NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 50, 51, 52, 53, 54, 71, and 100

[NRC–2025–0975]

RIN 3150–AL44

Modernizing Reactor Licensing, Safety Oversight, and Siting Practices

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: Consistent with Executive Order 14300, ''Ordering the Reform of the Nuclear Regulatory Commission,'' the U.S. Nuclear Regulatory Commission (NRC) is conducting a review and wholesale revision of its regulations. This proposed rule aims to modernize reactor licensing, safety oversight, and siting practices addressing sections 5(f), 5(h), and 5(i) of Executive Order 14300, and additional items that contribute to adding additional generation to the electrical grid. Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of further changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking.

DATES: Comments must be submitted electronically using *https://www.regulations.gov* by 11:59 p.m. eastern time on August 31, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration of only comments received before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2025–0975, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on *https://www.regulations.gov* to view public comments.

You can read a plain language description of this proposed rule at *https://www.regulations.gov/docket/NRC-2025-0975.* 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: Daniel Doyle, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3748, email: *Daniel.Doyle@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the NRC to undertake a review and wholesale revision of its regulations in title 10 of the *Code of Federal Regulations* (10 CFR) and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(f) of E.O. 14300, which directs the NRC to ''[e]stablish stringent thresholds for circumstances in which the NRC may demand changes to reactor design once construction is underway''; section 5(h) of E.O. 14300, which directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments focus on credible, realistic risks''; and section 5(i) of E.O. 14300, which directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of additional changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking.

These changes are the culmination of decades of combined experience, feedback from nuclear experts, lessons learned by the NRC and industry, international experience, and prior efforts to modernize the regulatory framework. They have undergone thoughtful preparation and internal vetting by the NRC technical experts. While some changes in this rule had not been advanced as regulatory priorities, the direction in the E.O. catalyzed agency efforts to accelerate modernization of 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' and 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' and make conforming changes to 10 CFR part 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants.'' Therefore, this proposed rule aims to modernize reactor licensing, safety oversight, and siting practices addressing sections 5(f), 5(h), and 5(i) of E.O. 14300 and additional items that would contribute to adding generation to the electrical grid. In developing the proposed changes, the NRC has considered the benefits of increased availability of, and innovation in, nuclear power to our economic and national security consistent with section 501(a) of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) and section 3 of E.O. 14300.

B. Major Provisions

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

Expedited Construction of Certain Structures, Systems, and Components

The NRC is proposing to amend its regulations applicable to the definition of construction in 10 CFR 50.10, ''License required; limited work authorization,'' 10 CFR 51.4, ''Definitions,'' and 10 CFR 53.020, ''Definitions,'' in order to focus the scope of activities that are considered construction on structures, systems, and components (SSCs) for which construction can affect attributes of the SSC material to the SSC's capability to perform a safety-significant function and thereby reduce the cost impact of the current definition of construction. Additionally, the NRC proposes to include new paragraphs in 10 CFR 50.10(h) and 53.1130(e), which would issue a general license for beginning construction upon docketing an application for a license that would authorize construction of a nuclear plant, subject to conditions that ensure safety, security, and appropriate environmental review.

Determinate and Data-Backed Thresholds for Reactor Safety Assessments

The NRC is proposing to amend its regulations by revising 10 CFR 50.2, ''Definitions,'' to add the terms ''design basis event'' (DBE) and ''beyond design basis event'' (BDBE). The proposed changes also include a conforming revision to the definition of DBE in 10 CFR 50.49, ''Environmental qualification of electric equipment important to safety for nuclear power plants.'' In parallel with the proposed changes, the NRC has developed draft regulatory guidance (DG)-1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' which (1) establishes determinate and data-backed thresholds for categorizing events into defined bins, (2) outlines graded assessment approaches for DBEs and BDBEs, and (3) clarifies the process for selecting ''design bases'' controlling parameters used as reference bounds in the design of SSCs.

Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

The NRC is proposing to revise the regulations in 10 CFR 50.49 to delete footnote 3, which clarifies that safety-related electric equipment is referred to as Class 1E equipment in Institute of Electrical and Electronics Engineers (IEEE) Standard 323–1974. The reference in this footnote is now unnecessary because the NRC has established the connection between ''safety-related'' electric equipment and ''Class 1E'' equipment elsewhere.

Expanded Alternative Requests Under 10 CFR 50.55a(z)

The NRC is proposing to amend its regulations to allow licensees to request a broader scope of alternatives to the requirements in 10 CFR 50.55a, ''Codes and standards.'' Currently, alternatives under 10 CFR 50.55a(z), ''Alternatives to codes and standards requirements,'' are limited to the requirements in 10 CFR 50.55a(b), ''Use and conditions on the use of standards,'' through (h), ''Protection and safety systems.'' Expanding the scope of alternatives permitted under 10 CFR 50.55a to all requirements in 10 CFR 50.55a would allow for added flexibility without requiring exemptions, while relying on the well-understood existing criteria of acceptable level of quality and safety (10 CFR 50.55a(z)(1)) and hardship without a compensating increase in quality or safety (10 CFR 50.55a(z)(2)) for consistent and predictable regulatory outcomes. This proposed action would allow nuclear power plant licensees and applicants for construction permits (CP), operating licenses (OL), combined licenses (COL), standard design certifications, standard design approvals, and manufacturing licenses (ML) to request authorization of voluntary alternatives to a broader scope of requirements in 10 CFR 50.55a.

Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

There are two proposed changes to 10 CFR 50.59, ''Changes, tests, and experiments.'' The first proposed change to the regulation would allow the use of quantitative risk results to demonstrate a change to the facility does not result in a ''more than minimal increase'' as the phrase is used in 10 CFR 50.59(c)(2)(i) and (ii). The second proposed change would allow licensees to make changes to methods that would previously have required NRC review under 10 CFR 50.59(c)(2)(viii) or 53.1550(a)(2)(iv), provided the licensee adopts an acceptable verification, validation, and uncertainty quantification (VVUQ) program in accordance with a proposed new 10 CFR 50.221, ''Credibility requirements for modeling and simulation.'' This shift would enable licensee-led evaluations and allow for the evaluation of advanced modeling methods through structured processes rather than fixed requirements.

Minimum Decommissioning Funding Assurance for Non-Large Light-Water Reactors

The NRC is proposing rule changes in 10 CFR 50.75, ''Reporting and recordkeeping for decommissioning planning,'' to allow certain new reactor applicants and licensees to submit a design-specific decommissioning cost estimate that is less than the approved table of minimum amounts (*i.e.,* ''formula'') values in 10 CFR 50.75(c). The current regulations restrict minimum funding assurance for decommissioning to the table of minimum amounts values or greater. The NRC is proposing similar changes to 10 CFR part 53, which currently only allows for a site-specific decommissioning cost estimate as the certification amount. These changes would more broadly accommodate new reactor technologies.

Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

This proposed rule would incorporate an appendix T, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50. The proposed appendix T to 10 CFR part 50 would provide a voluntary alternative to appendix B, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50 that applicants, who meet certain conditions, could use in their respective applications. This action would support implementation of E.O. 14300, section 5, through (1) the establishment of performance-based quality assurance (QA) criteria that provide explicit direction on the use of a graded approach for applying QA requirements to SSCs relative to their safety and risk contributions to the overall nuclear facility; (2) the incorporation of QA terminology and methodologies used across various industries; (3) enhanced regulatory certainty during the application process; and (4) the removal, when appropriate, of NRC oversight of suppliers and vendors of products and services related to nuclear power plant and fuel reprocessing plant SSCs subject to this proposed rule.

Updates to Construction Permit Requirements and Related Licenses

The proposed rule would revise the content of applications relevant to technical information required for CPs in 10 CFR 50.34, ''Contents of applications; technical information,'' to remove some overly-prescriptive wording; clarify that the level of detail provided in a preliminary safety analysis report should be sufficient to permit the NRC to make the findings in 10 CFR 50.35(a), 10 CFR 50.40, ''Common standards,'' and 10 CFR 50.50, ''Issuance of licenses and construction permits''; and adjust some of the light-water reactor (LWR)-centric language to be more technology-inclusive. Conforming changes to parallel sections in 10 CFR part 52 are also proposed.

Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

The NRC is proposing to amend its regulations by adding new, standalone provisions in 10 CFR 50.220 and 10 CFR 52.220, entitled ''Use of risk-informed and performance-based alternatives to acceptance criteria.'' These provisions would allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed or performance-based acceptance criteria as alternatives to existing prescriptive requirements.

In addition, the NRC is proposing revisions to appendix A to 10 CFR part 50 to update and clarify its regulations for General Design Criteria (GDC). The proposed changes would explicitly allow deviations from the GDCs without requiring exemptions and would revise GDC 28, ''Reactivity limits,'' to remove the prescriptive requirement to evaluate control rod ejection and drop accidents. Instead, applicants would be permitted to propose an alternative design basis accident for reactivity control systems.

Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

In response to E.O. 14300, section 5(f), the NRC is proposing to amend its regulations related to reactor design changes made during construction and operation under the 10 CFR parts 52 and 53 licensing approaches. These changes would impact licensees that reference a certified design or manufacturing license under 10 CFR part 52 or 53. The objectives of these proposed changes are to establish appropriate thresholds for NRC-initiated changes as well as provide additional flexibility and reduce unnecessary regulatory burden for licensee-initiated changes.

Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

The NRC is proposing to amend its regulations to create adaptable licensing pathways for emergency preparedness (EP). Consistent with E.O. 14300, the NRC's objectives for this proposed rule are to streamline the licensing process, provide regulatory certainty for the deployment of new reactor technologies, and remove prescriptive language of lesser safety significance for licensed facilities. Central to these proposed changes is a strengthened, more risk-informed approach to EP for providing reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Optional Submittal of Operational Programs

This rulemaking would allow a developer the option to voluntarily submit operational programs for NRC review and approval with an ML application. The intent is to allow construction permit/operating license (CP/OL) and COL applicants the flexibility to reference the standardized programs approved in the ML, use their own approved programs, or use a combination of both. Early review of these programs would support streamlined CP/OL or COL reviews.

Early Site Permit for Nuclear Power Plants

The NRC is proposing to amend its regulations by revising the provisions applicable to early site permit (ESP) licensing and approval processes for nuclear power plants. These amendments would eliminate the requirement for an ESP expiration date, clarify the applicability of various requirements to ESPs, and propose necessary conforming amendments throughout the NRC's regulations to enhance the NRC's necessary regulatory effectiveness and efficiency in implementing its licensing and approval processes.

Manufacturing License Term Extension

The NRC is proposing to amend the regulations in 10 CFR 52.173, ''Duration of manufacturing license,'' and 52.181, ''Duration of renewal,'' to change the duration of an ML to 40 years and the duration of the renewed ML to 40 years. By amending the regulations with these proposed changes, the ML would be consistent with the durations for certified designs, thereby increasing efficiency in building new reactors.

Nuclear Power Plant License Renewal

The NRC is proposing to amend its regulations for renewing nuclear power plant OLs. The revisions would extend the duration of renewed licenses, allow applicants to voluntarily propose alternative risk-informed and performance-based criteria, and remove several prescriptive requirements related to the application process and post-approval recordkeeping. These changes would enhance regulatory flexibility and efficiency to facilitate operational extensions for the current nuclear fleet.

Enhancing Flexibility of Reactor Site Criteria

The existing regulatory framework requires all stationary power reactor applications submitted after January 10, 1997, to follow the siting criteria in subpart B to 10 CFR part 100, ''Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997,'' without consideration of reactor type, size, output, radiological consequence, or other factors that can widely vary given the breadth of power reactor designs considered for future construction and deployment in the United States. Subpart A, ''Evaluation Factors for Stationary Power Reactor Site Applications Before January 10, 1997 and for Testing Reactors,'' to 10 CFR part 100, ''Reactor Site Criteria,'' provides less prescriptive regulatory requirements for reactor siting but only applies to power reactor applications submitted prior to January 10, 1997, or an application for a testing reactor, as defined in 10 CFR 50.2. To increase the flexibility of regulatory requirements for the full spectrum of prospective reactor technologies, including non-stationary reactors, this proposed change would (1) revise subpart A to 10 CFR part 100 to include Tier 1 power reactors, as defined in proposed 10 CFR 100.3, ''Definitions,'' and DG–4036, ''Graded Approach to Site Characterization for New Reactor Applications,'' in addition to testing reactors; (2) remove appendix A to 10 CFR part 100 that applies to subpart A to 10 CFR part 100; and (3) revise subpart B to 10 CFR part 100 to include Tier 2 power reactors, which are those reactors that do not meet the entry criteria for subpart A to 10 CFR part 100. This proposed change will be accompanied by draft guidance on application content, including the entry criteria for subpart A to 10 CFR part 100, a clarification on site parameters to be included in a site parameter envelope, and an explanation of a graded approach to site characterization for all external hazards to be considered under both subparts A and B to 10 CFR part 100. In addition, the NRC proposes to revise 10 CFR part 100 to maintain the agency's long-standing preference for siting reactors in areas of low population density, while providing flexibility to allow siting reactors in areas of greater population density when justified by an assessment comparing the societal risks and societal benefits of siting reactors in those areas. Implementing guidance for these assessments will be developed.

