discussed in the DGs, applicants and licensees would not be required to comply with the positions set forth in the DGs. Therefore, issuance of the DGs in final form would not constitute backfitting or forward fitting, as that term is defined and described in Management Directive 8.4, or affect the issue finality of any approval issued under part 52.

The NRC is issuing a revised NUREG for public comment with the proposed rule. NUREG-1021, “Operator Licensing Examination Standards for Power Reactors,” would be revised to support the implementation of regulatory changes associated with operator license applications, including requirements for plant walkthrough, waivers for examination and test requirements, and continuing training for operator license applicants. The NUREG relates to operators licensing, which is governed by part 55. Because § 50.109 does not apply to part 55, the issuance of the changes to this NUREG in final form would not constitute backfitting or forward fitting or affect the issue finality of any approval.

The NRC is also issuing six draft changes to the Standard Review Plan, NUREG-0800, that, if finalized, would provide guidance to the NRC for reviewing aspects of license applications related to this proposed rule. Changes in internal staff guidance, without further NRC action, are not matters that meet the definition of backfitting, affect the issue finality of a part 52 approval, or constitute forward fitting. Therefore, issuance of the changes to the SRP in final form would not constitute backfitting or forward fitting or affect the issue finality of any approval issued under part 52.

IX. Cumulative Effects of Regulation

The NRC is following its Cumulative Effects of Regulation (CER) process by engaging extensively with external stakeholders throughout this rulemaking and related regulatory activities. Opportunities for public involvement include: (1) a public meeting on January 15, 2019, to afford external stakeholders an opportunity to provide input to the technical areas to be addressed by this rulemaking; (2) a public meeting on November 21, 2019, to afford external stakeholders an opportunity to ask the NRC staff clarifying questions on the list of technical areas selected for inclusion in this rulemaking;

(3) the publication of the regulatory basis for public comment on January 29, 2021; and (4) a public meeting on March 2, 2021, to facilitate public comments on the regulatory basis.

The NRC welcomes public comment on this proposed rule. The NRC is issuing draft implementing guidance with this proposed rule to support more informed external stakeholder feedback. Further, the NRC will continue to hold public meetings throughout the rulemaking process. Section XV, “Availability of Guidance,” of this document describes how the public can access the draft implementing guidance for which the NRC seeks external stakeholder feedback.

Finally, the NRC is requesting CER feedback on the following questions:

1. In light of any current or projected CER challenges, do the effective date, compliance date, or submittal dates proposed provide sufficient time to implement the new requirements, including changes to programs, procedures, and the facility?
2. If CER challenges currently exist or are expected, what should be done to address them? For example, if more time is required for implementation of the new requirements, what period of time is sufficient?
3. Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule’s requirements?
4. Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule’s purpose and objectives? If so, what are the unintended consequences, and how should they be addressed?

5. Please comment on the NRC's cost and benefit estimates in the draft regulatory analysis that supports the proposed rule. The draft regulatory analysis is available as stated in the "Availability of Documents" section of this document.

X. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XI. National Environmental Policy Act

The NRC has determined that this proposed rule is the type of action described in § 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," specifically paragraphs (c)(1), (2), and (3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed rule.

XII. Paperwork Reduction Act

This proposed rule adds new collections of information to or amends existing collections of information contained in NRC Form 398 and parts 26, 50, 51, 52, 70, and 73 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

The collections of information have been submitted to the Office of Management and Budget for review and approval. The proposed changes to parts 2, 21, and 55 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995. Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150-0090 (NRC Form 398), 3150-0146 (part 26), 3150-0011 (part 50), 3150-0021 (part 51), 3150-0151 (part 52), 3150-0009 (part 70), and 3150-0002 (part 73).

Type of submission, new or revision: Revision.

The title of the information collection: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing, Proposed Rule

The form number if applicable: NRC Form 398.

How often the collection is required or requested: Once, on occasion, bimonthly, and annually.

Who will be required or asked to respond: Production and utilization facility licensees and applicants.

An estimate of the number of annual responses: 125.3 (116 responses for NRC Form 398, 0 response for 10 CFR part 26, -2 responses for 10 CFR part 50, 0.3 response for 10 CFR part 51, 11 responses for 10 CFR part 52, 0 responses for 10 CFR part 70, 0 responses for 10 CFR part 73).

The estimated number of annual respondents: 13.6 (1 respondent for NRC Form 398, 0.3 respondents for 10 CFR part 26, 7 respondents for 10 CFR part 50, 0.3 respondents for 10 CFR part 51, 5.6 respondents for 10 CFR part 52, 0 respondents for 10 CFR part 70, 0 respondents for 10 CFR part 73).

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 12,695 (580 hours for NRC Form 398, 70 hours for 10 CFR part 26, 13,192 hours for 10 CFR part 50, -362 hours for 10 CFR part 51, -785 hours for 10 CFR part 52, 0 hours for 10 CFR part 70, 0 hours for 10 CFR part 73).

Abstract: The proposed rule would result in changes in reporting, recordkeeping, and third-party disclosure requirements relative to existing rules by revising the NRC's regulations to better align licensing requirements in 10 CFR part 50 and 10 CFR part 52 and incorporate lessons learned from recent new power reactor licensing reviews. Information provided by applicants as part of their applications under 10 CFR part 50 and 10 CFR part 52 is crucial to the licensing process as it provides the NRC with the information it needs to make a decision with regard to the proposed plant's impact on the health and safety of the public. The NRC conducts a detailed review of all applications for licenses to construct and operate utilization and production facilities, in addition to applications for design approvals and certifications. The purpose of the detailed review is to ensure that the proposed facilities can be built and operated safely at the proposed locations, and that all structures, systems, and components important to safety will be designed to withstand the effects of postulated accident conditions without undue risk to

the health and safety of the public. For many years, new reactor licensing and guidance development activities have focused on the licensing processes in 10 CFR part 52 rather than those in 10 CFR part 50. As a result, some Commission decisions regarding new reactor licensing issues have been incorporated into 10 CFR part 52, without similar requirements consistently being incorporated into 10 CFR part 50. In addition, lessons learned from recent combined license, design certification, early site permit, and operating license reviews indicate 10 CFR parts 50 and 52 would benefit from revisions that would improve the clarity and effectiveness of these regulations. The proposed rule would, on balance, increase the paperwork burden imposed on production and utilization applicants and licensees under 10 CFR part 50 and 10 CFR part 52; however, these changes would revise regulations to ensure consistency in new reactor licensing reviews, promote an efficient new reactor licensing process, address other new reactor licensing issues deemed relevant by the NRC, and support the principles of good regulation, specifically openness, clarity, and reliability.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collection(s) contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package is available in ADAMS under Accession No. ML21334A147 or may be viewed free of charge by contacting the NRC's Public Document Room reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.resource@nrc.gov. You may obtain information and comment submissions related to the OMB clearance package by searching on https://www.regulations.gov under Docket ID NRC-2009-0196.

You may submit comments on any aspect of these proposed information collection(s), including suggestions for reducing the burden and on the aforementioned issues, by the following methods:

- Federal rulemaking website: Go to https://www.regulations.gov and search for Docket ID NRC-2009-0196.
- Mail comments to: FOIA, Library, and Information Collections Branch, Office of Information Services, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0151), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov*

Submit comments by **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number

XIII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this proposed rule that would amend or add §§ 50.34, 50.46, 50.54, 50.69, 50.71, 52.6, 55.45, 55.46, 70.22, 73.55, 73.56, and 73.67, as well as appendix E to part 50 and appendices A through E to 10 CFR part 52, under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in parts 21, 26, 50, 52, 55, 70, and 73 are discussed in §§ 21.62, 26.825, 50.111, 52.303, 55.73, 70.92, and 73.81.

XIV. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. The NRC is proposing to revise regulations associated with the licensing of new nuclear power reactors in parts 2, 21, 26, 50, 51, 52, 55, 70, and 73. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XV. Availability of Guidance

The NRC is issuing for comment seven draft regulatory guides (DGs), six revised sections of the Standard Review Plan (NUREG-0800), and Revision 13 to NUREG-1021 to support the implementation of this proposed rule. Comments on the draft guidance documents may be submitted by the methods outlined in the ADDRESSES section of this document. Interested persons may access the draft guidance documents and public comments on the draft guidance by searching on https://www.regulations.gov under Docket ID NRC-2009-0196.

1. DG-1384, "Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements," Revision 5 to RG 1.149
2. DG-1394, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Revision 4 to RG 1.174
3. DG-1395, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," Revision 4 to RG 1.200
4. DG-1398, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,'" Revision 4 to RG 1.187
5. DG-1399, "Applications for Nuclear Power Plants," Revision 2 to RG 1.206
6. DG-4031, "General Site Suitability Criteria for Nuclear Power Stations," Revision 4 to RG 4.7
7. DG-5069, "Fitness-For-Duty for New Nuclear Power Plant Construction Sites," Revision 1 to RG 5.84

8. Draft NUREG-0800 Standard Review Plan Section 1.0, “Introduction and Interfaces,” Revision 3 to Section 1.0

9. Draft NUREG-0800 Standard Review Plan Section 13.3, “Emergency Planning,” Revision 4 to Section 13.3

10. Draft NUREG-0800 Standard Review Plan Section 13.6.1, “Physical Security—Combined License and Operating Reactors,” Revision 3 to Section 13.6.1

11. Draft NUREG-0800 Standard Review Plan Section 13.6.4, “Access Authorization Operational Program,” Revision 1 to Section 13.6.4

12. Draft NUREG-0800 Standard Review Plan Section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors,” Revision 4 to Section 19.0

13. Draft NUREG-0800 Standard Review Plan Section 19.1, “Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities,” Revision 4 to Section 19.1

14. Draft NUREG-1021, “Operator Licensing Examination Standards for Power Reactors,” Revision 13

XVI. Public Meeting

The NRC will conduct a public meeting on the proposed rule for the purpose of describing this proposed rule to the public and facilitating development of public comments on this proposed rule.

The NRC will publish a notice of the location, time, and agenda of the meeting in the *Federal Register*, on www.regulations.gov, and on the NRC’s public meeting website

at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: https://www.nrc.gov/public-involve/public-meetings/index.cfm.