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

The NRC is proposing to amend its regulations related to the use of conventional and accident tolerant LWR fuel designs. The NRC's goal is to establish effective and efficient licensing of the use of fuels enriched to greater than 5.0 weight percent uranium-235 while continuing to provide reasonable assurance of adequate protection of public health and safety. The new requirements also would address fuel fragmentation, relocation, and dispersal in relation to the key accident tolerant fuel components of increased enrichment and burnup limits.

C. Cost and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative and qualitative costs of the proposed rule and associated guidance. The draft regulatory analysis concluded that the proposed rule and associated guidance would result in undiscounted total net savings of $1.86 billion to the NRC and industry ($802.10 million using a 7 percent discount rate and $1.26 billion using a 3 percent discount rate).

The draft regulatory analysis also considers qualitative factors to be considered in the NRC's rulemaking decision. Qualitative factors include regulatory efficiency. The 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.

For more information, the draft regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0975 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–2025–0975.

- *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 ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 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 of this document.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. 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 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.
- *Technical Library:* The Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852, is open by appointment only. Interested parties may make appointments to examine documents by contacting the NRC Technical Library by email at *Library.Resource@nrc.gov* between 8 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.
- *Public Meeting:* The NRC will conduct public meetings to describe the proposed amendments and answer questions from the public on the proposed rule. The NRC will publish a notice of the location, time, and agenda of the meetings on the NRC's public meeting website within 10 calendar days of the meetings. Stakeholders should monitor the NRC's public meeting website for information about the public meetings at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*

B. Submitting Comments

Comments must be submitted using *https://www.regulations.gov* by 11:59 p.m. Eastern Time on August 31, 2026. Please include Docket ID NRC–2025–0975 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. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the Nuclear Regulatory Commission (NRC) to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(f), which directs the NRC to ''[e]stablish stringent thresholds for circumstances in which the NRC may demand changes to reactor design once construction is underway''; section 5(h), which directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments focus on credible, realistic risks''; and section 5(i), which directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of additional changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking. In developing the proposed changes, the NRC has considered the benefits of increased availability of, and innovation in, nuclear power to our economic and national security consistent with section 501(a) of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) and section 3 of E.O. 14300.

III. Background—Expedited Construction of Certain Structures, Systems, and Components

A. Definition of Construction

Section 185 of the Atomic Energy Act of 1954, as amended (AEA), requires that the NRC grant construction permits (CPs) to applicants for licenses to construct or modify production or utilization facilities, if the applications for such permits are acceptable to the NRC. However, the term ''construction'' is not defined anywhere in the AEA. Instead, construction is defined within section 50.10, ''License required; limited work authorization'' of part 50, ''Domestic Licensing of Production and Utilization Facilities,'' in title 10 of the *Code of Federal Regulations* (10 CFR). The Commission last updated this definition in 2007 as part of the limited work authorization (LWA) final rule, ''Limited Work Authorizations for Nuclear Power Plants'' (72 FR 57416; October 9, 2007).

In developing this definition of construction in the 2007 LWA final rule, the Commission concluded that the definition of construction should parallel the agency's jurisdiction because activities outside the definition of construction would not require prior authorization. Therefore, the Commission ''determined that construction should include all of the activities that have a reasonable nexus to radiological health and safety, or common defense and security'' (72 FR 57429; October 9, 2007). For the 2007 LWA final rule, the scope of structures, systems, and components (SSCs) falling within the definition of construction was derived from the scope of SSCs that are included in the program for monitoring the effectiveness of maintenance at nuclear power plants, as defined in 10 CFR 50.65(b), because ''the definition is well understood and there is good agreement on its implementation'' (72 FR 57429–30; October 9, 2007). The SSCs were supplemented with those necessary to comply with emergency preparedness and security regulations because they also have a reasonable nexus to radiological safety or are required for the common defense and security.

New reactor designs and deployment strategies, as well as lessons learned from previous examples, warrant a fresh look at how application of the 10 CFR 50.10 definition of construction may unnecessarily restrict construction of nuclear power plants using modern construction techniques on optimized schedules. Additionally, some prospective applicants to construct a nuclear power reactor have indicated the desire to construct portions of the facility, such as permanent materials left in an excavation, or even balance of plant systems, in advance of a CP or combined license (COL), and without an LWA, based on their business needs and the lack of the SSCs' safety significance. The Commission recognizes that the activities undertaken to build or install some facility SSCs will not affect the safety-significant functions of those SSCs, even though the 2007 rule could have been understood to require a license to build or install them, and the NRC need not authorize such activities before they occur. Moreover, the NRC has considered and granted exemptions from the current definition of construction to allow an applicant to build SSCs over which the NRC exercises authority but for which construction is not material to the safety function of the SSC.

B. General Licenses

In regard to general licenses for utilization facilities, section 109 of the AEA, ''Component and Other Parts of Facilities,'' authorizes the Commission to ''issue general licenses for domestic activities required to be licensed under section 101 [of the AEA]'' with respect to those utilization facilities determined by the Commission under section 11cc.(2) of the AEA. Section 11cc.(2) of the AEA defines such facilities as ''any important component part especially designed for [a utilization facility as defined under sec. 11cc.(1) of the AEA] as determined by the Commission.'' Under section 109 of the AEA, the Commission may issue a general license authorizing construction of such ''important component parts'' if it ''determines in writing that such general licensing will not constitute an unreasonable risk to the common defense and security.''

In order to accommodate the business models for new reactor designs some prospective vendors are proposing and to enable rapid deployment strategies for advanced reactor technologies, the NRC plans to revise its regulations to allow the use of general licenses for construction of important component parts of a utilization facility.

IV. Discussion—Expedited Construction of Certain Structures, Systems, and Components

A. Definition of Construction

The NRC is proposing to revise its regulations to update the definition of ''construction'' in 10 CFR 50.10, 10 CFR 51.4, ''Definitions,'' and 10 CFR 53.020, ''Definitions,'' to facilitate the safe construction of nuclear power plants using modern construction techniques on optimized schedules.

Specifically, this proposed rule would revise the definition of construction to include SSCs for which construction can affect the SSC's capability to perform a safety-related or safety-significant function and will, therefore, require NRC approval before commencing construction. An additional purpose of this change is to afford license applicants, when justified, additional flexibility to build or install SSCs whose safety-related or safety-significant functions are not significantly affected by those activities at a site prior to the issuance of a license. Those SSCs that are constructed without NRC authorization may still be subject to additional operational requirements as part of any subsequent operating license (OL) that would be issued.

B. Safety Review

Since the issuance of the 2007 LWA final rule, the NRC has observed that prospective advanced reactor applicants have designed their facilities with separation between nuclear and balance of plant SSCs in mind, such that many of the criteria in the current definition for a construction activity are not met for certain SSCs. Some stakeholders have maintained that such SSCs do not have a reasonable nexus to safety and therefore the unmet criteria are not necessary to provide reasonable assurance of adequate protection to the health and safety of the public; therefore, those unmet criteria are not needed or do not serve the underlying purpose of the rule. Lacking a revision to the definition, the remaining unmet criteria prevent prospective applicants from constructing such components without first obtaining an LWA, CP, a COL, or an exemption.

The proposed construction definition would be limited to those SSCs for which construction activities may have a significant impact on radiological health and safety. For other SSCs, even those that may have a nexus to radiological health and safety during operation, operational requirements should suffice, and the NRC need not license the construction of those SSCs.

The flexibility afforded by this proposed change would rely on an applicant-performed analysis and categorization of the SSCs of the facility to those that do and those that do not meet the definition of construction.

The set of SSCs that would meet the definition of construction should include only those SSCs that perform safety-related functions or that perform safety-significant functions and the successful completion of those functions may be impacted by construction. For those SSCs, prior NRC approval for construction would be required because inadequate design or construction of those SSCs could have a substantial contribution to radiological risk during operation.

Activities undertaken to build onsite emergency facilities necessary to comply with either 10 CFR 50.160, ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,'' or 10 CFR 50.47, ''Emergency plans,'' and appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' or 10 CFR 53.855, ''Emergency preparedness,'' as applicable, would not be considered SSCs that meet the definition of construction. Historically, emergency response facilities (ERF) were included due to their reasonable nexus to radiological health and safety, but they would not fall under the criteria in proposed 10 CFR 50.10(a)(1)(i) through (iii) or 10 CFR 53.020. Instead, applicants would comply with the requirements of 10 CFR 50.160, or 10 CFR 50.47 and appendix E to 10 CFR part 50, or 10 CFR 53.855, as applicable. The applicant would need to be aware of all functional requirements of 10 CFR 50.160, or 10 CFR 50.47 and appendix E to 10 CFR part 50, or 10 CFR 53.855 for ERFs. These functional requirements would need to be validated in a preoperational exercise, which would satisfy the historical reasons why ERFs were previously included in the construction definition.

For license applicants under 10 CFR parts 50 and 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' the proposed revisions to the definition of construction would also support use of the SSC categorization methodology for designs licensed under the technology-inclusive, risk-informed, and performance-based methodology described in regulatory guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' dated June 2020. Under this framework, the applicant would use its probabilistic risk assessment (PRA) of the design to analyze the function of the SSCs. As explained in RG 1.233, the applicant's analysis would result in the classification of SSCs into one of four categories: ''safety-related,'' ''non-safety-related with special treatment,'' ''non-safety-related with no special treatment,'' and ''all other SSCs'' (with no special treatment required). Within the RG 1.233 methodology, ''safety-significant'' SSCs include all those SSCs classified as ''safety-related'' or ''non-safety-related with special treatment.'' Those SSCs whose construction could impact their safety-significant function, and thus would fall under the definition of construction in the amended 10 CFR 50.10(a)(1)(i) and (ii), would likely include only those SSCs that were analyzed and classified as safety-related or non-safety-related with special treatment. It is possible that a subset of some non-safety-related with special treatment SSCs could have no safety functions which would be impacted by the construction of the SSC. For these cases, an applicant could provide further information that justifies the exclusion of the SSC from the definition of construction. All SSCs classified as either ''non-safety-related with no special treatment'' or ''all other SSCs,'' would likely not be included in the definition of construction under those criteria because, as demonstrated in the PRA, their impact on safety as evaluated under the methodology would be negligible. Consequently, the proposed amendments to 10 CFR 50.10 would enable applicants referencing RG 1.233 greater flexibility to undertake preconstruction activities.

Applicants under 10 CFR part 50 or 52, when determining whether SSCs fall under the criteria in proposed 10 CFR 50.10(a)(1)(i) through (iii), would confirm that other considerations do not require that the resulting list of SSCs should otherwise be subject to NRC quality assurance (QA) requirements for design in appendix B to 10 CFR part 50, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.'' Criterion III of appendix B to 10 CFR part 50 sets forth requirements for design control, and appendix B to 10 CFR part 50 includes other requirements (*e.g.,* for records and audits) that apply to the design of SSCs subject to appendix B to 10 CFR part 50.

In addition, applicants under 10 CFR parts 50 and 52 would also confirm that other considerations would not require that any other SSC should be subject to general design criterion (GDC) 1, ''Quality standards and records,'' in appendix A to 10 CFR part 50. Criterion 1 of appendix A to 10 CFR part 50 also imposes corresponding requirements for SSCs important to safety but not safety-related to the extent such requirements are commensurate with an SSC's importance to safety. Safety-related SSCs are subject to all requirements in appendix B to 10 CFR part 50, including QA requirements applicable to facility operation.

Application of the QA requirements for design in proposed appendix T, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50 (see section XVI of this document), could also affect the definition of construction for applicants under 10 CFR part 50, 52, or 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants.'' Specifically, the definition of construction proposed in this rule would include SSCs subject to the requirements of proposed appendix T to 10 CFR part 50, and, in certain instances, the structures built for those SSCs.

Applicants under 10 CFR parts 50 and 52 must comply with criterion 1 of appendix A to 10 CFR part 50. This criterion requires that ''SSCs important to safety be designed, fabricated, erected, and tested'' to QA standards commensurate with the importance of the safety functions to be performed. However, an SSC could be subject to performance requirements for operation but would not warrant the application of QA measures under GDC 1 such as QA for design. Specifically, the SSC could be commercial grade but also subject to specified operational performance requirements. Such an SSC could be constructed without a license. The rationale for the approach rests on the fact that if no NRC QA requirement for design, fabrication, erection, and testing applies to an SSC, then there is nothing uniquely related to nuclear safety for the NRC to approve with respect to construction of the SSC. Further, design limits on the *operation* of the SSCs that do perform safety functions would prevent or mitigate the safety effects of the failure of SSCs not subject to NRC QA requirements applicable to construction. Accordingly, construction of such SSCs would not have a reasonable nexus to nuclear safety, even if operation of the SSC did have a reasonable nexus to nuclear safety.

The failure of an SSC that has an effect on the safety of operation could warrant operational requirements with respect to SSCs that perform safety functions in response to such failures and possibly operational requirements with respect to the SSCs themselves.

An applicant's designation of an SSC as something that does not meet the definition of construction would not restrict the NRC from imposing such operational requirements to address radiological health and safety.

The NRC encourages pre-application engagement when licensees plan to undertake significant preconstruction activities to assist the NRC staff to further understand which SSCs have a reasonable nexus to radiological health and safety at the construction phase. An applicant may communicate its plan to comply with the regulations, including an SSC classification methodology to the NRC as part of preapplication interactions. The NRC staff will provide feedback as appropriate. Alternatively, one or more prospective license applicants could propose a generic SSC classification methodology, which the NRC staff could review and endorse as acceptable guidance outside a particular licensing action. The approved methodology could then be referenced by multiple applicants.

Similar to the existing regulations, if an applicant under the proposed rule determines that an SSC falls within the scope of the definition of construction in the proposed 10 CFR 50.10 or 53.020, an exemption request or an LWA would need to be submitted to the NRC to allow for this construction activity to occur prior to issuance of a CP or COL. Similar to the existing processes, the LWA would be granted if the underlying requirements of 10 CFR 50.10(d) and (e) or 10 CFR 53.1130, ''Limited work authorizations, general licenses,'' as applicable, are met.

C. Environmental Review

As explained in section IV.A., ''Definition of Construction,'' of this document, a CP, COL, or LWA applicant does not need to obtain an NRC license to build SSCs that do not meet the definition of construction in 10 CFR 51.4. As long as there is no other Federal action authorizing these activities, under 10 CFR 51.20 through 51.22, an environmental review under the National Environmental Policy Act (NEPA) is not required. Activities undertaken to build SSCs excluded from the definition of construction are not part of an NRC licensing action because such construction activities do not have a reasonable nexus to nuclear safety, even if operation of a particular SSC does have a reasonable nexus to nuclear safety. An applicant's classification of an SSC as not safety-significant, that is built prior to issuance of a license, would not restrict the NRC from imposing operational requirements on those SSCs through a later action.

For SSCs that do meet the definition of construction where the NRC would authorize construction, the NRC must perform an environmental review in accordance with 10 CFR 50.10 or 53.610, ''Construction,'' as applicable, and the application requirements of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.''

D. General Licenses and Generic Finality

The NRC proposes to add new 10 CFR 50.10(h) and 53.1130(e), which would implement the authority in section 109 of the AEA to create a general license allowing construction of an important component part of a specified class of commercial nuclear plants. The specified class of plants would be those plants of a design the NRC previously approved in a licensing action in which the NRC also granted ''generic finality,'' as discussed later, and for which operation has been authorized. The important component part defined as a utilization facility under Section 11cc.(2) of the AEA and subject to the general license would be the portion of the plant constructed on site except for the reactor vessel, the reactor coolant system, and associated reactivity control and heat removal systems. The general license would authorize construction of the important component part upon docketing of an application for a license that would authorize construction of the nuclear plant, subject to conditions. The conditions would provide reasonable assurance of adequate protection of the health and safety of the public and common defense and security, and would also ensure an appropriate level of environmental review. The NRC also proposes a conforming change to 10 CFR 50.10(c) and 53.610(b) to provide that construction may occur under the general licenses issued in 10 CFR 50.10(h) and 53.1130(e), respectively.

The construction activities authorized by the general license would be limited to those SSCs for which a previously approved design was provided generic finality, but would not include the reactor vessel, the reactor coolant system, and associated reactivity control and heat removal systems. The NRC expects that the construction of SSCs approved through a general license would be for those SSCs that are not inherently sensitive to the site-specific characteristics of a proposed deployment site. Although construction of many SSCs in a particular design could conceptually be approved through a general license, the NRC cannot approve the construction of an entire utilization facility through this provision.

The proposed new regulations would enable future applicants to reference previously reviewed and approved information only when significant safety and environmental issues related to design, construction, and operation are generically resolved in a manner that applies to the intended use of the information. For example, to qualify for a general license, an applicant would have to reference a nuclear reactor design that was afforded generic finality by the NRC and successfully constructed under NRC oversight and placed into operation. Also, the applicant's proposed site would have to fall within the corresponding site parameter envelope that was provided in the request for generic finality. Therefore, an application that satisfies the proposed new regulation would provide reasonable assurance of adequate protection of public health and safety and common defense and security equivalent to satisfaction of existing regulations, and there would have been a prior hearing opportunity on the reactor design being referenced. Further, the proposed regulation would require the general licensee to allow for NRC inspections that the Commission deems necessary related to activities performed under the general license.

The general license regulation would also include conditions to address environmental considerations. The OL or COL (as applicable) of the plant for which generic finality was approved would either have met the criteria for categorical exclusion or had a finding of no significant impact after preparation of an environmental assessment. Provided that the environmental characteristics of the proposed plant fall within the environmental parameters for the plant for which generic finality was approved, the environmental effects of a subsequent plant would not exceed those of the approved plant and would be acceptable. In addition, the applicant proposing to use the general license would have to propose a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary. This proposed requirement would be similar to the requirements in 10 CFR 50.10(d)(3)(iii), which requires a redress plan as part of an application for an LWA, and 10 CFR 50.12(b)(2), which requires the Commission to consider redress of adverse environmental impacts in determining whether to grant an exemption permitting the conduct of construction activities prior to the issuance of a CP.

The proposed general license regulation would also require that the general licensee has notified the NRC that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action that the general licensee was responsible for obtaining have been obtained. In addition, the proposed general license would require that applicable Federal environmental consultations have been completed. This would ensure that construction activities would not begin unless the NRC has the information it would need to fulfill its obligations for environmental review under the AEA, NEPA, and other relevant laws.

In addition, the proposed general license regulation would clarify that any activities undertaken by the general licensee or on its behalf under the general license would be entirely at the risk of the general licensee and would have no bearing on the issuance of a license with respect to the requirements of the AEA, and rules, regulations, or orders issued under the AEA. However, the general licensee would be able to mitigate this additional regulatory risk through careful site selection to ensure that site characteristics are within the bounds of the postulated site parameters and by performing construction activities following appropriate QA and fitness-for-duty programs.

Based on the proposed general license requirements in 10 CFR 50.10(h) and 53.1130(e), the Commission has determined that such general licensing would be for only parts of utilization facilities, not constitute an unreasonable risk to the common defense and security, and, therefore, be consistent with the authority provided to the Commission by section 109a. of the AEA.

In addition, in order to facilitate the use of the general licensing concept, the NRC proposes to add conforming changes to the following regulations.

The NRC proposes to add new 10 CFR 50.34(b)(14) which would require an OL application for those 10 CFR part 50 applicants that request the NRC to make a finding on generic finality, to include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters. Similarly, the NRC proposes to add new paragraph (bb) to 10 CFR 53.1369, ''Contents of applications for operating licenses; technical information,'' for 10 CFR part 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants,'' OLs for the same purpose. For COL applications under 10 CFR part 52 or 53, this application content requirement would be included in a new 10 CFR 52.79(a)(48) and 53.1416(i), respectively. The site parameters may be the same as or more severe than the site characteristics established for the site of the reactor proposed in the OL or COL application that proposed generic finality.

The NRC also proposes to add a new 10 CFR 50.58(b)(7), which would require the Commission to include the request for generic finality as a proposed action in the notice of proposed action required by 10 CFR 2.105 for OL applications. Similarly, the NRC also proposes to add a new paragraph (b)(2) to 10 CFR 53.1375, ''Review of applications,'' which would require the Commission to include the request for generic finality as a proposed action in the notice of proposed action for a 10 CFR part 53 OL, required by 10 CFR 2.105. For COL applications, the NRC proposes to add a new 10 CFR 52.85(b) and 53.1422(b)(2), which would require the Commission to include the request for generic finality as a proposed action in the notice of hearing required by 10 CFR 2.104 for COL applications under 10 CFR parts 52 and 53, respectively. These changes would provide a hearing opportunity to the public on the request for generic finality. In addition, the Commission's ruling on a request for hearing or petition for leave to intervene under 10 CFR 2.309(d)(2) would consider that a petitioner may have an interest in the application if matters resolved in the licensing proceeding were to be afforded generic finality. This would enable petitioners whose property, financial, or other interests would not be directly affected by the issuance of the OL or COL for a particular reactor to have an opportunity to intervene on generic aspects of the design that would be afforded finality and would therefore not be subject to hearing if referenced in a later application that would affect the petitioner's property, financial, or other interest.

Consistent with the previous discussion, the NRC proposes to add new 10 CFR 50.57(d), which would permit the Commission to afford generic finality to generic aspects of the design of a utilization facility licensed under 10 CFR part 50, including postulated site parameters submitted pursuant to 10 CFR 50.34(b)(14), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design. For the same reason and with the same conditions, the NRC proposes to add new paragraph (e) to 10 CFR 53.1387, ''Issuance of operating licenses,'' which would permit the Commission to afford generic finality to generic aspects of the design of a commercial nuclear plant licensed under 10 CFR part 53, including postulated site parameters submitted pursuant to 10 CFR 53.1369(bb).

Similarly, the NRC proposes to add new 10 CFR 52.97(d) which would permit the Commission to afford generic finality to generic aspects of the design of a utilization facility licensed under 10 CFR part 52, including postulated site parameters submitted pursuant to 10 CFR 52.79(a)(48), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design. For the same reason and with the same conditions, the NRC proposes to add new paragraph (d) to 10 CFR 53.1440, ''Issuance of combined licenses,'' which would permit the Commission to afford generic finality to generic aspects of the design of a commercial nuclear plant licensed under 10 CFR part 53, including postulated site parameters submitted pursuant to 10 CFR 53.1416(i).

The regulations in 10 CFR 50.59, ''Changes, tests and experiments,'' that establish requirements for making changes to portions of the facility as described in the final safety analysis report (FSAR) for an OL are applicable to generic aspects of the design of a utilization facility that have been afforded generic finality because that design information would be included in the FSAR for the OL. Similarly, the regulations in 10 CFR 50.59 are applicable to generic aspects of the design of a utilization facility that are described in a COL FSAR and have been afforded generic finality.

Similarly, the regulations in 10 CFR part 53 that establish requirements for making changes to portions of the facility as described in the FSAR are applicable to generic aspects of the design of a utilization facility that have been afforded generic finality.

The NRC proposes to add new 10 CFR 50.58(b)(8) and 52.98(h) to include requirements to address finality for portions of 10 CFR part 50 OLs and 10 CFR part 52 COLs with respect to NRC reviews and hearings. Proposed 10 CFR 50.58(b)(8) would require the Commission to treat as resolved any issues referenced in following proceedings or in enforcement hearings (other than ones under 10 CFR 2.202(e)(1)) that were afforded finality pursuant to 10 CFR 50.57(d). The proposed 10 CFR 50.58(b)(8) would ensure that issues resolved in an approved request for generic finality (including, if applicable, the adequacy of a reactor design) are not re-adjudicated in the license proceedings where such information is referenced in the license applications. The proposed 10 CFR 52.98(h) would include substantially the same provisions for COLs with generic finality.

To address generic finality in 10 CFR part 53, the NRC proposes to add similar provisions to new paragraph (b) to 10 CFR 53.1390, ''Finality of operating licenses,'' and new paragraph (g) to 10 CFR 53.1443, ''Finality of combined licenses.''

Proposed 10 CFR 53.1390(b) would require the Commission, in the proceedings for issuance of a CP, an OL, or a COL or in any enforcement hearing (other than one initiated under 10 CFR 53.1390(a)), to treat as resolved those matters resolved in the proceedings on the application or renewal of the referenced OL, including, if applicable, the adequacy of a reactor design where the referenced OL was afforded finality pursuant to 10 CFR 53.1387(e).

Proposed 10 CFR 53.1443(g) would require the Commission, in the proceedings for issuance of a CP, an OL, or a COL or in any enforcement hearing (other than one initiated under 10 CFR 53.1443(a)), to treat as resolved those matters resolved in the proceedings on the application or renewal of the referenced COL, including, if applicable, the adequacy of a reactor design where the referenced COL was afforded finality pursuant to 10 CFR 53.1440(d).