XVII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as stated.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION
Supporting Analyses	
Draft Regulatory Analysis	ML21159A069
Backfitting and Issue Finality Assessment for the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing Proposed Rule	ML21335A022
Rulemaking: Proposed Rule: OMB Supporting Statements for the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing	ML21334A147
Draft Guidance Documents	
Draft Regulatory Guide DG-1384, "Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements," which would be Revision 5 to RG 1.149	ML21081A041
Draft Regulatory Guide DG-1394, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," which would be Revision 4 to RG 1.174	ML21203A006
Draft Regulatory Guide DG-1395, "Acceptability of Probabilistic Risk Assessment Results for Risk-Informed Activities," which would be Revision 4 to RG 1.200	ML21203A008
Draft Regulatory Guide DG-1398, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, And Experiments,'" which would be Revision 4 to RG 1.187	ML21214A014
Draft Regulatory Guide DG-1399, "Applications for Nuclear Power Plants," which would be Revision 2 to RG 1.206	ML21218A010
Draft Regulatory Guide DG-4031, "General Site Suitability Criteria for Nuclear Power Stations," which would be Revision 4 to RG 4.7	ML21203A005

Draft Regulatory Guide DG-5069, "Fitness-For-Duty for New Nuclear Power Plant Construction Sites," which would be Revision 1 to RG 5.84	ML21159A141
Draft NUREG-0800 Standard Review Plan Section 1.0, "Introduction and Interfaces," which would be Revision 3 to Section 1.0	ML21281A041
Draft NUREG-0800 Standard Review Plan Section 13.3, "Emergency Planning," which would be Revision 4 to Section 13.3	ML21287A189
Draft NUREG-0800 Standard Review Plan Section 13.6.1, "Physical Security—Combined License and Operating Reactors," which would be Revision 3 to Section 13.6.1	ML21281A044
Draft NUREG-0800 Standard Review Plan Section 13.6.4, "Access Authorization Operational Program," which would be Revision 1 to Section 13.6.4	ML21281A042
Draft NUREG-0800 Standard Review Plan Section 19.0, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," which would be Revision 4 to Section 19.0	ML21293A110
Draft NUREG-0800 Standard Review Plan Section 19.1, "Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," which would be Revision 4 to Section 19.1	ML21293A111
Draft NUREG-1021, "Operator Licensing Examination Standards for Power Reactors," which would be Revision 13 to NUREG-1021	ML21274A712
Other References	
NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants," dated December 1978	ML051390356
NUREG-0660, Volume 1, "NRC Action Plan Developed as a Result of the TMI-2 Accident," dated May 1980	ML072470526
NUREG-0718, "Licensing Requirements for Pending Applications for Construction Permits and Manufacturing Licenses," dated June 1981	ML20009F403 (package)
Federal Register notice—"Rule to Require Applicants to Evaluate Differences from the Standard Review Plan," dated March 18, 1982	47 FR 11651
Federal Register notice—"Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," dated August 8, 1985	50 FR 32138
Federal Register notice—"Nuclear Power Plant Standardization," dated September 15, 1987	52 FR 34884
Generic Letter No. 88-20, "Individual Plant Examination of External Events for Severe Accident Vulnerabilities – 10 CFR 5.54(f)," dated November 23, 1988	ML031150465
Federal Register notice—Proposed rule— "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated August 23, 1988	53 FR 32060
SECY-89-013, "Design Requirements Related to the Evolutionary Advanced Light Water Reactors," dated January 19, 1989	ML003707947
Federal Register notice—Final rule— "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated April 18, 1989	54 FR 15372

SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements," dated January 12, 1990	ML003707849
COMKR-90-1, "Principles of Good Regulation," dated April 6, 1990	ML15083A026
SRM-SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationships to Current Regulatory Requirements," dated June 26, 1990	ML003707885
SECY-90-377, "Requirements for Design Certification Under 10 CFR Part 52," dated November 8, 1990	ML003707889
SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated April 2, 1993	ML003708021
SRM-SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs," dated July 21, 1993	ML003708056
Federal Register notice—"Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," dated August 16, 1995	60 FR 42622
SECY-96-077, "Certification of two Evolutionary Designs," dated April 15,1996	ML003708129
Federal Register notice—"Reactor Site Criteria Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants," dated December 11, 1996	61 FR 65157
Federal Register notice—"Plain Language in Government Writing," dated June 10, 1998	63 FR 31885
SECY-98-282, "Part 52 Rulemaking Plan," dated December 4, 1998	ML992870013
SRM-SECY-98-282, "Part 52 Rulemaking Plan," dated January 14, 1999	ML032801439
"Pilot Study for Draft Management Directive 6.4, 'Generic Issue Program,'" dated July 21, 1999	ML20210F407
Federal Register notice—"Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Reactors," dated July 3, 2003	68 FR 40026
Federal Register notice—Proposed rule—"Combustible Gas Control in Containment," dated September 16, 2003	68 FR 54123
Federal Register notice—Proposed rule—"Licenses, Certifications, and Approvals for Nuclear Power Plants," dated March 13, 2006	71 FR 12782
Regulatory Guide 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," dated May 2006	ML061090627
NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," with updates through 2007	https://www.nrc.gov/reading-rm/doccollections/nuregs/staff/sr0800/index.html
NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 2.1.1, Revision 3, "Site Location and Description," dated March 2007	ML070550023
Regulatory Guide 1.206, Revision 0, "Combined License Applications for Nuclear Power Plants (LWR Edition)," dated June 2007	ML070720184 (package)

"Comment Summary Report: Final Rule for 10 CFR Part 52 Licenses, Certifications, and Approvals for Nuclear Power Plants," dated July 2007	ML063450216
Federal Register notice—Final rule—"Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49352
Federal Register notice—"Conduct of New Reactor Licensing Proceedings; Final Policy Statement," dated April 17, 2008	73 FR 20963
Interim Staff Guidance DC/COL-ISG-3, "Probabilistic Risk Assessment Information to Support Design Certification and Combined License Applications," dated June 11, 2008	ML081430675
Federal Register notice—"Policy Statement on the Regulation of Advanced Reactors," dated October 14, 2008	73 FR 60612
Interim Staff Guidance DC/COL-ISG-020, "Implementation of a Probabilistic Risk Assessment-Based Seismic Margin Analysis for New Reactors," dated March 15, 2010	ML100491233
Regulatory Guide 1.149, Revision 4, "Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements," dated April 2011	ML110420119
Regulatory Guide 5.66, "Access Authorization Program for Nuclear Power Plants," dated October 2011	ML112060028
Regulatory Guide 4.7, Revision 3, "General Site Suitability Criteria for Nuclear Power Stations," dated March 21, 2014	ML12188A053
Federal Register notice—"Economic Simplified Boiling Water Reactor Design Certification," dated October 15, 2014	79 FR 61944
SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," dated January 8, 2015	ML13277A420 (package)
Interim Staff Guidance COL-ISG-025, "Changes During Construction Under 10 CFR Part 52," dated July 2015	ML15058A377
Regulatory Guide 5.84, Revision 0, "Fitness-for-Duty for New Nuclear Power Plant Construction Sites," dated July 2015	ML15083A412
SRM-SECY-15-0002, "Staff Requirements – SECY-15-0002 – Proposed Updates of Licensing Policies, Rules and Guidance for Future New Reactor Applications," dated September 22, 2015	ML15266A023
NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 19.0, Revision 3, "Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors," dated December 2015	ML15089A068
NEI, NEI 14-09, Revision 1, "Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance," dated February 2016	ML16054A825
Federal Register notice—"Vogtle Electric Generating Plant Units 3 and 4; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia," dated April 8, 2016	81 FR 20690
Federal Register notice—"Vogtle Electric Generating Plant Unit 3; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia," dated June 30, 2016	81 FR 42745

Federal Register notice—"South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Units 2 and 3," dated August 18, 2016	81 FR 55237
Federal Register notice—"South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Unit 2," dated August 22, 2016	81 FR 56704
NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 2.0, Revision 1, "Site Characteristics and Site Parameters," dated October 2016	ML15279A105
Interim Staff Guidance DC/COL-ISG-028, "Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application," dated November 2016	ML16130A468
Regulatory Guide 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," dated January 2018	ML17317A256
Nuclear Innovation Alliance, NEI, and U.S. Nuclear Infrastructure Council, "Ensuring the Future of U.S. Nuclear Energy: Creating a Streamlined and Predictable Licensing Pathway to Deployment," dated January 23, 2018	ML18030A771
Regulatory Guide 1.234, "Evaluating Deviations and Reporting Defects and Noncompliance Under Part 21," dated April 2018	ML17338A072
Regulatory Guide 1.206, Revision 1, "Applications for Nuclear Power Plants," dated October 2018	ML18131A181
NEI, "Assessment of Licensing Impacts on Construction: Experience with Making Changes during Construction under Part 52," dated October 23, 2018	ML18305B421
Summary of January 15, 2019 Category 3 Public Meeting to Discuss the Proposed Rulemaking to Align the Regulations in Parts 50 and 52 to Address Updates to the Licensing Processes and Lessons Learned for Future New Reactor Applications, dated January 30, 2019	ML19023A046
SECY-19-0034, "Improving Design Certification Content," dated April 24, 2019	ML19080A032 (package)
Federal Register notice—"Advanced Power Reactor 1400 (APR1400) Design Certification," dated May 22, 2019	84 FR 23439
NRC Form 398, approved without change July 2, 2019	https://www.nrc.gov/reading-rm/doc-collections/forms/nrc398info.html
SECY-19-0084, "Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)," dated August 27, 2019	ML19161A169 (package)
Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019	ML18093B087
NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated December 2019	ML19347D139

Summary of November 21, 2019 Category 3 Public Meeting to Discuss the Regulatory Basis for Rulemaking to Align Licensing Processes and Apply Lessons Learned from New Reactor Licensing, dated December 17, 2019	ML19344C768
Federal Register notice—"Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020," dated June 19, 2020	85 FR 37250
NRC Office of Public Affairs Backgrounder, "Nuclear Power Plant Licensing Process," dated July 2020	ML052170295
NRC Staff Draft White Paper, "Analysis of Applicability of NRC Regulations for Non-Light Water Reactors," dated September 2020	ML20241A017
NRC Letter to NEI, "Part 50/52 Lessons-Learned Rulemaking: U.S. Nuclear Regulatory Commission Transparency and Stakeholder Engagement," dated September 8, 2020	ML20156A308
SRM-SECY-18-0106, "Consideration in the Rulemaking Process of Issue Raised in Petition for Rulemaking on Applicability of Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," dated September 10, 2020	ML20254A357 (package)
NEI Letter to NRC, "Part 50/52 Lessons Learned Rulemaking – Addressing the term 'Essentially Complete,'" dated September 24, 2020	ML20268C271
NEI, "NEI Input on Analysis of Applicability of NRC Regulations for Non-Light Water Reactors," dated October 30, 2020	ML20308A662 (package)
Regulatory Guide 1.200, Revision 3, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," dated December 2020	ML20238B871
Federal Register notice—Regulatory Basis, "Alignment of Licensing Processes and Lessons Learned From New Reactor Licensing," dated January 29, 2021	86 FR 7513
Announcement of March 2, 2021 Category 3 Public Meeting to Discuss the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing Rulemaking, dated February 17, 2021	ML21048A067
Regulatory Guide 1.237, Revision 0, "Guidance for Changes During Construction for New Nuclear Power Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR Part 52," dated February 25, 2021	ML20349A335
Summary of March 2, 2021 Category 3 Public Meeting to Discuss the Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing Rulemaking, dated March 19, 2021	ML21076A098
Federal Register notice—Direct Final Rule— "Advanced Boiling Water Reactor (ABWR) Design Certification Renewal," dated July 1, 2021	86 FR 34905
Updated NRC Staff Draft White Paper, "Analysis of Applicability of NRC Regulations for Non-Light Water Reactors," dated July 2021	ML21175A287
Federal Register notice—Petition for Rulemaking, Denial, "Linear No-Threshold Model and Standards for Protection Against Radiation," dated August 17, 2021	86 FR 45923
NUREG-1021, Revision 12, "Operator Licensing Examination Standards for Power Reactors," dated September 2021	ML21256A276

The NRC may post additional information, including public comments, on the Federal rulemaking website at https://www.regulations.gov under Docket ID NRC-2009-0196. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) navigate to the docket folder (NRC-2009-0196); 2) click the “Subscribe” link; and 3) enter an email address and click on the “Subscribe” link.

List of Subjects

10 CFR part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Confidential business information; Freedom of information, Environmental protection, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for

duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

10 CFR part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR part 55

Criminal penalties, Manpower training programs, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR part 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR part 73

Criminal penalties, Exports, Hazardous materials transportation, Imports, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 2, 21, 26, 50, 51, 52, 55, 70, and 73:

PART 2 – AGENCY RULES OF PRACTICE AND PROCEDURE

1. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232, 2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154,

10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note.

Section 2.205(j) also issued under 28 U.S.C. 2461 note.

2. In § 2.4, revise the definition of *Contested proceeding* to read as follows:

§ 2.4 Definitions.

*   *   *   *   *

Contested proceeding means –

(1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;

(2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under part 52 of this chapter;

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission; and

(4) A proceeding in which there is controversy as to whether the facility as constructed complies, or on completion of construction will comply, with the prescribed acceptance criteria in the combined license under part 52 of this chapter.

*   *   *   *   *

3. Revise § 2.100 to read as follows:

§ 2.100 Scope of subpart.

This subpart prescribes the procedure for issuance of a license; amendment of a license at the request of the licensee; transfer and renewal of a license; and issuance of a standard design approval or amendment of a standard design approval at the request of the standard design approval holder under subpart E of part 52 of this chapter.

4. In § 2.101, revise paragraph (a)(1) to read as follows:

§ 2.101 Filing of application.

(a)(1) An application for a permit, a license, a license transfer, a license amendment, a license renewal, a standard design approval, or a standard design approval amendment shall be filed with the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as prescribed by the applicable provisions of this chapter. A prospective applicant may confer informally with the NRC staff before filing an application.

* * * * *

5. In § 2.106, revise paragraph (b)(2)(ii) to read as follows:

§ 2.106 Notice of issuance.

* * * * *

(b) * * *

(2) * * *

(ii) A finding that the prescribed inspections, tests, and analyses have been performed and the prescribed acceptance criteria are met.

* * * * *

6. In § 2.110, revise paragraphs (a), (b), and (c) to read as follows:

§ 2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues.

(a)(1) A submittal for a standard design approval or standard design approval amendment under subpart E of part 52 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

(2) Except as specifically provided otherwise by the provisions of appendix Q to part 50 of this chapter, a submittal for early review of site suitability issues under appendix Q to part 50 of this chapter shall be subject to § 2.101(a)(2) through (4) to the same extent as if it were an application for a permit or license.

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under appendix Q of part 50 of this chapter, or for a standard design approval or standard design approval amendment under subpart E of part 52 of this chapter, the Director, Office of Nuclear Reactor Regulation, shall publish in the *Federal Register* a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

(c)(1) Upon completion of review by the NRC staff and the ACRS of a submittal for a standard design approval or standard design approval amendment, the Director, Office of Nuclear Reactor Regulation, shall publish in the *Federal Register* a determination as to whether or not the design is acceptable, subject to terms and conditions as may be appropriate, and shall make available at the NRC website, https://www.nrc.gov, a report that analyzes the design.

(2) Upon completion of review by the NRC staff and, if appropriate, by the ACRS, of a submittal for early review of site suitability issues, the NRC staff shall prepare a staff site report which shall identify the location of the site, state the site suitability issues

reviewed, explain the nature and scope of the review, state the conclusions of the staff regarding the issues reviewed and state the reasons for those conclusions. Upon issuance of an NRC staff site report, the NRC staff shall publish a notice of the availability of the report in the *Federal Register* and shall make the report available at the NRC website, https://www.nrc.gov. The NRC staff shall also send a copy of the report to the Governor or other appropriate official of the State in which the site is located, and to the chief executive of the municipality in which the site is located or, if the site is not located in a municipality, to the chief executive of the county.

Subpart E [Removed and Reserved]

7. Remove and reserve subpart E, consisting of §§ 2.500 through 2.501.

PART 21 – REPORTING OF DEFECTS AND NONCOMPLIANCE

8. The authority citation for part 21 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

9. In § 21.3, revise the definitions for *Commercial grade item*, *Critical characteristics*, *Dedicating entity*, and *Dedication* to read as follows:

§ 21.3 Definitions.

*	*	*	*	*

Commercial grade item. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50 or 10 CFR part 52, or to standard design certifications or standard design approvals under part 52 of this chapter, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (*i.e.*, one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

(3) When applied to standard design certifications and standard design approvals under part 52 of this chapter, commercial grade item means, in addition to the definition in paragraph (1) of this definition, the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof that affects its safety function, that was not designed and will not be manufactured as a basic component.

*   *   *   *   *

Critical characteristics. When applied to nuclear power plants licensed pursuant to 10 CFR part 50 or 10 CFR part 52, or to standard design certifications or standard

design approvals under part 52 of this chapter, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed pursuant to 10 CFR part 50 or 10 CFR part 52, or to standard design certifications or standard design approvals under part 52 of this chapter, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 50 or 10 CFR part 52, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR part 50, appendix

B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR part 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

* * * * *

PART 26 – FITNESS FOR DUTY PROGRAMS

10. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

11. In § 26.3, revise paragraph (a) and the introductory text to paragraph (c) to read as follows:

§ 26.3 Scope.

(a) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57, and holders of a combined license under 10 CFR part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall comply with the requirements of this part, except for subpart K of this part, and implement the FFD program before the initial fuel load into the reactor.

* * * * *

(c) Before the initial fuel load into the reactor, the following licensees and other entities shall comply with the requirements of this part, except for subpart I of this part;

and, no later than the initial fuel load into the reactor, the following licensees and other entities shall comply with the requirements of this part:

*   *   *   *   *

12. Amend § 26.4, by:

a. Revising paragraphs (e)(1), (5), and (6);

b. Adding paragraph (e)(7); and

c. Revising paragraph (f).

The revisions and addition read as follows:

§ 26.4 FFD program applicability to categories of individuals.

*   *   *   *   *

(e) * * *

(1) Serves as security personnel required by the NRC before the initial fuel load into the reactor, at which time individuals who serve as security personnel required by the NRC must meet the requirements applicable to security personnel in paragraph (a)(5) of this section;

*   *   *   *   *

(5) Supervises or manages the construction of safety- or security-related SSCs;

(6) Directs, as defined in § 26.5, or implements the access authorization program, including:

(i) Having access to the information used by the licensee or other entity to make access authorization determinations, including information stored in electronic format;

(ii) Making access authorization determinations;

(iii) Issuing entry-control picture badges in accordance with access authorization determinations;

(iv) Conducting background investigations or psychological assessments used by the licensee or other entity to make access authorization determinations, except that he or she shall be subject to behavioral observation only when he or she is present at the location where the nuclear power plant will be constructed and operated, and licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR part 40 to collect his or her specimens for drug and alcohol testing;

(v) Adjudicating reviews or appeals of access authorization determinations;

(vi) Auditing the access authorization program; or

(vii) Performing any of the activities or having any of the duties listed in paragraph (e)(6) of this section for any C/V upon whom the licensee's or other entity's access authorization program will rely; or

(7) Escorts an individual or small group of individuals, as determined by the licensee or other entity.

(f) Any individual who is constructing or directing the construction of safety- or security-related SSCs must be subject to an FFD program that meets the requirements of subpart K of this part, unless the licensee or other entity subjects the individual to an FFD program that meets all of the requirements of this part, except for subparts I and K of this part, or the individual is escorted.

* * * * *

13. In § 26.5, add the definition for *Escort* in alphabetical order and revise the definition for *Reviewing official* to read as follows:

§ 26.5 Definitions.

*　　*　　*　　*　　*

Escort means a person who is designated by the licensee or other entity to be responsible for directly observing an individual who has been assigned to perform duties and responsibilities or maintain the type of access described in § 26.4(f) but is not subject to the requirements in this part.

*　　*　　*　　*　　*

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c) who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual including, but not limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization, or, for licensees and other entities that receive, after [**EFFECTIVE DATE OF FINAL RULE**], a license or other authorization that requires them to be subject to this part, performing the suitability and fitness evaluation requirement in § 26.419.

*　　*　　*　　*　　*

14. In § 26.401, revise paragraph (b) to read as follows:

§ 26.401 General.

*　　*　　*　　*　　*

(b) Licensees and other entities who intend to implement an FFD program under this subpart shall submit a description of the FFD program and its implementation as part of the license, permit, or limited work authorization application.

*   *   *   *   *

15. In § 26.403, revise paragraph (a) and add a new paragraph (b)(3) to read as follows:

§ 26.403 Written policy and procedures.

(a) Licensees and other entities who implement an FFD program under this subpart shall ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program or escorted. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy.

*   *   *   *   *

(b) * * *

(4) The processing, escorting, and control of individuals under escort and the duties and responsibilities of the escort.

16. In § 26.405, revise paragraph (g) to read as follows:

§ 26.405 Drug and alcohol testing.

*   *   *   *   *

(g) Licensees and other entities shall provide for an MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results and at the licensee's or other entity's discretion, dilute test results obtained through the licensee's or other entity's testing program to determine whether the donor has violated the FFD

policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.419.

17. Revise § 26.419 to read as follows:

§ 26.419 Suitability and fitness evaluations.

Licensees and other entities who implement FFD programs under this subpart shall develop, implement, and maintain procedures for evaluating whether to assign individuals to construct and, for licensees and other entities that receive, after [**EFFECTIVE DATE OF FINAL RULE**], a license or other authorization that requires them to be subject to this part, construct or direct the construction of, safety- and security-related SSCs. These procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse and, for licensees and other entities that receive, after [**EFFECTIVE DATE OF FINAL RULE**], a license or other authorization that requires them to be subject to this part, as determined by the individual designated (i.e., the Reviewing Official) by the licensee or other entity.

PART 50 – DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

18. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201,

202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Sec. 109, Pub. L. 96-295, 94 Stat. 783.

19. Amend § 50.34 by:

a. In paragraph (a)(3)(iii), removing the period at the end of the paragraph and adding in its place a semicolon;

b. Adding new paragraph (a)(3)(iv);

c. Revising the last sentence of paragraph (a)(4);

d. Adding new paragraphs (a)(14) through (16);

e. Revising the second sentence of paragraph (b)(4);

f. Adding a new paragraph (b)(6)(viii);

g. Revising paragraph (b)(9);

h. Adding new paragraphs (b)(13) through (15);

i. Revising paragraph (f) introductory text;

j. Removing and reserving paragraph (f)(1);

k. Revising paragraph (f)(2) introductory text to;

l. Removing and reserving paragraph (f)(2)(i);

m. Revising paragraphs (f)(2)(ii) through (v);

n. Removing and reserving paragraph (f)(2)(vi);

o. Revising paragraphs (f)(2)(vii) and (viii);

p. Removing and reserving paragraph (f)(2)(ix);

q. Revising paragraphs (f)(2)(x) through (xiii), (xiv) introductory text, and (xv);

r. Removing and reserving paragraph (f)(2)(xvi);

s. Revising paragraphs (f)(2)(xvii)(E) and (xviii) through (xxi);

t. Removing and reserving paragraphs (f)(2)(xxii) through (xxv);

u. Revising paragraphs (f)(2)(xxvi) through (xxviii);

v. Revising paragraphs (f)(3)(i) and (ii), (iii)(H), and (iv);

w. Removing and reserving paragraphs (f)(3)(v) and (vi);

x. Revising paragraph (f)(3)(vii)(E);

y. Removing and reserving paragraph (h); and

r. Removing footnote 10 and redesignating footnote 11 as footnote 10.