As written, the proposed generic finality provisions would allow the NRC to take appropriate action under the applicable backfitting or issue finality provision if the NRC determines that the generic finality approval or associated technical information presents safety concerns that warrant NRC action. As stated above, the generic finality that would be afforded under the proposed rule provisions would *not* apply to certain enforcement hearings. For example, proposed 10 CFR 50.58(d)(8) provides that finality would apply, in part, to ''any enforcement hearing *other than one initiated by the Commission under § 2.202(e)(1) of this chapter*'' (emphasis added). Enforcement hearings under 10 CFR 2.202(e)(1) are those which involve a backfit to modify a 10 CFR part 50 license, and 10 CFR 50.109 must be followed for such orders and the associated proceedings. Thus, generic finality would not apply in such cases so that the NRC could take appropriate action if the backfitting requirements in 10 CFR 50.109 are satisfied. Similarly, the proposed generic finality provisions in 10 CFR 52.98(h), 53.1390(b), and 53.1443(g) would provide that generic finality applies except in enforcement hearings initiated under the issue finality provisions in 10 CFR 52.98(a), 53.1390(a), and 53.1443(a), respectively.

V. Background—Determinate and Data-Backed Thresholds for Reactor Safety Assessments

Section 5(h) of E.O. 14300 directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments are focused on credible, realistic risks.''

The NRC evaluated ''reactor safety assessments,'' focusing on assessments conducted to (1) demonstrate the capability of safety-related SSCs during design basis events (DBEs) (*e.g.,* as described in Chapter 15, ''Transient and Accident Analysis,'' of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition''), and (2) verify the ability of SSCs to withstand certain design basis conditions, including natural phenomena and environmental conditions (*e.g.,* high winds, seismic events, and conditions during normal operation and accident scenarios). To effectively address the direction in E.O. 14300, the NRC concluded that the most appropriate approach would be to clarify the terminology in 10 CFR 50.2, ''Definitions,'' to ensure that safety assessments are focused on credible, realistic risks.

The selection of DBEs and associated design basis parameters is a critical prerequisite for determining the safety of a nuclear facility. DBEs serve to identify the subset of SSCs subject to more stringent QA requirements and to establish the performance capabilities those SSCs must demonstrate under normal operation, anticipated operational events, and accident conditions. For example, 10 CFR 50.46, ''Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,'' requires analysis of postulated loss-of-coolant accidents to verify the adequacy of emergency core cooling system (ECCS) designs. In addition to the general requirement to analyze SSC performance during DBEs, other regulations specify additional, event-specific accident analyses, often referred to as beyond design basis events (BDBEs). For example, 10 CFR 50.63, ''Loss of all alternating current power,'' provides requirements related to plants' abilities to withstand for a specified duration and recover from a station blackout (SBO).

The technical information required in applications for CPs and OLs, including the content of preliminary and FSARs, is outlined in 10 CFR 50.34, ''Contents of applications; technical information.'' Among other requirements, an applicant is required to evaluate siting considerations and the design and performance of SSCs that are intended to prevent accidents and mitigate their consequences. The regulatory processes described in 10 CFR part 52 include similar technical information requirements for the content of applications (*e.g.,* as specified in 10 CFR 52.17, ''Contents of applications; technical information,'' 52.47, ''Contents of applications; technical information,'' 52.79, ''Contents of applications; technical information in final safety analysis report,'' 52.137, ''Contents of applications; technical information,'' and 52.157, ''Contents of applications; technical information in final safety analysis report'').

The technical information associated with the performance of safety assessments is documented in the preliminary or FSAR for CPs or OLs and COLs, respectively. The FSAR describes the evaluation methods used to establish design bases and perform safety analyses, the design and performance requirements for SSCs, and the methods used to demonstrate that those SSCs can perform their intended safety functions. Accordingly, the FSAR serves as an essential component of the licensing basis for a nuclear facility. It is also used to determine the appropriate regulatory process for licensing basis changes, such as those governed by 10 CFR 50.59, ''Changes, tests and experiments,'' or 10 CFR 50.90, ''Application for amendment of license, construction permit, or early site permit.''

Within the power reactor licensing framework, the term ''safety-related'' is used to identify SSCs that require special treatment, including QA controls, environmental qualification, and compliance with applicable industry codes and standards. The current definition of ''safety-related SSCs,'' provided in 10 CFR 50.2, uses the term ''design basis events'' to define the scope of safety assessments needed to identify safety-related SSCs. However, 10 CFR 50.2 does not include a corresponding definition of ''design basis event'' or provide criteria for selecting events to be considered in the design basis. While 10 CFR 50.49, ''Environmental qualification of electric equipment important to safety for nuclear power plants,'' includes a definition of DBEs, that definition does not explicitly apply to the definition of safety-related SSCs in 10 CFR 50.2 and does not reference the use of determinate, data-backed thresholds.

Traditionally, the spectrum of DBEs used to identify safety-related SSCs, as defined in 10 CFR 50.2, has been based on information contained in Chapter 15 of NUREG–0800. While this approach had been effective for licensing large light-water reactors (LWRs) with designs similar to the currently operating power reactor fleet, the DBEs described in NUREG–0800 can have limited applicability to evolutionary LWR designs and non-LWR designs. For example, the lack of a more technology-inclusive definition for the term DBE in the current definition has created challenges with respect to clarity and reliability on the subset of SSCs that warrant special treatment. Furthermore, it has created the potential to require safety assessments that may not be focused on credible, realistic risks. Therefore, clarifying what constitutes a DBE based on determinate, data-backed thresholds would enhance the efficiency and consistency of future power reactor licensing reviews. Consequently, the NRC proposes to provide a definition for DBE in 10 CFR part 50.

Nonetheless, the NRC has not identified a need to propose a corresponding revision to the term ''design bases'' in 10 CFR 50.2. The term ''design bases'' is defined in 10 CFR 50.2 as information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. The definition further clarifies that design basis values may be (1) constraints derived from generally accepted ''state-of-the-art'' practices for achieving functional goals or (2) requirements based on analyses of the effects of postulated accidents for which an SSC must meet specified functional goals. Design bases are connected to safety assessments in two ways: (1) the performance capabilities of SSCs, as established through evaluations of DBEs and BDBEs, and (2) the design parameters for SSCs, which are derived from the operational context in which the function is to be performed, including considerations of natural phenomena and environmental factors. The NRC has determined that the existing definition of design bases in 10 CFR 50.2 provides sufficient flexibility to support the use of determinate, data-backed thresholds. In practice, the NRC has already applied determinate and data-backed thresholds for the selection of design bases attributes in several areas, including high winds, flooding, and seismic hazards. Therefore, a rulemaking to revise the definition of design bases is not necessary. However, the NRC is issuing draft guidance (DG) that will provide additional detail within DG–1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' to support consistent application in this area.

The term BDBE has not previously been defined in 10 CFR 50.2. However, lessons learned from ongoing studies of nuclear plant risks, as well as operational experience, have historically led the NRC to identify and address plant events and conditions beyond the originally defined set of DBEs that could result in the release of radioactive material sufficient to pose a hazard to public health and safety. Accordingly, the NRC has imposed additional requirements to address such events when risk insights emerged from operational experience (*e.g.,* SBO in 10 CFR 50.63 and anticipated transients without scram (ATWS) in 10 CFR 50.62, ''Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants''). These requirements extended regulatory attention beyond the traditional scope of DBEs. When developing this proposed rulemaking, the NRC initially considered a framework where these types of events were included in the DBE category. However, experience with regulating events such as SBO and ATWS has demonstrated that these types of events can be adequately addressed without the same regulatory treatment as DBEs. Therefore, the formal inclusion of the BDBE category in this proposed rule would provide a framework for applying graded regulatory treatment to such events. It would enable the NRC to address risks to public health and safety that do not warrant mitigation exclusively through safety-related SSCs or conservative safety assessments. Consequently, the NRC proposes to provide a definition for BDBE in 10 CFR part 50.

VI. Discussion—Determinate and Data-Backed Thresholds for Reactor Safety Assessments

The proposed changes would revise 10 CFR 50.2 to add definitions for the terms ''design basis events'' and ''beyond design basis events.'' The proposed changes would include a conforming revision to the definition of ''design basis event'' in 10 CFR 50.49(b)(1)(ii). These changes would apply to future 10 CFR part 50 and 52 applications submitted on or after the date that would be 180 days after the effective date of a final rule if this proposed rule were issued as a final rule; however, existing applicants, licensees, and approval holders under 10 CFR part 50 or 52 could voluntarily choose to adopt them. In parallel with the proposed changes, the NRC has developed DG–1454, which would (1) describe determinate and data-backed thresholds for categorizing events as DBEs or BDBEs, (2) outline graded assessment approaches for each event category, and (3) clarify the process for selecting design bases controlling parameters used as reference bounds in the design of SSCs. This guidance would use initiating event frequencies and qualitative criteria for categorizing events, maintaining consistency with the current safety assessment framework described in 10 CFR part 50 (and referenced in 10 CFR part 52). In addition, this guidance would describe acceptable approaches for identifying, grouping, and quantifying initiating events to ensure they are binned into appropriate categories. While alternate approaches, such as defining thresholds in terms of event sequences could be used, they would typically require the development of a full risk assessment or other systematic risk evaluation to determine sequence frequencies. To avoid imposing additional requirements not currently included in 10 CFR part 50, anchoring event selection to initiating event frequencies would provide a determinate and data-backed approach without adding regulatory burden.

Adding generally applicable definitions for DBE and BDBE would improve regulatory clarity and enable the use of objective criteria in selecting initiating events. Establishing threshold criteria, graded assessment approaches, and the selection process for design basis parameters within guidance would ensure that applicants and licensees are provided with an approach acceptable to the NRC, while ensuring flexibility for applicants to justify unique approaches, if desired, without the need for an exemption.

The addition of a definition of BDBE and corresponding thresholds would allow a reduction in unnecessary conservatism applied in the safety assessments of lower frequency events. The NRC concluded that reactor safety assessments associated with BDBEs are within the scope of the existing contents of application requirements of 10 CFR 50.34 and analogous sections of 10 CFR part 52. Specifically, requirements related to analysis and evaluation of the design and performance of SSCs of the facility with the objective of assessing the risk to public health and safety include consideration of BDBEs. Several existing regulations already address specific events not originally considered in the licensing basis or considered BDBEs (examples include but are not limited to ATWS, loss of all alternating current power events resulting in SBOs, and combustible gas control). For current applicants, licensees, or approval holders who may opt to adopt the proposed definitions for DBE and BDBE, as well as future applicants who would be mandated to use the proposed definitions, this rulemaking would not change the treatment of BDBEs specifically addressed by regulation such as ATWS and SBO. However, adoption of the BDBE definition could eliminate some events not specifically addressed by regulation from consideration that are determined to be non-credible.

Similarly, evaluations that assume substantial release of fission products would still be performed in accordance with 10 CFR 50.34(a) and 10 CFR 50.67, ''Accident source term.'' For LWRs, the release would be into containment. For other designs, it may be expressed as releases to the environment considering expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of accidents. These evaluations would address the safety features that are engineered into a facility and those barriers that must be breached as a result of an accident before a radiological release to the environment can occur. Evaluations required to comply with 10 CFR 50.34(a) and 10 CFR 50.67 rely on conservative modeling assumptions. For example, as described in RG 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors,'' source term fission product release fractions are derived from a set of accident sequences and many physical processes and phenomena are represented by bounding assumptions rather than being modeled directly. In addition, these evaluations credit only safety-related features in providing mitigation capability. Therefore, this evaluation is generally included in the spectrum of DBEs analyzed in Chapter 15 of NUREG–0800 (*e.g.,* Sections 15.0.1 or 15.0.3).

The current definition of design bases in 10 CFR 50.2 provides that controlling parameters may be derived either from accepted ''state-of-the-art'' practices or from analysis (based on calculations or experiments). The NRC has determined that this definition is sufficiently broad to accommodate the use of determinate, data-backed thresholds as implemented through guidance without the need for a rulemaking change. Design bases are identified through two primary means:

(1) the functional performance capabilities required to mitigate DBEs and BDBEs; and (2) the design parameters derived from the operational context in which the function is to be performed, including natural hazards and environmental conditions. The first element is addressed through the addition of proposed definitions of DBE and BDBE in 10 CFR 50.2 that would focus safety assessments on credible and realistic risks. With regard to the second element, the NRC has gained substantial experience in developing appropriate determinate and data-backed thresholds to address protection against natural phenomena and environmental conditions. Examples include assessment of tornado winds (RG 1.76, ''Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants''), hurricane winds (RG 1.221, ''Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants''), and seismic hazards (RG 1.208, ''A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion''). The NRC has developed DG–1454 to leverage existing practices in this area and further clarify the selection of design bases.

VII. Background—Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

Safety-related structures, systems and components are defined in 10 CFR 50.2, ''Definitions.'' The relationship between safety-related electric equipment and Class 1E equipment was initially established through footnote 3 of 10 CFR 50.49, ''Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants.'' The final rule promulgating 10 CFR 50.49, including footnote 3 of 10 CFR 50.49, (48 FR 2733; January 21, 1983) stated, in part: ''The scope of the final rule covers that portion of equipment important to safety commonly referred to as ''safety-related'' (which the Commission interprets as essentially ''Class 1E'' equipment defined in [Institute of Electrical and Electronics Engineers (IEEE)]–323–1974).''

The connection between ''safety-related'' and ''Class 1E'' is now established in a more up-to-date standard—IEEE Standard 308, ''IEEE Standard Criteria for Class 1E Power Systems for Nuclear Power Generating Stations,'' which the NRC endorsed in RG 1.32, ''Criteria for Power Systems for Nuclear Power Plants.''

VIII. Discussion—Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

The proposed action would remove footnote 3 of 10 CFR 50.49. Footnote 3 references an old standard that is no longer utilized as the sole means to establish the connection between ''safety-related'' and ''Class 1E.'' Instead, this connection is established in the more up-to-date IEEE Standard 308, which the NRC endorsed in RG 1.32. Removal of this footnote would improve regulatory clarity and would be consistent with the NRC modernizing and improving its regulations to reflect best practices and the maturity of the nuclear industry.

In addition, a minor editorial change is proposed to redesignate the current footnote 4 of 10 CFR 50.49 as footnote 1 given the previous and proposed deletions of the preceding footnotes.

IX. Background—Expanded Alternative Requests Under 10 CFR 50.55a(z)

In 10 CFR 50.55a, ''Codes and standards,'' the NRC incorporates by reference certain parts of editions and addenda of specified codes and standards through rulemaking. Upon incorporation by reference of these specified codes and standards into 10 CFR 50.55a, the provisions of these codes and standards are legally-binding NRC requirements as delineated in 10 CFR 50.55a, subject to the conditions on certain specific provisions that are set forth in 10 CFR 50.55a. Currently, in paragraph (z), ''Alternatives to codes and standards requirements,'' of 10 CFR 50.55a, an applicant or licensee may request authorization of alternatives to the requirements of paragraphs (b), ''Use and conditions on the use of standards,'' through (h), ''Protection and safety systems,'' of 10 CFR 50.55a, if the applicant or licensee demonstrates either that the proposed alternative would provide an acceptable level of quality and safety or that compliance with the specified requirements would result in hardship or unusual difficulty without a compensating increase in the level of quality and safety. Since its initial promulgation in 1971 (36 FR 11423; June 12, 1971), 10 CFR 50.55a has allowed for the consideration of proposed alternatives under these same two criteria. Over the years, 10 CFR 50.55a has been periodically updated to reflect revised and updated codes and standards for nuclear power plants.

On March 15, 1984 (49 FR 9711), the NRC issued a final rule that made procedural changes by, among other things, clarifying the procedures for alternatives, expressly noting that alternatives can be authorized by the Director of the Office of Nuclear Reactor Regulation. In the November 5, 2014, final rule, ''Approval of American Society of Mechanical Engineers' [ASME] Code Cases'' (79 FR 65776), the NRC restructured 10 CFR 50.55a to align with the Office of the Federal Register's guidelines for incorporation by reference and to allow proposed alternatives to NRC-approved Code Cases rather than only to ASME Code provisions. In this restructuring, the proposed alternatives provisions were moved from their prior location in paragraph (a)(3) of 10 CFR 50.55a to a newly designated paragraph (z) of 10 CFR 50.55a. However, these rulemakings addressed only procedural clarifications and a restructuring of existing regulations, not changes in the scope of opportunities for alternatives. In the July 17, 2024, final rule, ''American Society of Mechanical Engineers Code Cases and Update Frequency'' (89 FR 58039), the NRC added paragraph (y), ''Definitions,'' to 10 CFR 50.55a. These definitions provide consistency and clarity throughout 10 CFR 50.55a and accommodate new opportunities to change code of record intervals. However, these definitions were added outside the scope of paragraph (z) of 10 CFR 50.55a because the Commission had not approved the use of 10 CFR 50.55a(z) for definitions or the newly defined intervals.

X. Discussion—Expanded Alternative Requests Under 10 CFR 50.55a(z)

Currently, the proposed alternative provisions of paragraph (z) of 10 CFR 50.55a apply to the codes and standards requirements in paragraphs (b) through (h) of 10 CFR 50.55a. The addition of paragraph (y) to 10 CFR 50.55a in the July 17, 2024, final rule, without an associated expansion of the scope of paragraph (z), has resulted in unanticipated exemptions under 10 CFR 50.12, ''Specific exemptions,'' to use alternate definitions to those included in paragraph (y) of 10 CFR 50.55a. Moreover, the criteria of paragraph (z)(1), ''Acceptable level of quality and safety,'' or (z)(2), ''Hardship without a compensating increase in quality and safety,'' of 10 CFR 50.55a provide appropriate controls for requested alternatives to all requirements in 10 CFR 50.55a, so there is no need to restrict the application of 10 CFR 50.55a(z) to only some paragraphs in 10 CFR 50.55a. Therefore, the NRC proposes to remove the restriction limiting proposed alternatives to paragraphs (b) through (h) of 10 CFR 50.55a so that proposed alternatives would now be permitted for all regulatory requirements in 10 CFR 50.55a using the existing criteria in paragraphs (z)(1) and (2) of 10 CFR 50.55a. The proposed removal of this scope restriction would also allow for the use of the proposed alternatives provision in paragraph (z) of 10 CFR 50.55a for any future additions or modifications to 10 CFR 50.55a without the need for further revision to paragraph (z).

In addition to creating paragraph (y) of 10 CFR 50.55a, the revisions in the July 17, 2024, final rule provided more flexibility to licensees by expanding the code of record interval from 10 years to two consecutive inservice testing and inservice inspection intervals. In that final rule's preamble, the Commission stated, in part, that licensees may request future alternatives based upon the code of record interval. This revision, coupled with the staff position in SECY–23–0061, ''Clarification of the Staff's Position on Certain American Society of Mechanical Engineers Code Alternatives for More Than One 10-Year Inservice Inspection Interval Under Title 10 of the *Code of Federal Regulations* 50.55a,'' dated July 21, 2023, clarified that, when appropriately justified, the duration of an alternative need not be limited to the length of a single inservice testing or inservice inspection interval. Rather, the NRC may approve specific alternatives for longer durations when the technical bases supporting the requested alternative ensure that an acceptable level of quality and safety will be maintained. These existing flexibilities would be unchanged by this proposed rule.

The proposed change would provide additional flexibility to a licensee or applicant, while maintaining the same requirements for an acceptable level of quality and safety or the presence of a hardship without a compensating increase in quality and safety, which have been foundational to proposed alternatives since their initial promulgation.

XI. Background—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

A. Use of Quantitative Risk Results

The AEA requires a licensee to seek an amendment for significant changes to its facility or procedures. The Commission possesses substantial discretion to define, by rule, the threshold that constitutes a change significant enough to require a license amendment.

The current regulation in 10 CFR 50.59 was developed in response to issues involving inconsistency in how licensees applied the previous criteria to determine whether changes, tests, or experiments require prior NRC approval. The NRC is proposing to amend 10 CFR 50.59 to allow licensees to consider risk insights from PRAs when applying the criteria in that provision. The statements of consideration for the 10 CFR 50.59 final rule, ''Changes, Tests, and Experiments'' (64 FR 53582; October 4, 1999), did not allow licensees to use PRA insights at that time, but the Commission recognized the possibility that the NRC could one day develop the regulatory infrastructure to support the use of PRAs in 10 CFR 50.59 analyses.

The NRC now proposes to incorporate the use of quantitative risk results, like Core Damage Frequency (CDF) and Large Early Release Frequency (LERF), to evaluate changes under 10 CFR 50.59(c)(2)(i) and (ii).

The current state of practice in the nuclear fleet for quantitative risk assessment is the use of Level 1/limited Level 2 PRAs. The quantitative risk metrics output by these PRAs are CDF and LERF, and they, along with their changes (*i.e.,* ΔCDF and ΔLERF), are the metrics used as part of risk-informed decision-making processes. As described in RG 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, these risk metrics are based on the Commission's safety goals and the associated quantitative health objectives. Similarly, the NRC proposes to use the small changes in CDF and LERF jointly as means to determine the importance of the effect of the proposed change on accident frequency and SSC malfunction rate under 10 CFR 50.59.

B. Improved Flexibility for Changes to Methods of Evaluation

Currently, 10 CFR 50.59 allows licensees to make certain changes to their facility or procedures without prior NRC approval, provided those changes do not meet specific thresholds that would require a license amendment. One of those thresholds, stated in 10 CFR 50.59(c)(2)(viii), requires NRC review of any change in a methodology that results in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analysis. As explained in the preamble of the 10 CFR 50.59 final rule in 1999, this language was chosen to ensure NRC oversight of the safety margins and conservatisms that form the basis of the NRC's licensing decision. The Commission stated that the language of 10 CFR 50.59(c)(2)(viii) was selected ''to allow licensees only a small degree of flexibility in methods where the results are tending in the non-conservative direction'' (64 FR 53598; October 4, 1999).

In SECY–97–035, ''Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, and Experiments),'' dated February 12, 1997, which transmitted proposed 10 CFR 50.59 guidance to the Commission ahead of the proposed rulemaking, the staff recognized that, ''as the knowledge base increases and computing power increases, new methods of analysis will more accurately predict the actual plant response.'' However, the staff found that a comparison of the analytical results from two different methodologies was not valid to make a 10 CFR 50.59 determination. To make the 10 CFR 50.59 determination using a new methodology, the new methodology must be valid (*e.g.,* previously approved by the NRC) and the analysis in question must be performed for the situation before the change and the situation after the change using the same methodology.

In the decades since the original rule was written, there have been substantial advancements in computational capabilities and modeling practices. New data, improved understanding, and increased computing power now allow for faster iteration and refinement of methods used in safety analyses. Due to this substantial increase in computational power and the rapid growth in the use of modeling and simulation, other industries are beginning to shift away from model-by-model reviews and are instead focusing on the processes by which organizations establish the credibility of their models—specifically through verification, validation, and uncertainty quantification (VVUQ) programs. The U.S. Food and Drug Administration has taken the most prominent step in this direction by issuing new guidance centered on credibility assessments (FDA–2021–D–0980; November 17, 2023). The aviation industry is actively developing a VVUQ standard through an industry-led, Federal Aviation Administration-supported initiative.

The existing requirements of 10 CFR 50.59(c)(2)(viii) mandate a license amendment for any departure from a method of evaluation described in the FSAR. As defined in the regulation, a departure is a change to any element of a methodology, unless the results are ''conservative or essentially the same,'' or any change from one method to another method, unless the method has been previously approved by the NRC for the specific application. Paragraph (a)(2)(iv) of 10 CFR 53.1550 limits changes to methods similarly to 10 CFR 50.59, allowing changes without NRC review and approval only when results are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used under an NRC-approved consensus code or standard. The rapid advancement in computational modeling and simulation can offer more realistic and accurate safety analyses than the legacy methods documented in many plants' original FSARs. Thus, the current regulations can create an unnecessary regulatory burden by requiring licensees to seek amendments to use superior analytical tools, since these new tools would constitute a departure from a method of evaluation described in the FSAR as contemplated in the existing regulatory frameworks. This can disincentivize the adoption of better technology and expend both licensee and NRC resources on reviewing license amendment requests that ultimately enhance, rather than degrade, safety analysis quality. The purpose of the proposed rule change, therefore, would be to increase regulatory efficiency and flexibility, consistent with the objectives of the 1999 rule revision, the ADVANCE Act, and the Executive orders.

XII. Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

A. Use of Quantitative Risk Results

The NRC proposes rulemaking to establish an alternative pathway that would allow the use of quantitative risk metrics, like CDF and LERF, along with consideration of safety margins and defense in depth, to evaluate a proposed change, test, or experiment against the criteria of 10 CFR 50.59(c)(2)(i) and (ii), while leaving all other criteria in 10 CFR 50.59(c)(2) in place. New proposed 10 CFR 50.59(e) would establish a risk-informed alternative to the existing regulation and would not alter or impede the current practice for evaluating proposed changes against the text of 10 CFR 50.59(c)(2)(i) and (ii), as written. A licensee could continue to use qualitative assessments, engineering judgement, and other existing practices and techniques to evaluate a proposed change, test, or experiment.

Under the proposed 10 CFR 50.59(e), a licensee could demonstrate that a change would not result in a ''more than a minimal increase'' under 10 CFR 50.59(c)(2)(i) and (ii) by using quantitative risk results based on a PRA of appropriate scope and quality that provides appropriate risk metrics. The change would also need to maintain defense-in-depth and safety margins. ''Appropriate scope and quality'' in this context would mean that the licensee's model fully encompasses the proposed change and that the model has been found to be acceptable for use in a previous NRC-approved application. ''Appropriate risk metrics'' in this context would mean quantitative results that demonstrate the effects on the proposed change and can provide a baseline for judging facility risk. For traditional PRAs, these metrics are CDF, LERF, and the changes (Δs) to CDF and LERF. Extensive discussion of maintaining defense in depth and safety margins can be found in RG 1.174, Revision 3. The NRC has proposed guidance for 10 CFR 50.59(e) in DG–1466, draft Revision 4 to RG 1.187, ''Guidance for Implementation of 10CFR50.59, 'Changes, Tests, And Experiments.'''