The additions and revisions read as follows:

§ 50.34 Contents of applications; technical information.

(a) * * *

(3) * * *

(iv) A description and analysis of the fire protection design features for the plant necessary to comply with General Design Criterion 3 of appendix A to this part.

(4) * * * Analysis and evaluation of ECCS cooling performance and the need for high point vents following postulated loss-of-coolant accidents must be performed, as applicable, in accordance with the requirements of § 50.46 and § 50.46a.

* * * * *

(14) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a permit to construct a power reactor under this part must submit a description of the plant-specific probabilistic risk assessment (PRA) and its results.

(15) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a permit to construct a light-water power reactor under this part must submit a description and analysis of design features for the prevention and mitigation of severe accidents.

(16) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a permit to construct a light-water power reactor under this part shall submit a discussion on proposed technical resolutions of all generic issues identified since July 21, 1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21, 1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in the NRC's NUREG-0933, "Resolution of Generic Safety Issues.").

(b) * * *

(4) * * * Analysis and evaluation of ECCS cooling performance following postulated loss-of-coolant accidents shall be performed, as applicable, in accordance with the requirements of § 50.46.

* * * * *

(6) * * *

(viii) A description and analysis of the fire protection design features for the plant necessary to comply with § 50.48 and a description of the fire protection program required by § 50.48 and its implementation.

* * * * *

(9) Provided the terms of § 50.61(b)(1) apply, a description of protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as defined in § 50.61(b)(1) and (2).

* * * * *

(13) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a license to operate a light-water power reactor under this part must submit a description and analysis of design features for the prevention and mitigation of severe accidents.

(14) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a license to operate a power reactor under this part must submit a description of the plant-specific probabilistic risk assessment and its results.

(15) On or after **[EFFECTIVE DATE OF FINAL RULE]**, applicants for a license to operate a light-water power reactor under this part shall submit a discussion on proposed technical resolutions of all generic issues identified since July 21, 1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21, 1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in the NRC's NUREG0933, "Resolution of Generic Safety Issues").

*   *   *   *   *

(f) *Additional TMI-related requirements.* Each applicant for a design certification, design approval, combined license, or manufacturing license under part 52 of this chapter and each applicant for a power reactor construction permit or power reactor operating license under this part must demonstrate compliance with the technically relevant portions of the requirements in paragraphs (f)(2) and (f)(3) of this section.

*   *   *   *   *

(2) The application shall provide sufficient information to demonstrate that the following requirements have been met. The information must be of the type customarily required to satisfy § 50.35(a)(2) or to address unresolved generic safety issues.

*   *   *   *   *

(ii) Establish a program, to begin during construction and follow into operation, for developing and maintaining plant procedures. The scope of the program must include

emergency procedures, reliability analyses, human factors engineering, crisis management, and operator training.

(iii) Provide, for Commission review, a control room design that reflects state-of-the-art human factor principles prior to committing to fabrication or revision of fabricated control room panels and layouts.

(iv) Provide for displaying to operators a minimum set of parameters defining the safety status of the plant, capable of displaying a full range of important plant parameters and data trends on demand, and capable of indicating when process limits are being approached or exceeded.

(v) Provide for automatic indication of the bypassed and operable status of safety systems.

*   *   *   *   *

(vii) Perform radiation and shielding design reviews of spaces around systems that may, as a result of an accident, contain accident source term[10] radioactive materials, and design as necessary to permit adequate access to important areas and to protect safety equipment from the radiation environment.

(viii) Provide a capability to promptly obtain and analyze samples from the reactor coolant system and containment that may contain accident source term[10] radioactive materials without radiation exposures to any individual exceeding 5 rems to the whole body or 50 rems to the extremities. Materials to be analyzed and quantified include certain radionuclides that are indicators of the degree of core damage (e.g., noble gases, radioiodines and cesiums, and nonvolatile isotopes), hydrogen in the containment atmosphere, dissolved gases, chloride, and boron concentrations.

*   *   *   *   *

(x) Provide a test program and associated model development and conduct tests to qualify reactor coolant system relief and safety valves and, for PWRs, PORV block valves, for all fluid conditions expected under operating conditions, transients and accidents. Consideration of anticipated transients without scram (ATWS) conditions shall be included in the test program. Actual testing under ATWS conditions need not be carried out until subsequent phases of the test program are developed.

(xi) Provide direct indication of relief and safety valve position (open or closed) in the control room.

(xii) Provide automatic and manual auxiliary feedwater (AFW) system initiation, and provide auxiliary feedwater system flow indication in the control room. (Applicable to PWRs only)

(xiii) Provide pressurizer heater power supply and associated motive and control power interfaces sufficient to establish and maintain natural circulation in hot standby conditions with only onsite power available. (Applicable to PWRs only)

(xiv) Provide containment isolation systems that:

*   *   *   *   *

(xv) Provide a capability for containment purging/venting designed to minimize the purging time consistent with ALARA principles for occupational exposure. Provide and demonstrate high assurance that the purge system will reliably isolate under accident conditions.

*   *   *   *   *

(xvii) * * *

(E) Noble gas effluents at all potential, accident release points. Provide for continuous sampling of radioactive iodines and particulates in gaseous effluents from all

potential accident release points, and for onsite capability to analyze and measure these samples.

(xviii) Provide instruments that provide in the control room an unambiguous indication of inadequate core cooling, such as primary coolant saturation meters in PWRs, and a suitable combination of signals from indicators of coolant level in the reactor vessel and in-core thermocouples in PWRs and BWRs.

(xix) Provide instrumentation adequate for monitoring plant conditions following an accident that includes core damage.

(xx) Provide power supplies for pressurizer relief valves, block valves, and level indicators such that:

(A) Level indicators are powered from vital buses;

(B) Motive and control power connections to the emergency power sources are through devices qualified in accordance with requirements applicable to systems important to safety and

(C) Electric power is provided from emergency power sources. (Applicable to PWRs only).

(xxi) Design auxiliary heat removal systems such that necessary automatic and manual actions can be taken to ensure proper functioning when the main feedwater system is not operable. (Applicable to BWRs only).

*   *   *   *   *

(xxvi) Provide for leakage control and detection in the design of systems outside containment that contain (or might contain) accident source term[10] radioactive materials following an accident. Applicants shall submit a leakage control program, including an initial test program, a schedule for re-testing these systems, and the actions to be taken for minimizing leakage from such systems. The goal is to minimize potential exposures

to workers and public, and to provide reasonable assurance that excessive leakage will not prevent the use of systems needed in an emergency.

(xxvii) Provide for monitoring of in plant radiation and airborne radioactivity as appropriate for a broad range of routine and accident conditions.

(xxviii) Evaluate potential pathways for radioactivity and radiation that may lead to control room habitability problems under accident conditions resulting in an accident source term[10] release, and make necessary design provisions to preclude such problems.

* * * * *

(3) * * *

(i) Provide administrative procedures for evaluating operating, design and construction experience and for ensuring that applicable important industry experiences will be provided in a timely manner to those designing and constructing the plant.

(ii) Ensure that the quality assurance (QA) list required by criterion II, appendix B, 10 CFR part 50 includes all structures, systems, and components important to safety.

(iii) * * *

(H) Providing a QA role in design and analysis activities.

(iv) Provide one or more dedicated containment penetrations, equivalent in size to a single 3-foot diameter opening, in order not to preclude future installation of systems to prevent containment failure, such as a filtered vented containment system.

* * * * *

(vii) * * *

(E) The degree of top level management oversight and technical control to be exercised by the applicant during design and construction, including the preparation and implementation of procedures necessary to guide the effort.

* * * * *

[10] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events, that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

20. In § 50.46, revise paragraphs (a)(3)(i) and (iii) to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a) * * *

(3)(i) Each applicant for or holder of an operating license or construction permit issued under this part, or a combined license or a manufacturing license issued under part 52 of this chapter, shall estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, a significant change or error is one that results in a calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

* * * * *

(iii) Each applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification regulation) or an applicant for or holder of a standard design approval under part 52 of this chapter shall estimate the

effect of any change to or error in an acceptable evaluation model or in the application of such a model. For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder shall document the nature of the change or error and its estimated effect on the limiting ECCS analysis. For any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (b) of this section, the affected applicant or holder must propose appropriate steps to the Commission within 30 days to demonstrate compliance with § 50.46 requirements, along with a report of the nature of the changes or errors that resulted in an inability to assure compliance and an estimate of their effect on the limiting transient.

* * * * *

21. Amend § 50.54 by:

a. In the introductory text, adding "(q)(2), " after "(n)," in the second sentence and adding a new third sentence;

b. In paragraph (j), removing the word "reactor" and adding in its place the words "utilization facility";

c. In paragraph (k), adding the word "utilization" before the word "facility";

d. In paragraph (m)(1), adding the word "utilization" before the word "facility" wherever it appears;

e. In paragraph (n), adding the words "production or utilization" before the word "facility"; and

f. In paragraph (q)(4), removing the text "after February 21, 2012";

g. In paragraph (q)(5), removing the text "after February 21, 2012,";

h. In paragraph (s)(2)(ii), removing the word “reactor” and adding in its place the words “production or utilization facility”;

i. In paragraph (z), removing the words “utilization facility” and adding in their place the words “nuclear power reactor”; and

j. In paragraph (ee)(1), removing the word “reactor” and adding in its place the words “production or utilization facility”.

The addition reads as follows:

§ 50.54 Conditions of licenses.

* * * The following paragraphs of this section, with the exception of paragraphs (a)(1) through (4), (m)(2) and (3), (o), (q)(6), (r), (s)(1), (u), (w)(1) through (4), (z), (bb), (ff), (gg)(1) and (2), and (jj) are conditions in every non-power production or utilization facility operating license issued under this part.

* * * * *

22. In § 50.59:

a. Amend paragraph (c)(2)(vii) by removing the word “or”;

b. Amend paragraph (c)(2)(viii) by removing the period and adding a semicolon in its place; and

c. Add new paragraphs (c)(2)(ix) and (x) to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(c) * * *

(2) * * *

(ix) For a power reactor licensed after **[EFFECTIVE DATE OF FINAL RULE]**, result in a substantial increase in the probability of an ex-vessel severe accident such that a particular ex-vessel severe accident previously evaluated and determined to be not credible could become credible; or

(x) For a power reactor licensed after **[EFFECTIVE DATE OF FINAL RULE]**, result in a substantial increase in the consequences to the public of a particular ex-vessel severe accident previously evaluated.

*   *   *   *   *

23. In § 50.69, revise paragraph (b)(1) introductory text to read as follows:

§ 50.69 Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors.

*   *   *   *   *

(b) * * *

(1) This section describes alternative requirements for the SSCs of a light-water reactor plant. Holders of an operating license or construction permit under this part, a combined license or manufacturing license under part 52 of this chapter, or a renewed license under part 54 of this chapter may voluntarily comply with the requirements in this section. Compliance with the requirements in this section may be proposed when applying for a standard design certification or approval, manufacturing license, or combined license under part 52 of this chapter and when applying for a construction permit or operating license under this part. For RISC–3 and RISC–4 SSCs, the requirements in this section are an alternative to compliance with the following:

*   *   *   *   *

24. In § 50.71, revise paragraphs (e)(3)(iii) and (h) and add new paragraph (i) to read as follows:

§ 50.71 Maintenance of records, making of reports.

*   *   *   *   *

(e) * * *

(3) * * *

(iii) During the period from the docketing of an application for a combined license under subpart C of part 52 of this chapter until the Commission makes the finding under § 52.103(g) of this chapter, the update to the FSAR must be submitted annually by combined license applicants except those who have requested the NRC to suspend its review of the combined license application, or combined license holders who have informed the NRC that they do not plan to pursue construction. If a combined license applicant requests that the NRC resume its review, or a combined license holder notifies the NRC that the combined license holder plans to commence or resume construction, then the combined license applicant or holder shall submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.

*   *   *   *   *

(h)(1) No later than the scheduled date for initial loading of fuel, each holder of an operating license for a power reactor issued after **[EFFECTIVE DATE OF FINAL RULE]** under this part or a combined license under subpart C of part 52 of this chapter shall develop a level 1 and a level 2 probabilistic risk assessment (PRA). The PRA must cover those initiating events and modes for which NRC-endorsed consensus standards

on PRA exist when the construction permit was issued under this part or the combined license was issued under part 52 of this chapter, as applicable.

(2) Each licensee required to develop a PRA shall maintain the PRA to reflect the as-built, as-operated facility. In addition, the licensee must upgrade the PRA to cover initiating events and modes of operation contained in consensus standards on PRA that are endorsed by the NRC. The upgrade must be completed within 5 years of NRC endorsement of the standard. The PRA must be maintained and upgraded until the permanent cessation of operations under § 50.82(a)(1) or § 52.110(a) of this chapter.

(3) Each licensee required to develop a PRA shall, no later than the date on which the licensee submits an application for a renewed license, upgrade the PRA required by paragraph (h)(1) of this section to cover all modes and all initiating events.

(i) Each licensee shall notify the Commission as specified in § 50.4 or § 52.3 of this chapter, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.

§ 50.100 [Amended]

25. Amend § 50.100 by removing the phrase “or a combined license under part 52 of this chapter”.

26. Amend § 50.109 by:

a. Revising paragraphs (a)(1) introductory text and paragraphs (a)(1)(i) and (iii);

b. Removing and reserving paragraph (a)(1)(v); and

c. Revising paragraph (a)(1)(vii) to read as follows:

§ 50.109 Backfitting.

(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the design approval for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after:

(i) The date of issuance of the construction permit for the facility for facilities having construction permits issued after October 21, 1985. If the construction permit references a standard design certification rule under subpart B of 10 CFR part 52, then the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, provided however, that if any specific backfitting limitations are included in a referenced design certification rule, then those limitations shall govern. If the construction permit uses a reactor manufactured under a manufacturing license under subpart F of 10 CFR part 52, then the provisions of § 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding;

* * * * *

(iii) The date of issuance of the operating license for the facility for facilities having operating licenses. If the operating license references a standard design certification rule under subpart B of 10 CFR part 52, then the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, provided however, that if any specific backfitting limitations are included in a referenced design certification rule, then those limitations shall govern. If the operating license uses a reactor manufactured under a manufacturing license under

subpart F of 10 CFR part 52, then the provisions of § 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding;

*   *   *   *   *

(vii) The date of issuance of a combined license under subpart C of part 52 of this chapter. If the combined license references a standard design certification rule under subpart B of 10 CFR part 52, then the provisions in § 52.63 of this chapter apply with respect to the design matters resolved in the standard design certification rule, provided however, that if any specific backfitting limitations are included in a referenced design certification rule, then those limitations shall govern. If the combined license uses a reactor manufactured under a manufacturing license under subpart F of 10 CFR part 52, then the provisions of § 52.171 of this chapter apply with respect to matters resolved in the manufacturing license proceeding.

*   *   *   *   *

27. Amend appendix E to part 50 by:

a. Revising paragraphs IV.F.2.a.(i) through (iii);

b. Redesignating paragraphs IV.F.2.j.(iii) through (vi) as paragraphs IV.F.2.j.(iv) through (vii), respectively, and adding a new paragraph IV.F.2.j.(iii); and

c. Removing and reserving newly redesignated paragraphs IV.F.2.j.(vi) and (vii).

The revisions read as follows:

Appendix E to Part 50 - Emergency Planning and Preparedness for Production and Utilization Facilities

*   *   *   *   *

IV. * * *

F. * * *

2. * * *

a. * * *

(i) For an operating license issued under this part, this exercise must be conducted within 2 years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway EPZ and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than 1 year prior to issuance of an operating license for full power, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before issuance of an operating license for full power. This exercise need not have State or local government participation

(ii) For a combined license issued under part 52 of this chapter, this exercise must be conducted within 2 years before the scheduled date for initial loading of fuel. If the first full participation exercise is conducted more than 1 year before the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before the scheduled date for initial loading of fuel. This exercise need not have State or local government participation. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

(iii) For a combined license issued under part 52 of this chapter, if the licensee currently has an operating reactor at the site, an exercise, either full or partial

participation, shall be conducted for each subsequent reactor constructed on the site. The exercise for each subsequent reactor is not required if, in its application for a combined license, the licensee includes an analysis that shows that an exercise for the new reactor would not demonstrate any new features (e.g., emergency response organization, facilities, procedures) or capabilities beyond those in the emergency plan for the existing reactor(s). This exercise may be incorporated in the exercise requirements of sections IV.F.2.b. and c. of this appendix. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

* * * * *

j. * * *

(iii) Licensees with 8-calendar-year site exercise cycles as of [**EFFECTIVE DATE OF FINAL RULE**] and licensees that receive their operating licenses issued under this part or combined licenses issued under part 52 of this chapter after [**EFFECTIVE DATE OF FINAL RULE**] shall maintain these site exercise cycles. For a licensee that receives its operating license issued under this part or combined license issued under part 52 of this chapter after [**EFFECTIVE DATE OF FINAL RULE**], an 8-calendar-year exercise cycle shall begin in the calendar year of the completion of the first subsequent exercise conducted to meet the requirements in paragraphs 2.b and c of this section. If the nuclear power reactor operated by a licensee that receives its operating license issued under this part or combined license issued under part 52 of this chapter after [**EFFECTIVE DATE OF FINAL RULE**] is located at a site where one or more nuclear

power reactors is already operating and has a site-wide exercise cycle, then the exercises conducted by the licensee to meet the requirements in paragraphs 2.b and c of this section may be conducted in accordance with the site-wide exercise cycle.

(iv) In each 8-year exercise cycle, nuclear power reactor licensees shall vary the content of scenarios during exercises conducted under paragraph 2 of this section to provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to respond to the following scenario elements:

*   *   *   *   *

PART 51 – ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

28. The authority citation for part 51 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Start Printed Page 67843 Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

29. In § 51.50, revise paragraph (a) to read as follows:

§ 51.50 Environmental report - construction permit, early site permit, or combined license stage.

(a) *Construction permit stage*. Each applicant for a permit to construct a production or utilization facility covered by § 51.20 shall submit with its application a separate document, entitled “Applicant’s Environmental Report—Construction Permit

Stage," which shall contain the information specified in §§ 51.45, 51.51, and 51.52 as modified in this paragraph. Each environmental report shall identify procedures for reporting and keeping records of environmental data, and any conditions and monitoring requirements for protecting the non-aquatic environment, proposed for possible inclusion in the license as environmental conditions in accordance with § 50.36b of this chapter. The construction permit environmental report may reference information contained in a final environmental document previously prepared by the NRC staff. As stated in § 51.23, no discussion of the environmental impacts of the continued storage of spent fuel is required in this report.

(1) *Application referencing an early site permit.* If the construction permit references an early site permit, then the construction permit environmental report must contain:

(i) Information to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit;

(ii) Information to resolve any significant environmental issue that was not resolved in the early site permit proceeding;

(iii) Any new and significant information for issues related to the impacts of construction and operation of the facility that were resolved in the early site permit proceeding;

(iv) A description of the process used to identify new and significant information regarding the NRC's conclusions in the early site permit environmental impact statement. The process must use a reasonable methodology for identifying such new and significant information; and

(v) A demonstration that all environmental terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the

construction permit. Any terms or conditions of the early site permit that could not be met by the time of issuance of the construction permit, must be set forth as terms or conditions of the construction permit.

(2) *Application referencing standard design certification.* If the construction permit references a standard design certification, then the construction permit environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the referenced design certification. If the design certification environmental assessment is referenced, then the construction permit environmental report must contain information to demonstrate that the site characteristics for the construction permit site fall within the site parameters in the design certification environmental assessment.

(3) *Application referencing a manufactured reactor.* If the construction permit application proposes to use a manufactured reactor, then the construction permit environmental report may incorporate by reference the environmental assessment previously prepared by the NRC for the underlying manufacturing license. If the manufacturing license environmental assessment is referenced, then the construction permit environmental report must contain information to demonstrate that the site characteristics for the construction permit site fall within the site parameters in the manufacturing license environmental assessment. The environmental report need not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

(4) *Additional requirement for applications for non-light-water reactors*. For power reactors other than light-water-cooled nuclear power reactors, the environmental report must contain the basis for evaluating the contribution of the environmental effects of fuel cycle activities for the nuclear power reactor.

*	*	*	*	*

PART 52 – LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

30. The authority citation for part 52 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

31. In § 52.1, add the definitions for *Essentially complete nuclear power plant design*, *Tier 1*, *Tier 2 information*, and *Tier 2** in alphabetical order to read as follows:

§ 52.1 Definitions.

*	*	*	*	*

Essentially complete nuclear power plant design means a design that includes all structures, systems, and components that can affect safe operation of the plant except for site-specific elements such as the service water intake structure and the ultimate heat sink.

*	*	*	*	*

Tier 1 means, for design certifications issued after **[EFFECTIVE DATE OF FINAL RULE]**, the qualitative and functional-level portion of the design-related information contained in the generic design control document that is approved and certified by a standard design certification. The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. For design

certifications issued prior to **[EFFECTIVE DATE OF FINAL RULE]**, see the definition of this term in the applicable appendix to this part.

Tier 2 means, for design certifications issued after **[EFFECTIVE DATE OF FINAL RULE]**, the portion of the design-related information contained in the generic design control document that is approved, but not certified, by a standard design certification. Compliance with Tier 2 is required, but generic changes to, and plant-specific departures from, Tier 2 are governed by section VIII of the applicable appendix to this part. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in section VIII of the applicable appendix to this part. Regardless of these differences, an applicant or licensee must meet the requirement in section III.B of the applicable appendix to this part to reference Tier 2 when referencing Tier 1. For design certifications issued prior to **[EFFECTIVE DATE OF FINAL RULE]**, see the definition of this term in the applicable appendix to this part.