The use of PRA would not replace or supplant the deterministic licensing basis but would supplement it with a powerful analytical tool. Since the initial licensing of the current fleet, the NRC and the industry have developed and matured PRA methodologies, which provide a holistic, integrated assessment of plant safety. PRA can identify contributors to risk and potential vulnerabilities that may not be apparent from a purely deterministic analysis.

Incorporating CDF and LERF into the 10 CFR 50.59 process would not be an attempt to re-license plants on a probabilistic basis. Instead, it would provide an alternative methodology licensees could voluntarily choose for conducting analyses under 10 CFR 50.59. It would use risk insights to inform the judgment of the safety significance of changes to the existing deterministic design. A change that results in a very small, quantifiable increase in calculated risk could be reasonably judged not to undermine the fundamental safety basis established through deterministic principles. This approach would allow for a more consistent, predictable, and efficient screening process, directly fulfilling the original purpose of 10 CFR 50.59 to differentiate between changes that require prior NRC review and those that do not.

This integration would be consistent with decades of evolving NRC policy and practice. The agency has successfully used risk-informed approaches in many other regulatory applications, including 10 CFR 50.65, ''Requirements for monitoring the effectiveness of maintenance at nuclear power plants''; 10 CFR 50.48(c), ''National Fire Protection Association Standard NFPA 805''; the Reactor Oversight Process; and RG 1.174. Using quantitative risk results, such as from a PRA, in the 10 CFR 50.59 process would be a logical evolution that would enhance the existing framework by leveraging modern analytical tools to better focus licensee and agency resources on issues of genuine safety significance.

B. Improved Flexibility for Changes to Methods of Evaluation

The NRC proposes two regulatory amendments, which would work in concert to allow licensees greater flexibility to implement changes to analytical methods described in the FSAR.

First, the NRC proposes a targeted revision to 10 CFR 50.59(c)(2)(viii) and 53.1550(a)(2)(iv). This change would allow licensees to implement certain changes to analytical methods described in the FSAR (as updated) without prior NRC approval, provided those changes are undertaken pursuant to an NRC-approved VVUQ program under 10 CFR 50.221, ''Credibility requirements for modeling and simulation.'' Proposed guidance for compliance with proposed 10 CFR 50.221 is in DG–1468, ''Guidance for Implementation of 10 CFR 50.221, 'Credibility requirements for modeling and simulation.''' This revision would clarify that appropriate changes made using a risk-informed and graded VVUQ framework would be permissible under 10 CFR 50.59 without prior NRC approval. The proposed rule would allow such changes without prior NRC approval only if the VVUQ program were approved by the NRC for the method of evaluation in question, and the new method of evaluation met the credibility criteria established in the approved VVUQ. These measures would maintain safety and ensure appropriate controls over licensee changes to methods or evaluations while affording flexibility through reliance on the NRC-approved VVUQ program.

Second, the NRC proposes to adopt an optional regulation on VVUQ at 10 CFR 50.221 that would establish the requirements a VVUQ program must meet. The new regulation would establish clear requirements and structure for VVUQ activities used to support regulatory decisions. Specifically, the proposed 10 CFR

50.221 would specify that licensees and applicants could voluntarily establish a VVUQ program and determine the scope of the models and simulations the VVUQ program would cover. Licensees and applicants that establish a VVUQ program would be required to establish a process under the VVUQ program for demonstrating the credibility of models and simulations through VVUQ activities and assessments and could use only models and simulations within the scope of the program for which the licensee or applicant has successfully completed VVUQ activities and assessments. Additionally, the licensee or applicant adopting a VVUQ program would need to ensure that the VVUQ activities and assessments were commensurate with the overall risk from the model or simulation. The NRC has prepared guidance in DG–1468 on an acceptable approach for a VVUQ program that would conform to the proposed regulation. This approach would provide a consistent, technology-neutral framework for demonstrating model credibility across the NRC's regulatory structure.

Via these proposed changes, the NRC would shift focus away from evaluating each individual model or simulation directly and toward evaluating the process by which models are determined to be credible—specifically through structured VVUQ programs. In this context, credibility would refer to the level of trust in a model's ability to produce accurate and appropriate predictions for its intended use. An NRC-approved VVUQ program would establish a new licensing basis that focuses on how methods are selected and applied, rather than the characteristics of the specific method and the inherent conservatisms. Where appropriate, VVUQ-based credibility assessments could serve as a viable alternative to full NRC review of each new or revised model. However, a single generic VVUQ process would not be appropriate due to the significant variability in physical phenomena, modeling assumptions, numerical techniques, and uncertainties across different reactor technologies and methods of evaluation. A tailored VVUQ process approved by the NRC for the intended application would be required for each method of evaluation to provide the necessary specificity to ensure credible, defensible assessments of model performance for each unique application for all possible reactor technologies and their vastly different physical domains.

This approach could be particularly beneficial for new and advanced reactor designs. Unlike the current fleet, which has decades of operational data and analytical stability, advanced reactors often lack extensive experimental databases at the time of initial licensing. Requiring them to demonstrate method maturity at the level of existing plants would demand significant upfront testing and analysis, delaying deployment and increasing cost. Many of these designs are being developed as test reactors specifically to generate such data. A rule change would provide a clear, structured mechanism for these reactors to update their methods over time, based on data collected during operation, without needing to go through repeated full NRC reviews—so long as the updates are made through an approved VVUQ process.

XIII. Background—Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors

The regulation in 10 CFR 50.75, ''Reporting and recordkeeping for decommissioning planning,'' establishes requirements for indicating to the NRC how an applicant or licensee will provide reasonable assurance that funds will be available for the decommissioning process. During the operational phase of a reactor facility, an applicant or licensee must certify that funding is being provided in an amount that may be more, but not less, than the amount described in 10 CFR 50.75(c)(1) and (2) (also known as the table of minimum amounts, minimum funding assurance, or ''formula'' amount). As the NRC stated in the 1988 decommissioning rule (53 FR 24018–24030; June 27, 1988), the ''formula'' amount in 10 CFR 50.75(c) does not represent the actual cost of decommissioning for specific reactors but rather serves as a reference level established to ensure that the bulk of the funds necessary for a safe decommissioning is being considered and planned for early in facility life by licensees. This provides assurance that the facility will not become a risk to public health and safety when it is decommissioned.

The table of minimum amounts and the associated adjustment factors were developed and designed specifically for the large light-water reactor technologies (boiling water reactors and pressurized water reactors) that make up the current commercial power reactor fleet in the U.S. However, new reactors may incorporate different technologies and output capacities that may not require the amount of decommissioning funding assurance described in 10 CFR 50.75(c). In order to address different decommissioning funding needs for these new technologies without requiring an exemption from NRC regulations, the NRC is proposing updates to its regulations to allow certain new reactor applicants and licensees the flexibility to certify adequate decommissioning funding assurance during operations through the use of either the table of minimum amounts or the submission of a design-specific decommissioning cost estimate. Allowing for the use of a design-specific decommissioning cost estimate that may be less than the table of minimum amounts would provide a path for certain new reactor applicants and licensees to demonstrate financial responsibility for safe decommissioning based on factors specific to the reactor facility.

XIV. Discussion—Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors

The NRC proposes an amendment to 10 CFR 50.75 to allow certain new reactor applicants and licensees to submit a design-specific decommissioning cost estimate to demonstrate minimum decommissioning funding assurance during operations that may be less than the table of minimum amounts provided in 10 CFR 50.75(c). The values in the current table of minimum amounts are based on funding assumptions associated with the decommissioning of large light-water reactor facilities. This proposed rule would allow certain new reactor applicants and licensees to certify financial assurance for decommissioning through the use of either the minimum formula amount or through the submission of a design-specific decommissioning cost estimate. Thus, the proposed rule would provide flexibility for new reactor applications that represent smaller output and size considerations than large light-water reactor designs.

Specifically, the NRC is proposing to add a new paragraph (b)(2) to 10 CFR 50.75 that describes the certification amount process and minimum requirements, including reliance on design-specific decommissioning cost estimates, for new reactor applicants and licensees seeking to use the alternative pathway. Additionally, the NRC is proposing to delete language in the table of minimum amounts in 10 CFR 50.75(c)(1) that requires reactors of less than 1200 megawatts thermal (MWt) to use the certification amount for a 1200 MWt reactor. It is conceivable that new LWR designs could have an output less than 1200 MWt. Therefore, requiring a new reactor applicant or licensee to assure to an amount well above what is needed to establish decommissioning funding assurance could be financially limiting and unnecessary to meet the intent of decommissioning funding assurance regulations.

A certification relying on a design-specific decommissioning cost estimate would be required to include a description of the factors used to develop the design-specific decommissioning cost estimate, including generic activities performed in the major decommissioning phases of a decommissioning project (*e.g.,* pre-decommissioning engineering and planning, reactor deactivation, and dismantlement). Similar to the table of minimum amounts for large light-water reactor designs, design-specific decommissioning cost estimates should represent the bulk of funds necessary to safely decommission a facility, as applicable to the specific reactor technology being utilized and the design of the facility. Additionally, similar to the table of minimum amounts for large light-water reactor designs, the design-specific decommissioning cost estimate would have to be adjusted annually at a rate at least equal to the formula in 10 CFR 50.75(c)(2). This certification process would include NRC review and approval. However, once an initial design-specific decommissioning cost estimate is approved by the agency as a sufficient certification amount for financial assurance for decommissioning, other applicants or licensees using similar technology could reference and justify use of this amount (escalated in accordance with NRC regulations and guidance) as the certification amount required by proposed 10 CFR 50.75(b) for a different application. Once a licensee nears permanent cessation of operations, a site-specific decommissioning cost estimate that encompasses the design-specific cost as well as costs associated with the site and operational period of the facility, would be required for funding assurance purposes, as described in current regulations in 10 CFR 50.82, ''Termination of license.'' Finally, the NRC is proposing to revise 10 CFR 50.75(e)(1)(i) and (ii) to allow reactor licensees that have prepaid or collected funds based on a design-specific estimate to take credit for projected earnings on the prepaid or collected decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations.

The NRC is proposing a similar change to 10 CFR part 53. Currently, 10 CFR part 53 only allows for a site-specific decommissioning cost estimate as the certification amount. Therefore, the NRC is proposing to add conforming language to 10 CFR 53.1010, ''Financial assurance for decommissioning,'' and 53.1020, ''Cost estimates for decommissioning,'' to allow new reactor applicants and licensees to submit a design-specific decommissioning cost estimate to demonstrate minimum decommissioning funding assurance during operations. Finally, the NRC is proposing to add conforming language to 10 CFR 53.1040, ''Methods for providing financial assurance for decommissioning,'' to allow new reactor applicants and licensees that have prepaid or collected funds based on a design-specific estimate to take credit for projected earnings on the prepaid or collected decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations.

Additionally, conforming changes would be made to 10 CFR 50.75(e) to include references to the requirements of proposed 10 CFR 50.75(b)(2), where appropriate. In addition, this proposed rule would revise 10 CFR 50.75(e) to include ''applicant or'' in all appropriate places where currently only ''licensee'' is referenced, as directed by the Commission in staff requirements memorandum (SRM)-SECY–23–0021: Enclosure 4, ''Table of Typographical errors and Inconsistencies,'' dated March 4, 2024. Similar changes are proposed in 10 CFR 53.1040 and 10 CFR 53.1050, ''NRC oversight'' for consistency. Collectively, these changes would clarify that applicants and licensees would be subject to the requirements under 10 CFR 50.75(e), 53.1040, and 53.1050, as applicable.

This proposed rule also would make minor editorial changes in 10 CFR 50.75(e), (g), and (h) by removing errant commas, correcting capitalization errors, correcting references by indicating paragraphs instead of sections, and removing ''of this part,'' where necessary.

XV. Background—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

A. Historic Quality Assurance Requirements Perspectives and Emergent Issues

During the early days of nuclear power (1950s-1960s), the Atomic Energy Commission (AEC), the NRC's predecessor agency, focused on developing and licensing nuclear reactors. As the nuclear industry grew, it became clear that systematic quality assurance (QA) was essential to ensure nuclear safety, especially given the complexity and potential hazards of nuclear technology. By the 1960s, nuclear power plants were becoming more complex, and the consequences of failures were more severe. Incidents and near-misses highlighted the need for formalized QA programs to prevent design, fabrication, and construction errors. Appendix B was added to 10 CFR part 50 by the AEC in 1970 (35 FR 10498; June 27, 1970) to (1) establish minimum QA requirements for safety-related structures, systems, and components (SSCs) and (2) ensure that these SSCs are designed, fabricated, constructed, and tested to perform their intended safety functions.

Applicants for CPs, OLs, early site permits (ESPs), COLs, design certifications, standard design approvals, and manufacturing licenses (MLs) must include in their respective application a description of the QA program that discusses how the applicable requirements of appendix B to 10 CFR part 50 are satisfied.