*Tier 2** means, for design certifications issued after **[EFFECTIVE DATE OF FINAL RULE]**, the portion of the Tier 2 information, designated as such in the generic design control document, that is subject to the change process in section VIII.B.6 of the applicable appendix to this part. This designation expires for some Tier 2* information under section VIII.B.6. For design certifications issued prior to **[EFFECTIVE DATE OF FINAL RULE]**, see the definition of this term in the applicable appendix to this part.

32. In § 52.3, revise paragraph (b)(1) to read as follows:

§ 52.3 Written communications.

* * * * *

(b) * * *

(1) *Applications for amendment of permits, approvals, and licenses; reports; and other communications.* All written communications (including responses to generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of holders of early site permits, standard design approvals, combined licenses, or manufacturing licenses issued under this part must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (7) of this section: to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under subpart F of this part.

§ 52.6 [Amended]

33. In § 52.6, amend paragraph (b) by removing the phrase “Administrator of the appropriate Regional Office” and adding in its place the phrase “Director of the Office of the Nuclear Reactor Regulation”.

§ 52.11 [Amended]

34. Amend § 52.11(b) by removing the text “52.57,” and “B, C,”.

34. In § 52.17, remove and reserve paragraph (a)(1)(xii) and revise paragraph (b)(4) to read as follows:

§ 52.17 Contents of applications; technical information.

* * * * *

(b) * * *

(4)(i) Under paragraph (b)(1) of this section, if any contacts and arrangements have been made with Federal, State, local governmental agencies regarding the mitigation or elimination of a significant physical impediment(s) to the development of emergency plans, those contacts and arrangements must be described in the site safety analysis report. If any formal agreements or commitments have been established with those agencies, the agreements or commitments also must be included in the site safety analysis report.

(ii) Under paragraph (b)(2)(i) of this section, the site safety analysis report must include a description of all contacts and arrangements made with Federal, State, and local governmental agencies with emergency planning responsibilities that support the proposed major features of the emergency plan. The site safety analysis report also must contain any certifications that have been obtained. Certifications, for purposes of this section, are any documented agreements with Federal, State, or local response organizations stating that the proposed emergency plans are practicable; the agencies are committed to participating in ongoing development of the plans, including any necessary field demonstrations; the agencies are committed to executing their responsibilities under the plan in the event of an emergency; or a combination thereof. If certifications cannot be obtained, the site safety analysis report must contain information, including utility plans, sufficient to show that the proposed major features of the emergency plan provided are acceptable in accordance with the applicable standards of § 50.47 of this chapter and the requirements of appendix E to part 50 of this chapter.

(iii) Under paragraph (b)(2)(ii) of this section, the site safety analysis report must include a description of all contacts and arrangements made with Federal, state, and

local governmental agencies with emergency planning responsibilities. The site safety analysis report also must contain all certifications that have been obtained. These certifications are defined in paragraph (b)(4)(ii) of this section. If certifications cannot be obtained, the site safety analysis report must contain information, including utility plans, sufficient to show that the proposed emergency plan provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

* * * * *

§ 52.18 [Amended]

35. In § 52.18, remove the phrase "there is not significant impediment to the development of emergency plans that cannot be" and add in its place the phrase "any significant impediment(s) to the development of emergency plans identified by the applicant can be".

§ 52.41 [Amended]

36. In 52.41, amend paragraph (b)(1) by removing the phrase "an essentially complete" and adding in its place the word "a".

37. Amend § 52.47 by:

a. In paragraph (a) introductory text, adding the words "identifies Tier 1, Tier 2, and Tier 2* information," after the word "facility,";

b. In paragraph (a)(2)(iii), removing the word "and";

c. In paragraph (a)(2)(iv)(B), adding the word “and” at the end of the paragraph;

d. Adding paragraph (a)(2)(v);

c. In paragraph (a)(4), adding the words “, as applicable,” after the words “shall be performed”;

d. In paragraph (a)(8), removing the text “, except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v)”;

e. Removing and reserving paragraph (a)(9);

f. In paragraph (a)(14), removing the word “A” and adding in its place the words “Provided the terms of § 50.61(b)(1) of this chapter apply, a”;

g. In paragraph (a)(15), removing the word “Information” and adding in its place the words “Provided the terms of § 50.62(a) of this chapter apply, information”;

h. In paragraph (a)(16), removing the word “A” and adding in its place the words “Provided the terms of § 50.63(a)(1) of this chapter apply, a”; and

i. Revising paragraph (a)(21).

The additions and revisions read as follows:

§ 52.47 Contents of applications; technical information.

* * * * *

(a) * * *

(2) * * *

(v) The design information designated as Tier 1, 2, and 2*, as defined in § 52.1;

* * * * *

(21) Proposed technical resolutions of all generic issues identified since July, 21 1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21, 1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months

before the docket date of the application (for example, the issues listed in the NRC's NUREG-0933, "Resolution of Generic Safety Issues,";

* * * * *

§ 52.55 [Amended]

38. Amend § 52.55 by removing the section heading "Duration of certification" and adding in its place the section heading "Referencing a design certification application" and removing and reserving paragraphs (a) and (b).

§§ 52.57, 52.59, and 52.61 [Amended]

39. Remove and reserve §§ 52.57, 52.59, and 52.61.

§ 52.63 [Amended]

40. In § 52.63:

a. Amend paragraph (a)(1) introductory text by removing the words "while a standard design certification rule is in effect under §§ 52.55 or 52.61,";

b. Amend paragraph (a)(4) introductory text by removing the words "while a design certification rule is in effect under § 52.55 or § 52.61";

c. Amend paragraph (b)(1) by removing the third sentence.

41. In § 52.73(a), revise the first sentence to read as follows:

§ 52.73 Relationship to other subparts.

(a) An application for a combined license under this subpart may, but need not, reference a standard design certification, standard design approval, or more than one standard design approval, provided each referenced standard design approval is for different portions of the same reactor design, or manufacturing license issued under subparts B, E, or F of this part, respectively, or an early site permit issued under subpart A of this part. * * *

* * * * *

42. In § 52.79:

a. Amend paragraph (a)(5) by adding the words ", as applicable," after the words "shall be performed";

b. Amend paragraph (a)(7) by removing the word "A" and adding in its place the words "Provided the terms of § 50.61(b)(1) of this chapter apply, a";

c. Amend paragraph (a)(9) by removing the word "The" and adding in its place the words "Provided the terms of § 50.63(a)(1) of this chapter apply, the";

d. Amend paragraph (a)(12) by removing the word "A" and adding in its place the words "For water-cooled power reactors, a";

e. Amend paragraph (a)(13) by removing the word "A" and adding in its place the words "For water nuclear power reactors, a";

f. Amend paragraph (a)(16)(ii) by removing the word "A" and adding in its place the words "For water-cooled power reactors, a";

g. Amend paragraph (a)(17) by removing the words ", with the exception of § 50.34(f)(1)(xii), (f)(2)(ix), (f)(2)(xxv), and (f)(3)(v)";

h. Revise paragraph (a)(20);

i. Remove and reserve paragraph (a)(41);

j. Amend paragraph (a)(42) by removing the word “Information” and adding in its place the words “Provided the terms of § 50.62(a) of this chapter apply, information”;

k. Revise paragraphs (c) introductory text, and (c)(1) and (2); and

l. Add paragraphs (c)(3) and (4) and (d)(4) and (5).

The additions and revisions read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(20) Proposed technical resolutions of all generic issues identified since July 21,1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21,1999, that are relevant to the design. These issues are based upon the applicant’s review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in the NRC’s NUREG-0933, “Resolution of Generic Safety Issues.”

* * * * *

(c) If the combined license application references one or more standard design approvals, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with each design approval referenced, provided, however, that the final safety analysis report must either include or incorporate by reference each standard design approval final safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in each design approval. In addition, the plant-specific PRA information must

use the PRA information for each design approval and must be updated to account for site-specific design information and any design changes or departures.

(2) The final safety analysis report must demonstrate that all terms and conditions that have been included in each design approval will be satisfied by the date of issuance of the combined license.

(3) The final safety analysis report must demonstrate that the interfaces between a referenced standard design approval and the balance of the nuclear power plant not described in a referenced standard design approval conform to the descriptions, analyses, and evaluations stated in the referenced standard final safety analysis report.

(4) If the combined license application references more than one standard design approval, the final safety analysis report must demonstrate that the interfaces between each of the referenced standard design approvals conform to the descriptions, analyses, and evaluations stated in each referenced standard final safety analysis report.

(d) * * *

(4) The combined license application must incorporate by reference the appendix to part 52 containing the standard design certification referenced in the combined license application.

(5) The combined license application must include:

(i) A plant-specific DCD containing the same type of information as the generic DCD for the referenced design certification, as modified and supplemented by the applicant's exemptions and departures;

(ii) The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of the referenced design certification appendix;

(iii) Plant-specific technical specifications, consisting of the generic and site-specific technical specifications, that are required by 10 CFR 50.36 and 50.36a;

(iv) Information demonstrating that the site characteristics fall within the site parameters and that the interface requirements have been met;

(v) Information that addresses the COL action items; and

(vi) Information required by 10 CFR 52.47 that is not within the scope of the referenced design certification appendix.

*   *   *   *   *

43. In § 52.93, redesignate paragraphs (c) and (d) as paragraphs (d) and (e), respectively, add new paragraph (c), and revise newly designated paragraphs (d) and (e) to read as follows:

§ 52.93 Exemptions and variances.

*   *   *   *   *

(c) An applicant for a construction permit, combined license, or manufacturing license who has filed an application referencing a standard design approval issued under subpart E of this part may include in the application a request for a variance from one or more design characteristics, site parameters, terms and conditions, or approved design of the reactor or major portions thereof. In determining whether to grant the variance, the NRC staff shall apply the same technically relevant criteria as were applicable to the application for the original or amended standard design approval. Once a construction permit, combined license, or manufacturing license is issued, a referenced standard design approval is subsumed, to the extent referenced, into the construction permit, combined license, or manufacturing license.

(d) An applicant for a combined license who has filed an application referencing a nuclear power reactor manufactured under a manufacturing license issued under subpart F of this part may include in the application a request for a departure from one or

more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of 10 CFR 52.7.

(e) Issuance of a variance under paragraphs (b) or (c) or a departure under paragraph (d) of this section is subject to litigation during the combined license proceeding in the same manner as other issues material to that proceeding.

§ 52.97 [Amended]

44. In § 52.97, amend paragraph (a)(2) by removing the words “have been met” wherever they appear and adding in their place the words “are met”, and by removing the words ”will be” and adding in their place the word “are” in the second sentence.

§ 52.99 [Amended]

45. In § 52.99(a), second sentence, remove “1 year” and add in its place “6 months” and remove “30 days” and add in its place “60 days”.

46. In § 52.133, revise paragraph (a) to read as follows:

§ 52.133 Relationship to other subparts.

(a) This subpart applies to a person that requests a standard design approval from the NRC staff separately from an application for a construction permit filed under 10 CFR part 50 or a combined license filed under subpart C of this part. An applicant for a construction permit, operating license, combined license, or manufacturing license may reference a standard design approval, or more than one standard design approval,

provided each referenced standard design approval is for different portions of the same reactor design.