Although appendix B to 10 CFR part 50 is foundational to nuclear safety, commenters have expressed concerns over its implementation, flexibility, and alignment with modern practices. These concerns include the following topics.

- *Inflexibility:* Appendix B to 10 CFR part 50 (1) is prescriptive and has not been substantively updated since 1970; (2) lacks risk-informed or performance-based flexibility, which modern quality systems increasingly emphasize; and (3) does not facilitate tailoring of QA programs to low-risk activities or innovative technologies.
- *Outdated Language:* The language in appendix B to 10 CFR part 50 is reflective of technologies from the 1970s and does not explicitly address digital systems, software QA, and additive manufacturing. As a result, applicants must rely on guidance, which could result in inconsistent implementation across applicants due to applicants interpreting the guidance differently based on their specific technologies.
- *Vendor and Supply Chain Challenges:* Many suppliers, especially non-nuclear vendors, are unfamiliar with appendix B to 10 CFR part 50, and thus applicants and licensees have challenges in procuring products and services for the nuclear power plants.
- *Lack of Harmonization with International Standards:* Appendix B to 10 CFR part 50 is United States-specific and not aligned with international standards and best practices and, thus, creates challenges for international collaboration and global supply chains.

In light of these considerations, commenters have advocated for a modernized, risk-informed QA framework that retains the safety rigor of appendix B to 10 CFR part 50 while allowing for graded application based on safety significance that is integrated with modern quality systems.

B. NRC Responses to These Issues

As a result of these issues, the NRC is proposing to add appendix T to 10 CFR part 50 as a voluntary alternative to appendix B to 10 CFR part 50. The proposed appendix T would draw on international QA standards to incorporate the following elements:

- Performance-based QA criteria that provide explicit direction on use of a graded approach for applying QA requirements to SSCs relative to their safety and risk contributions to the overall nuclear facility.
- Quality assurance requirements specific to software used in digital items and for design and analysis.
- Quality assurance terminology and methodologies used across various safety critical industries and in international standards for quality management, thus allowing applicants to leverage cross-industry and global supply chains.

XVI. Discussion—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

This proposed rule would add a new appendix T to 10 CFR part 50 to provide streamlined QA criteria that could be used for applications of COLs, CPs, and OLs under certain eligibility requirements.

A. Introduction and Scope

As discussed in section XV, ''Background—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' of this document, NRC stakeholders have expressed interest in utilizing a streamlined approach to QA that better aligns with international standards. Therefore, the NRC has developed a proposed appendix T to 10 CFR part 50 that would provide an alternative to the current QA requirements in appendix B to 10 CFR part 50 based on International Standard, ISO 19443, ''Quality management systems—Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety [ITNS],'' (2018–05). The International Standard Organization collaborated closely with the International Atomic Energy Agency in developing ISO 19443.

The proposed section I, ''Introduction and Scope,'' of appendix T to 10 CFR part 50 would provide the eligibility requirements for using appendix T to 10 CFR part 50 as a voluntary alternative to appendix B to 10 CFR part 50. Specifically, applicants for CPs, OLs, and COLs would have the option to use appendix T to 10 CFR part 50 as an alternative to appendix B to 10 CFR part 50, provided that the three conditions in section I are met.

Proposed condition I.A would require that the application is for an nth-of-a-kind (NOAK) plant and would require the application to identify the first-of-a-kind (FOAK) reference plant.

Proposed condition I.B would require that any departures from the FOAK reference plant in the application of the NOAK plant would not result in a change to the classification, design, and method of manufacture, construction, and operation of SSCs identified in licensing basis of the referenced plant.

Proposed condition I.C would require the application to include procedures and work processes for implementing the requirements in proposed appendix T to 10 CFR part 50.

The NRC would define FOAK nuclear power plants and fuel reprocessing plants in proposed appendix T as the initial implementation of a new reactor design or technology or new fuel reprocessing plant design that has not been previously constructed and operated at commercial scale, either within the U.S. or internationally. The FOAK plant would serve as a reference plant for NOAK nuclear power plants and fuel reprocessing plants. The NRC would define NOAK nuclear power plants and fuel reprocessing plants in proposed appendix T to be any subsequent implementation of a FOAK reactor design or technology or fuel reprocessing plant design after the FOAK plant has been designed, constructed, and operated.

Proposed conditions I.A, I.B, and I.C would limit the use of proposed appendix T to 10 CFR part 50 to those applications that could potentially leverage the following:

- the design maturity of the FOAK completed plant design information;
- standardized components and systems to streamline procurement and construction;
- skilled labor and contractors from the FOAK projects;
- FOAK operational data to help NOAK commissioning procedures, standard operating procedures, emergency operating procedures, training, design, and operational programs; and
- established processes and procedures for implementing the requirements in proposed appendix T to 10 CFR part 50, including an established mechanism to ensure deviations from FOAK reliability in NOAK would be identified and promptly corrected.

In recent cases, the NRC has noticed that design details and QA procedures are not available during the licensing review of a CP, OL, or COL for a FOAK plant. Therefore, during licensing and construction for FOAK plants, the NRC conducts vendor inspections to confirm the detailed design and as-built SSCs meet the technical and quality requirements committed to by the applicant. However, because a NOAK applicant could reference design details and QA procedures developed during the FOAK licensing, these additional QA activities, such as vendor inspections, may be unnecessary, especially for vendors previously inspected by the NRC. Therefore, when the conditions I.A, I.B, and I.C are met, the proposed appendix T to 10 CFR part 50 may eliminate the need for NRC oversight of suppliers and vendors who supply applicants with approved appendix T to 10 CFR part 50 compliant QA programs because (1) the list of SSCs that would be governed by proposed appendix T to 10 CFR part 50 would be standardized and verified to be acceptable using information from the reference FOAK plant; (2) the design of these SSCs would be complete and verified to be acceptable using information from the reference FOAK plant; and (3) the manufacturing and construction methods for these SSCs would be established and verified to be acceptable during oversight of manufacturing and construction processes for the referenced FOAK plant.

B. Definitions

The proposed section II, ''Definitions,'' of proposed appendix T to 10 CFR part 50, would include definitions for terms used in the proposed appendix.

The NRC would define ''first-of-a-kind'' nuclear power plants and fuel reprocessing plants as the initial implementation of a new reactor design or technology or new fuel reprocessing plant design that has not been previously constructed and operated at commercial scale.

The NRC would define ''nth-of-a-kind'' nuclear power plants and fuel reprocessing plants as any subsequent implementation of a reactor design or technology or fuel reprocessing plant design after the FOAK has been designed, constructed, and operated.

The NRC would define ''quality assurance'' as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system that provide a means to ensure the material, structure, component, or system meets predetermined requirements. This proposed definition is equivalent to the definition used in appendix B to 10 CFR part 50.

The NRC would define ''quality assurance program'' as the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work necessary to achieve QA.

The NRC would define ''quality management system'' (QMS) as a structured framework that documents an organization's processes, procedures, and responsibilities for ensuring quality. This term and definition are used broadly by other safety-critical industries, nuclear regulatory bodies and industry abroad, and vendors and third-party suppliers to these industries. The QMS is different from the terminology ''quality assurance program description'' (QAPD) used in appendix B to 10 CFR part 50 in that the QMS has a broader scope and is a system framework that includes quality planning, controls, assurance, and improvement; whereas a QAPD is a descriptive document that is narrowly focused on QA.

The NRC would define ''functional design criteria'' as metrics for the performance of SSCs. For safety-related SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in 10 CFR 53.210, ''Safety criteria for design-basis accidents.'' For non-safety-related but safety-significant SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in 10 CFR 53.220, ''Safety criteria for licensing-basis events other than design-basis accidents.'' This proposed definition would be added to proposed appendix T to 10 CFR part 50 to align with the definition and use of this term in 10 CFR part 53.

The NRC would define ''non-safety-related but safety-significant SSCs'' as those SSCs that are not safety-related but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment. This proposed definition would be added to proposed appendix T to 10 CFR part 50 to align with the definition and use of this term in 10 CFR part 53.

C. General Requirements

The proposed section III, ''General Requirements,'' of proposed appendix T to 10 CFR part 50 would provide general requirements for establishing and maintaining a QA program for applicants that choose to meet proposed appendix T.

Proposed section III.A, ''Integrated Quality Assurance Program,'' of proposed appendix T to 10 CFR part 50 would require that the integrated QA program ensures that safety-related and non-safety-related but safety-significant SSCs are designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those SSCs perform. Proposed section III.A of in proposed appendix T to 10 CFR part 50 would include the following seven items that any application using in proposed appendix T to 10 CFR part 50 would be required to identify and explain in the integrated QA program:

• Responsibilities (1) are properly assigned to specific individuals or teams in charge of executing QA activities and (2) ensure any delegated responsibilities are properly identified and controlled.

• The design requirement of SSCs are sufficiently captured in corresponding documents; the design bases requirements are adequately translated into specifications, drawings, procedures, and instructions; outputs reflect the correct design inputs; the design is properly verified and validated; the as-built and as-operated SSC properly meet the intended function and safety margin.

• Means and methods are established to communicate relevant technical, quality, and regulatory requirements, expectations, and concerns between the applicant and its vendors and third-party suppliers.

• Measures are established to (1) ensure that procured SSCs and related services meet technical and quality requirements and (2) assess the capability of vendors or third-party suppliers that supply the SSCs and related services.

• Measures are established to (1) verify and validate that products and services meet the technical and quality requirements of the procured products and services, and (2) audit the vendors or third-party suppliers that are providing the products and services.

• Processes are implemented to address reoccurrence of issues and failures.

• Recordkeeping and documentation protocols for the QA program are established.

Proposed section III.B.1 of proposed appendix T to 10 CFR part 50 would require the applicant document the QA program in the QMS and submit the QMS to the NRC for review and approval. Proposed section III.B.1 would require the QA program, as documented in the QMS, to contain a graded approach for implementing the requirements of the QA program.

Proposed section III.B.2 of proposed appendix T to 10 CFR part 50 would require the QMS to describe how the requirements in section IV of the appendix would be met. Proposed section IV of appendix T to 10 CFR part 50 would identify general QA criteria and software QA criteria. Proposed section III.B.3 of appendix T to 10 CFR part 50 would require the applicant to invoke the applicant's QA requirements in procurement documents to all relevant contractors, vendors, suppliers, and third-parties.

Proposed section III.B.4 of proposed appendix T to 10 CFR part 50 would require the applicant to select the appropriate industry standards that are used to achieve quality consistent with regulatory requirements and the NRC's policies. This proposed section would state that the applicant would need to document the selection of ASME Nuclear Quality Assurance (NQA)–1, ''Quality Assurance Requirements for Nuclear Facility Applications'' or another appropriate industry standard. Proposed section III.B.4 of appendix T to 10 CFR part 50 would also require that gaps between the selected industry standards and the proposed section IV, ''Quality Assurance Requirements,'' of appendix T to 10 CFR part 50 are addressed within the QMS.

D. Quality Assurance Requirements

Proposed section IV.A, ''Quality Assurance Criteria,'' of proposed appendix T to 10 CFR part 50, identifies QA criteria that would be applicable to all applications that reference proposed appendix T to 10 CFR part 50. This proposed section would include 11 criteria that cover topical areas in management, performance, and assessment. The proposed requirements in these topical areas are consistent with International Standards for QMSs such as ISO 9001, ''Quality Management System—Requirements,'' which are used by many safety-critical industries, and ASME NQA–1, ''Quality Assurance Requirements for Nuclear Facility

Applications,'' which is used by the nuclear industry.

(i) Management

Proposed section IV.A.1, ''Criterion 1—Management: Program,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to define the organizational structure, functional responsibilities, levels of authority, and interfaces for performing the work necessary to implement the QA program, and develop management processes to plan, schedule, and assign resources to perform this work.

Proposed section IV.A.2, ''Criterion 2—Management: Personnel Training and Qualifications,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to develop processes for indoctrination and continuous training of employees for performing the work necessary to implement the QA program.

Proposed section IV.A.3, ''Criterion 3—Management: Quality Improvement,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement a process for identifying and controlling issues and failures that could adversely impact quality, safety, and regulatory compliance. The proposed section IV.A.3 would also require applicants to include prevention of recurrence of issues as part of corrective actions and implement processes for continuous improvement of the QA program.

Proposed section IV.A.4, ''Criterion 4—Management: Documents and the Associated Records,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to prepare, review, approve, issue, use, and revise documents that prescribe processes, specify requirements, or establish the design of the SSC, and maintain these documents as records for the QA program.

(ii) Performance

Proposed section IV.A.5, ''Criterion 5—Performance: Work Processes,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to perform work, including hazard controls. Hazard controls are systematic measures designed to prevent, detect, and correct issues that could compromise quality, safety, and regulatory compliance. Examples of hazard controls applicable to QA programs include:

- embedded work processes to ensure quality such as inspection and testing protocols, hold points and witness points, and nonconformance reporting protocols;
- monitoring and detection programs to ensure detection of deviations and malfunctions in real time such as surveillance and audits;
- structured approaches to identify quality issues and implement corrective and preventive actions.