*   *   *   *   *

47. In § 52.137:

a. Amend paragraph (a)(4) by adding the words ", as applicable," after the words "shall be performed";

b. Amend paragraph (a)(8) by removing the words ", except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v) of 10 CFR 50.34(f)";

c. Remove and reserve paragraph (a)(9);

d. Amend paragraph (a)(14) by removing the word "A" and adding in its place the words "Provided the terms of § 50.61(b)(1) of this chapter apply, a";

e. Amend paragraph (a)(15) by removing the word "Information" and adding in its place the words "Provided the terms of § 50.62(a) of this chapter apply, information"; and

f. Amend paragraph (a)(16) by removing the word "The" and adding in its place the words "Provided the terms of § 50.63(a)(1) of this chapter apply, the"; and

g. Revise paragraph (a)(21) to read as follows.

§ 52.137 Contents of applications; technical information.

(a) * * *

(21) Proposed technical resolutions of all generic issues identified since July 21,1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21,1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months

before the docket date of the application (for example, the issues listed in the NRC's NUREG-0933, "Resolution of Generic Safety Issues."

* * * * *

48. In § 52.145:

a. Redesignate paragraph (c) as paragraph (f); and

b. Add new paragraphs (c), (d), and (e);

The additions read as follows:

§ 52.145 Finality of standard design approvals; information requests.

* * * * *

(c) Upon issuance of a construction permit, operating license, combined license, or manufacturing license, any referenced standard design approval is subsumed, to the extent referenced, into the construction permit, operating license, combined license, or manufacturing license.

(d) An applicant for a construction permit, operating license, combined license, or manufacturing license referencing one or more standard design approvals may include in its application a request for a variance from one or more provisions of the standard design approval, or from the associated final safety analysis report. In determining whether to grant the variance, the NRC staff shall apply the same technically relevant criteria applicable to the application for the original standard design approval.

(e) The holder of a standard design approval may not make changes to the design of the nuclear power reactor or major portions thereof without prior NRC staff approval. The request for a change to the design must be in the form of an amendment application as specified in § 52.3 of this chapter. The application shall fully describe the

changes desired, following the form prescribed for original applications insofar as it applies. The NRC staff's review of the amendment application will be guided by the applicable considerations governing the issuance of the initial approval. Upon completion of its review of the application for the amendment the NRC staff shall publish a determination in accordance with § 52.143.

*   *   *   *   *

§ 52.147 [Removed and Reserved]

49. Remove and reserve § 52.147.

50. In § 52.153, revise paragraph (b) to read as follows:

§ 52.153 Relationship to other subparts.

*   *   *   *   *

(b) Subpart B of this part governs the certification by rulemaking of the design of standard nuclear power facilities. Subpart E of this part governs the NRC staff review and approval of standard designs for a nuclear power facility. A manufacturing license applicant may reference a standard design certification or a standard design approval, or more than one standard design approval, provided each referenced standard design approval is for different portions of the same reactor design. These subparts may also be used independently of the provisions in this subpart.

51. In § 52.157:

a. Revise paragraph (f)(6);

b. Amend paragraph (f)(12) by removing the words “, except paragraphs (f)(1)(xii), (f)(2)(ix), and (f)(3)(v)”;

c. Revise paragraph (f)(28); and

d. Remove and reserve paragraph (f)(30).

The revisions read as follows:

§ 52.157 Contents of applications; technical information in final safety analysis report.

* * * * *

(f) * * *

(6) A description of the program, and its implementation, required by § 50.49(a) of this chapter for the environmental qualification of electric equipment important to safety and the list of electric equipment important to safety that is required by 10 CFR 50.49(d);

* * * * *

(28) Proposed technical resolutions of all generic issues identified since July 21,1999, unresolved safety issues, and medium- and high-priority generic safety issues identified before July 21,1999, that are relevant to the design. These issues are based upon the applicant's review of publicly available information published up to 6 months before the docket date of the application (for example, the issues listed in the NRC’s NUREG-0933, "Resolution of Generic Safety Issues.")

* * * * *

52. In § 52.171:

a. Revise paragraph (a)(1); and

b. Amend paragraph (b)(2) by removing the phrase “, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure”.

The revision reads as follows:

§ 52.171 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in 10 CFR 50.109, the Commission may not modify, rescind, or impose new requirements on the design of a nuclear power reactor manufactured or being manufactured under a manufacturing license, or the requirements for the manufacture of a nuclear power reactor manufactured or being manufactured under a manufacturing license, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

*   *   *   *   *

53. Revise § 52.173 to read as follows:

§ 52.173 Duration of manufacturing license.

(a) A manufacturing license issued under this subpart may be valid for not less than 5, nor more than 40 years from the date of issuance. A holder of a manufacturing license may not initiate the manufacture of a reactor less than 3 years before the expiration of the license even though a timely application for renewal has been docketed with the NRC. Upon expiration of the manufacturing license, the manufacture of any

uncompleted reactors must cease unless a timely application for renewal has been docketed with the NRC.

(b) An applicant for a construction permit or a combined license may, at its own risk, reference in its application a design for which a manufacturing license application has been docketed but not granted.

54. Revise § 52.181 to read as follows:

§ 52.181 Duration of renewal.

A renewed manufacturing license may be issued for a term of not less than 5, nor more than 40 years, plus any remaining years on the manufacturing license then in effect before renewal. The renewed license shall be subject to the requirements of §§ 52.171 and 52.175.

§ 52.303 [Amended]

55. In § 52.303, amend paragraph (b) by removing the section numbers “52.57, 52.59, 52.61,”, “52.147,”, and “52.179, 52.181,”.

56. In appendix A to part 52:

a. Remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively;

b. Remove and reserve paragraph VII;

c. Amend paragraph VIII.B.3 introductory text by removing the words “, while this appendix is in effect under § 52.55 or § 52.61”;

d. Amend paragraph VIII.B.5.a. by adding a sentence to the end of the paragraph;

e. Add a new paragraph VIII.B.5.h; and

f. Revise paragraph VIII.C.5, second sentence.

The additions and revisions read as follows:

Appendix A to Part 52 - Design Certification Rule for the U.S. Advanced Boiling Water Reactor

* * * * *

VIII. * * *

B. * * *

5.

a. * * * The provisions in paragraph B.5.b of this section do not apply to proposed departures when applicable regulations establish more specific criteria for accomplishing such departures.

* * * * *

h. * * *

(1) Notwithstanding the provisions of paragraph B.5.a of this section, during the period when the plant is being constructed prior to a Commission finding under 10 CFR 52.103(g), a licensee may construct an SSC in accordance with a proposed departure from Tier 2 or Tier 2* information, excluding the Tier 2* departures covered under paragraph B.6.b of this section, of the plant-specific DCD for a COL covered by 10 CFR 52.98(c)(1) without first obtaining a license amendment, provided:

i. A licensee must submit the request for a license amendment required to authorize the departure from Tier 2 or Tier 2* of the plant-specific DCD within 45 days after the licensee approves the design of an SSC as changed and begins construction of the SSC;

ii. A licensee is not permitted to begin construction in accordance with a design that departs from Tier 2 or Tier 2* unless the SSC under construction is located within the restricted area defined in 10 CFR part 20 and described in the FSAR, as updated; and

iii. If the NRC does not approve a request for a license amendment as submitted, the licensee is obligated to construct the facility in accordance with the FSAR, as updated, including the plant-specific DCD.

(2) Notwithstanding the provisions of paragraph B.5.a of this section regarding the license amendment required under paragraph B.5.b of this section, after the 10 CFR 52.103(g) finding by the Commission, a prior approval from the NRC is required before implementing a proposed departure from Tier 2 information under paragraph B.5.b of this section. A prior approval is required for departures from Tier 2* in accordance with paragraphs B.5.a and B.6.b of this section.

* * * * *

C. * * *

5. * * * Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate either why special circumstances as defined in 10 CFR 2.335 are present or that the change is necessary for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in section V of this appendix. * * *

* * * * *

Appendix B to Part 52 [Removed and Reserved]

57. Remove and reserve appendix B to part 52.

Appendix C to Part 52 [Removed and Reserved]

58. Remove and reserve appendix C to part 52.

59. In appendix D to part 52:

a. Remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively;

b. Amend the first sentence in paragraph V.A by adding the number “52” in numerical order;

c. Remove and reserve section VII;

d. Amend paragraph VIII.B.3 introductory text by removing the words “while this appendix is in effect under 10 CFR 52.55 or 52.61”;

e. Amend paragraph VIII.B.5.a. by adding a sentence to the end of the paragraph;

f. Add a new paragraph VIII.B.5.h;

g. Revise paragraph VIII.C.5, second sentence; and

h. Remove and reserve paragraph IX.

The additions and revisions read as follows:

Appendix D to Part 52 - Design Certification Rule for the AP1000 Design

*   *   *   *   *

VIII. * * *

B. * * *

5.

a. * * * The provisions in paragraph B.5.b of this section do not apply to proposed departures when applicable regulations establish more specific criteria for accomplishing such departures.

* * * * *

h. * * *

(1) Notwithstanding the provisions of paragraph B.5.a of this section, during the period when the plant is being constructed prior to a Commission finding under 10 CFR 52.103(g), a licensee may construct an SSC in accordance with a proposed departure from Tier 2 or Tier 2* information, excluding the Tier 2* departures covered under paragraph B.6.b of this section, of the plant-specific DCD for a COL covered by 10 CFR 52.98(c)(1) without first obtaining a license amendment, provided:

i. A licensee must submit the request for a license amendment required to authorize the departure from Tier 2 or Tier 2* of the plant-specific DCD within 45 days after the licensee approves the design of an SSC as changed and begins construction of the SSC;

ii. A licensee is not permitted to begin construction in accordance with a design that departs from Tier 2 or Tier 2* unless the SSC under construction is located within the restricted area defined in 10 CFR part 20 and described in the FSAR, as updated; and

iii. If the NRC does not approve a request for a license amendment as submitted, the licensee is obligated to construct the facility in accordance with the FSAR, as updated, including the plant-specific DCD.

(2) Notwithstanding the provisions of paragraph B.5.a of this section regarding the license amendment required under paragraph B.5.b of this section, after the 10 CFR 52.103(g) finding by the Commission, a prior approval from the NRC is required before

implementing a proposed departure from Tier 2 information under paragraph B.5.b of this section. A prior approval is required for departures from Tier 2* in accordance with paragraphs B.5.a and B.6.b of this section.

* * * * *

C. * * *

5. * * * Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate either why special circumstances as defined in 10 CFR 2.335 are present, or that the change is necessary for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in section V of this appendix. * * *

* * * * *

60. In appendix E to part 52:

a. Remove paragraph IV.A.1 and redesignate paragraphs IV.A.2, 3, and 4 as paragraphs IV.A.1, 2, and 3, respectively;

b. Revise paragraph IV.A.1;

c. Amend paragraph V.A by adding the number “52” in numerical order;

d. Remove and reserve section VII;

e. Amend paragraph VIII.B.3 introductory text by removing the words “while this appendix is in effect under 10 CFR 52.55 or 52.61”;

f. Amend paragraph VIII.B.5.a by adding a sentence to the end of the paragraph;

g. Add a new paragraph VIII.B.5.h; and

h. Revise paragraph VIII.C.5, second sentence.

The additions and revisions read as follows:

Appendix E to Part 52 - Design Certification Rule for the ESBWR Design

* * * * *

IV. * * *

A.* * *

1. Include, as part of its application:

a. Information demonstrating that hurricane loads on those structures, systems, and components described in Section 3.3.2 of the generic DCD are either bounded by the total tornado loads analyzed in Section 3.3.2 of the generic DCD or will meet applicable NRC requirements with consideration of hurricane loads in excess of the total tornado loads; and hurricane-generated missile loads on those structures, systems, and components described in Section 3.5.2 of the generic DCD are either bounded by tornado-generated missile loads analyzed in Section 3.5.1.4 of the generic DCD or will meet applicable NRC requirements with consideration of hurricane-generated missile loads in excess of the tornado-generated missile loads; and

b. Information demonstrating that the spent fuel pool level instrumentation is designed to allow the connection of an independent power source, and that the instrumentation will maintain its design accuracy following a power interruption or change in power source without requiring recalibration.

2. Include, in the plant-specific DCD, the sensitive, unclassified, non-safeguards information (including proprietary information and security-related information) and safeguards information referenced in the ESBWR generic DCD.

3. Include, as part of its application, a demonstration that an entity other than GE-Hitachi Nuclear Energy is qualified to supply the ESBWR design unless GE-Hitachi Nuclear Energy supplies the design for the applicant's use.

* * * * *

VIII. * * *

B. * * *

5.

a. * * * The provisions in paragraph B.5.b of this section do not apply to proposed departures when applicable regulations establish more specific criteria for accomplishing such departures.

* * * * *

h. * * *

(1) Notwithstanding the provisions of paragraph B.5.a of this section, during the period when the plant is being constructed prior to a Commission finding under 10 CFR 52.103(g), a licensee may construct an SSC in accordance with a proposed departure from Tier 2 or Tier 2* information, excluding the Tier 2* departures covered under paragraph B.6.b of this section, of the plant-specific DCD for a COL covered by 10 CFR 52.98(c)(1) without first obtaining a license amendment, provided:

i. A licensee must submit the request for a license amendment required to authorize the departure from Tier 2 or Tier 2* of the plant-specific DCD within 45 days after the licensee approves the design of an SSC as changed and begins construction of the SSC;

ii. A licensee is not permitted to begin construction in accordance with a design that departs from Tier 2 or Tier 2* unless the SSC under construction is located within the restricted area defined in 10 CFR part 20 and described in the FSAR, as updated; and

iii. If the NRC does not approve a request for a license amendment as submitted, the licensee is obligated to construct the facility in accordance with the FSAR, as updated, including the plant-specific DCD.

(2) Notwithstanding the provisions of paragraph B.5.a of this section regarding the license amendment required under paragraph B.5.b of this section, after the 10 CFR 52.103(g) finding by the Commission, a prior approval from the NRC is required before implementing a proposed departure from Tier 2 information under paragraph B.5.b of this section. A prior approval is required for departures from Tier 2* in accordance with paragraphs B.5.a and B.6.b of this section.

*   *   *   *   *

C. * * *

5. * * * Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate either why special circumstances as defined in 10 CFR 2.335 are present, or that the change is necessary for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in section V of this appendix. * * *

*   *   *   *   *

61. In appendix F to part 52:

a. Remove paragraphs IV.A.1 and 2 and redesignate paragraphs IV.A.3 and 4 as paragraphs IV.A.1 and 2, respectively;

b. Remove and reserve section VII;

c. Amend paragraph VIII.B.3 introductory text by removing the words “, while this appendix is in effect under § 52.55 or § 52.61”;

d. Amend paragraph VIII.B.5.a. by adding a sentence to the end of the paragraph;

e. Add a new paragraph VIII.B.5.h; and

f. Revise paragraph VIII.C.5, second sentence.

The additions and revisions read as follows:

Appendix F to Part 52 - Design Certification Rule for the APR1400 Design

*   *   *   *   *

VIII. * * *

B. * * *

5.

a. * * * The provisions in paragraph B.5.b of this section do not apply to proposed departures when applicable regulations establish more specific criteria for accomplishing such departures.

*   *   *   *   *

h. * * *

(1) Notwithstanding the provisions of paragraph B.5.a of this section, during the period when the plant is being constructed prior to a Commission finding under 10 CFR 52.103(g), a licensee may construct an SSC in accordance with a proposed departure from Tier 2 or Tier 2* information, excluding the Tier 2* departures covered under paragraph B.6.b of this section, of the plant-specific DCD for a COL covered by 10 CFR 52.98(c)(1) without first obtaining a license amendment, provided:

i. A licensee must submit the request for a license amendment required to authorize the departure from Tier 2 or Tier 2* of the plant-specific DCD within 45 days after the licensee approves the design of an SSC as changed and begins construction of the SSC;

ii. A licensee is not permitted to begin construction in accordance with a design that departs from Tier 2 or Tier 2* unless the SSC under construction is located within

the restricted area defined in 10 CFR part 20 and described in the FSAR, as updated; and

iii. If the NRC does not approve a request for a license amendment as submitted, the licensee is obligated to construct the facility in accordance with the FSAR, as updated, including the plant-specific DCD.

(2) Notwithstanding the provisions of paragraph B.5.a of this section regarding the license amendment required under paragraph B.5.b of this section, after the 10 CFR 52.103(g) finding by the Commission, a prior approval from the NRC is required before implementing a proposed departure from Tier 2 information under paragraph B.5.b of this section. A prior approval is required for departures from Tier 2* in accordance with paragraphs B.5.a and B.6.b of this section.

*   *   *   *   *

C. * * *

5. * * * Such petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate either why special circumstances as defined in 10 CFR 2.335 are present, or that the change is necessary for compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in section V of this appendix. * * *

*   *   *   *   *

PART 55 – OPERATORS' LICENSES

62. The authority citation for part 55 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 107, 161, 181, 182, 183, 186, 187, 223, 234 (42 U.S.C. 2137, 2201, 2231, 2232, 2233, 2236, 2237, 2273, 2282); Energy

Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); 44 U.S.C. 3504 note.

63. In § 55.4, revise the definitions for *plant-referenced simulator* and *reference plant* to read as follows:

§ 55.4 Definitions.

*   *   *   *   *

Plant-referenced simulator means a simulator modeling the systems of the reference plant with which the operator interfaces or, for a plant that is being constructed, will interface, in the control room, including operating consoles, and which permits use of the reference plant's procedures.

Reference plant means the specific nuclear power plant from which a simulation facility's control room configuration, system control arrangement, and design data are derived. The reference plant may or may not be actually constructed.

*   *   *   *   *

64. In § 55.31, redesignate paragraph (a)(4) as paragraph (a)(4)(i) and remove the words "of this part", and add new paragraph (a)(4)(ii) to read as follows:

§ 55.31 How to apply.

(a) * * *

(4) * * *

(ii) If the NRC Form 398 is submitted before the facility licensee is required to have the requalification program described in § 55.59 in effect as described under

§ 50.54(i-1) of this chapter, describe how the applicant's knowledge, skills, and abilities will be maintained sufficient to safely perform the functions of an operator or senior operator after the applicant passes the written examination described in §§ 55.41 and 55.43 and the operating test described in § 55.45, and prior to participation as a licensed operator in the requalification program. In lieu of this description, the Commission will accept a statement that the applicant will participate in a Commission-approved continuing training program developed by using a systems approach to training within 3 months of receiving notice that the applicant has passed the written examination and operating test;

* * * * *

65. In § 55.45, revise paragraph (b) to read as follows:

§ 55.45 Operating tests.

* * * * *

(b) *Implementation - Administration.* (1) The operating test will be administered in a plant walkthrough and in either a simulation facility that the Commission has approved for use after application has been made by the facility licensee under § 55.46(b), a plant-referenced simulator (§ 55.46(c)), or the plant, if approved for use in the administration of the operating test by the Commission under § 55.46(b).

(2) If a facility is under construction, suitable alternatives may be used in lieu of the plant walkthrough portion of the operating test.

66. In § 55.46, revise paragraph (c)(2)(i) to read as follows:

§ 55.46 Simulation facilities.

* * * * *

(c) * * *

(2) * * *

(i) The plant-referenced simulator utilizes models relating to nuclear and thermal-hydraulic characteristics that either replicate the most recent core load in the nuclear power reference plant for which a license is being sought, or prior to initial fuel load, replicate the intended initial core load for the nuclear power reference plant for which a license is being sought; and

* * * * *

67. Amend § 55.47 by:

a. Revising paragraph (a)(1);

b. Removing paragraphs (a)(2) and (3);

c. Redesignating paragraphs (b) and (c) as paragraphs (a)(2) and (3), respectively; and

c. Adding a new paragraph (b) to read as follows:

§ 55.47 Waiver of examination and test requirements.

(a) * * *

(1) Has had extensive actual operating experience at a comparable facility, as determined by the Commission, within two years before the date of application; has discharged his or her responsibilities competently and safely and is capable of continuing to do so; and has learned the operating procedures for, and is qualified to operate competently and safely, the facility designated in the application.

*   *   *   *   *

(b) On application, the Commission may waive any or all of the requirements for a written examination and operating test for a licensee who applies for a license to operate one or more subsequent units at a multiunit site, licensed collectively or individually, if it finds that the:

(1) Subsequent unit(s) is/are approved to be, or was/were constructed to, the same standard design or modular design, as defined in § 52.1 of this chapter, as the unit(s) on which the applicant is already licensed, or the subsequent unit(s) is/are otherwise essentially identical to the unit(s) on which the applicant is already licensed; and

(2) The applicant has been sufficiently trained on the differences between the units.

PART 70 –- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

68. The authority citation for part 70 is revised to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§ 70.22 [Amended]

69. In § 70.22, amend paragraph (k) by removing the phrase “part 50 of this chapter,” and adding in its place the phrase “part 50 or 52 of this chapter, provided that

the special nuclear material is located within a protected area and protected pursuant to 10 CFR 73.55,”.

PART 73 – PHYSICAL PROTECTION OF PLANTS AND MATERIALS

70. The authority citation for part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

§ 73.55 [Amended]

71. In § 73.55, amend paragraph (a)(4) by removing the phrase “before fuel is allowed onsite (protected area)” and adding in its place the phrase “before initial fuel load into the reactor”.

§ 73.56 [Amended]

72. In § 73.56, amend paragraph (a)(3) by removing the phrase “before fuel is allowed onsite (protected area)” and adding in its place the phrase “before initial fuel load into the reactor”.

§ 73.67 [Amended]

73. In § 73.67, amend paragraph (d) introductory text and paragraph (f) introductory text by removing the phrase “part 50, shall” and adding in its place the

phrase “part 50 or 52 of this chapter, provided that the special nuclear material is located within a protected area and protected in accordance with § 73.55, shall”.

Dated <MONTH DAY, 2022.>

For the Nuclear Regulatory Commission.

Brooke. P. Clark,
Secretary of the Commission.