Proposed section IV.A.5 of proposed appendix T to 10 CFR part 50, would also require the applicant to establish and implement work processes for identifying and controlling items to ensure proper use; maintain items to prevent damage, loss, or deterioration; and calibrate and maintain equipment used for activities affecting quality.

Proposed section IV.A.6, ''Criterion 6—Performance: Design,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement measures for controlling the design of SSCs, including requirements for controlling design changes, design interfaces, and verifying and validating the adequacy of the design. Verify in the context of design control means to perform the set of activities to demonstrate that design conforms to specifications and occurs during the design and development process. Examples include reviews, inspections, and unit tests. Validate in the context of design control means to perform the set of activities to demonstrate that the as-developed or as-built SSC performs the intended safety-functions and occurs after the development process. Examples include integrated tests, analysis, and simulations.

Proposed section IV.A.7, ''Criterion 7—Performance: Procurement,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for procurement of items and services, including processes to verify that procured items and services meet established requirements, evaluate and select prospective suppliers, and verify that the approved suppliers continue to provide acceptable items and services.

Proposed section IV.A.8, ''Criterion 8—Performance: Inspection and Acceptance Testing,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for performing inspection and acceptance testing for procured items and services.

Proposed section IV.A.9, ''Criterion 9—Performance: Maintenance of Structures, Systems, and Components,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes to control the storage of SSCs in accordance with cleanliness and environmental standards. These requirements would ensure that a process is used to prevent foreign material from being introduced to the SSC during storage and to store SSCs in accordance with the required environmental conditions (*e.g.,* humidity, temperature).

(iii) Assessment

Proposed section IV.A.10, ''Criterion 10—Assessment: Management Assessment,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for management of the organization to assess the continued effectiveness of the QA program.

Proposed section IV.A.11, ''Criterion 11—Assessment: Independent Assessment,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for independent assessment of each aspect of the QA program. These requirements would ensure that those performing these assessments have sufficient authority and freedom from their management and are technically qualified and knowledgeable to perform the assessment.

E. Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety

Proposed section IV.B, ''Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety,'' of proposed appendix T to 10 CFR part 50, would identify QA criteria for software used for design and analysis of SSCs and for digital items important to safety.

Proposed section IV.B.1 of proposed appendix T to 10 CFR part 50, would require that applicants establish and implement processes within the QA program to ensure that (1) software used in digital items that perform a safety function, (2) software used for design verification for any SSC, and (3) software used for design analysis for any SSC, are documented, managed, and controlled throughout the software life cycle to ensure that the related SSCs perform their intended safety function.

Proposed section IV.B.2 would require the applicant to use appropriate national or internal software engineering standards. Examples of such standards include ASME, Institute for Electrical and Electronics Engineers (IEEE), National Institutes of Standards and Technology (NIST), and American Nuclear Society (ANS).

F. Proposed Conforming Changes to 10 CFR 50.4, 50.34, 50.54, 50.55, 52.79, 53.020, 53.040, 53.460, 53.500, 53.865, 53.1309, 53.1369, 53.1416, and 53.1565

Proposed conforming changes to 10 CFR 50.34(a)(7) would allow a CP applicant who meets the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a CP, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 50.34(a)(7) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 50.34(b)(6)(ii) would allow an OL applicant who meets the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to include in its application for an OL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 50.34(b)(6)(ii) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 50.34(f)(3)(ii) would add a reference to the proposed appendix T to 10 CFR part 50 for the requirement on ensuring all SSCs important to safety are included in the QA list.

Proposed conforming changes to 10 CFR 50.54(a)(1) would incorporate requirements for:

• Each nuclear power plant or fuel reprocessing plant licensee subject to the QA criteria in proposed appendix T of 10 CFR part 50, to implement, under 10 CFR 50.34(b)(6)(ii) or 52.79, the QMS described or referenced in the safety analysis report, including changes to that report.

• For holders of a COL under 10 CFR part 52, to implement the QMS described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for initial loading of the fuel.

The proposed conforming addition of 10 CFR 50.54(a)(5) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation.

Proposed conforming changes to 10 CFR 50.55(f)(1) would incorporate requirements for nuclear power plant or fuel reprocessing plant CP holders subject to the QA criteria in proposed appendix T of 10 CFR part 50, to implement, pursuant to 10 CFR 50.34(a)(7), the QMS described or referenced in the safety analysis report, including changes to that report.

The proposed conforming addition of 10 CFR 50.55(f)(5) would add requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation.

The proposed conforming addition of paragraph (b)(7)(iii) to 10 CFR 50.4, ''Written communications,'' would require a change to the safety analysis report QMS under the proposed 10 CFR 50.54(a)(5) or 10 CFR 50.55(f)(5), or a change to a licensee's NRC-accepted QMS topical report under 10 CFR 50.54(a)(5) or 10 CFR 50.55(f)(5), to be submitted to the NRC's Document Control Desk, with a copy to appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

Proposed conforming changes to 10 CFR 52.79(a)(25) and (27) would allow a COL applicant who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for COL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 52.79(a)(25) and (27) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.020 would modify the definition of QA to align with the definition of QA in the proposed appendix T to 10 CFR part 50.

The proposed conforming addition of paragraph (b)(7)(iii) to 10 CFR 53.040, ''Written communications,'' would require a change to the safety analysis report QMS under the proposed 10 CFR 53.1565, ''Evaluating changes to programs included in licensing-basis information,'' or a change to a licensee's NRC-accepted QMS topical report under 10 CFR 53.1565, to be submitted to the NRC's Document Control Desk, with a copy to appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

Proposed conforming changes to paragraphs (b)(1) and (2) of 10 CFR 53.460, ''Safety categorization and special treatments,'' would allow, for applicants that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, the special treatments for safety-related SSCs (under proposed 10 CFR 53.460(b)(1)), and non-safety-related safety-significant SSCs and safety-related SSCs beyond 10 CFR 53.460(b)(1) (under proposed 10 CFR 53.460(b)(2)), to meet applicable QA requirements from proposed appendix T to 10 CFR part 50, as an alternative to these SSCs having to meet the applicable QA requirement in appendix B to 10 CFR part 50.

Proposed conforming changes to paragraph (b) of 10 CFR 53.500, ''General siting and siting assessment,'' would allow, for applicants that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of 10 CFR part 53 to satisfy the QA requirements from proposed appendix T to 10 CFR part 50, as an alternative for these activities to meet the applicable QA requirement in appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.865, ''Quality assurance,'' for holders of an OL or COL under 10 CFR part 53 that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to develop, implement, and maintain a QA program in accordance with proposed appendix T to 10 CFR part 50, as an alternative to appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1309(a)(2)(i) would allow a CP applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a CP, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.109(a)(2)(i) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1369(l) would allow an OL applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for an OL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.1369(l) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1416(a)(12) would allow a COL applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a COL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.1416(a)(12) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1565(d)(1)(i) would clarify the applicability of QA criteria of appendix B of 10 CFR part 50 for each holder of an OL or COL under 10 CFR part 53, after the Commission makes the finding under 10 CFR 53.1452(g).

Proposed conforming addition of 10 CFR 53.1565(d)(1)(iii) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation for each holder of an OL or COL under 10 CFR part 53, after the Commission makes the finding under 10 CFR 53.1452(g).

Proposed conforming changes to10 CFR 53.1565(d)(2) would modify the numbering scheme and clarify the applicability of QA criteria of appendix B to 10 CFR part 50 for each holder of a CP or COL under 10 CFR part 53, before the Commission makes the finding under 10 CFR 53.1452(g).

The proposed conforming addition of 10 CFR 53.1565(d)(2)(ii) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation for each holder of a CP or COL under 10 CFR part 53, before the Commission makes the finding under 10 CFR 53.1452(g).

XVII. Background—Updates to Construction Permit Requirements and Related Licenses

The regulations in 10 CFR 50.34 specify the requirements for technical information to accompany an application for a CP or an OL. These regulations were amended in 1968 (33 FR 18610; December 17, 1968) to add paragraph (a) of 10 CFR 50.34 to require an applicant for a CP to submit a preliminary safety analysis report. Paragraph (a) of 10 CFR 50.34 specifies the minimum technical information in the preliminary safety analysis report, including preliminary design information and a description and safety assessment of the site on which the facility is to be located. As stated in the 1968 final rule, the preliminary safety analysis report requirement was ''intended to provide early and adequate information which is expected to expedite the processing of CP applications by reducing the time-consuming exchanges between the applicant and the AEC staff required to fill information gaps.'' Subsequent changes to 10 CFR 50.34 from 2007 to the present were additions due to new requirements, as well as clarifications and relaxations, but the majority of 10 CFR 50.34 is unchanged since 1968.

The NRC may issue the CP if the agency makes the findings specific to a CP that are listed in paragraph (a) of 10 CFR 50.35, ''Issuance of construction permits,'' as well as the more general findings for issuance of licenses and permits in 10 CFR 50.40, ''Common standards,'' and 10 CFR 50.50, ''Issuance of licenses and construction permits.'' The findings in 10 CFR 50.35(a) stem from the early practices of the AEC, when a ''provisional'' CP would be issued when an applicant had not submitted all the technical information necessary to complete the application and to approve all proposed design features. Since almost all issued ''provisional'' CPs were never converted to a ''final'' CP, the AEC proposed codifying this practice (34 FR 6540; April 16, 1969). The final amendment to the regulations in 10 CFR 50.35 eliminated the term ''provisional'' CP, but the criteria in 10 CFR 50.35(a) for issuing a CP remained the same as those previously required for a ''provisional'' CP (35 FR 5317; March 31, 1970). The current regulations for issuing a CP in 10 CFR 50.35(a) have not been modified since 1970.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to reform the NRC's licensing process for future nuclear power plants. The rule established new approval processes in 10 CFR part 52 for ESPs, standard design certifications, and COLs that were additions to the two-step licensing process that already existed in 10 CFR part 50. This 10 CFR part 52 rule also included processes for standard design approvals and MLs. On August 28, 2007 (72 FR 49352), the NRC issued a final rule with changes to 10 CFR part 52 to clarify the applicability of various requirements to each of the 10 CFR part 52 approval processes.

XVIII. Discussion—Updates to Construction Permit Requirements and Related Licenses

This proposed rule would include updates to the language in 10 CFR 50.34(a) to more clearly link the level of detail required to be submitted with a CP application to the findings the NRC is required to make in 10 CFR 50.35(a), 50.40, and 50.50 to issue a CP. During its review of recent CP applications, the NRC has noted that applicants may provide a higher level of detail for some of the technical areas listed in 10 CFR 50.34(a), and a lower level of detail for others, while still providing sufficient information for the NRC to make the findings required by 10 CFR 50.35(a), 50.40, and 50.50 to issue the CP. The proposed revisions to footnote 1 of 10 CFR 50.34(a) would clarify that the level of detail provided in a preliminary safety analysis report to satisfy the minimum technical requirements in 10 CFR 50.34(a) would be deemed sufficient if the provided information allows the NRC to make the findings required by 10 CFR 50.35(a), 50.40, and 50.50.

This proposed rule would also remove a sentence in 10 CFR 50.34(a)(4) specifying in detail the need to perform loss of coolant accident (LOCA) analyses required in 10 CFR 50.46 and the need for high-point vents in proposed 10 CFR 50.46b, ''Acceptance criteria for reactor coolant system venting systems.'' The NRC considers that these requirements are already implicitly included in the preceding sentence of 10 CFR 50.34(a)(4), which specifies the need to include an evaluation of ''the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.'' These requirements are also referred to in 10 CFR 50.34(b)(4), and the NRC proposes to remove a sentence from 10 CFR 50.34(b)(4) that similarly specifies in detail the need to perform LOCA analyses required in 10 CFR 50.46.

Conforming changes are also proposed to the similar regulatory text and footnotes in each subpart of 10 CFR part 52 to ensure consistency between the power reactor licensing and approval pathways. These changes would be made in 10 CFR 52.47, which applies to standard design certifications; 10 CFR 52.79, which applies to COLs; 10 CFR 52.137, which applies to standard design approvals; and 10 CFR 52.157, which applies to MLs. This change would reflect a more technology-inclusive approach and remove prescriptive language that could be read to mean that a LOCA analysis methodology is fully developed and validated at the CP stage.

The proposed rule would also adjust the wording in 10 CFR 50.34(a)(1)(ii)(D) to be meaningful for designs with functional containments which are evaluated as a release barrier or series of barriers taken together to perform the containment safety function. Specifically, with the proposed changes, the regulation would no longer prescriptively state that the assumed fission product release be ''from the core into the containment'' and would be replaced with technology-inclusive language that refers to ''leakage rates from potential flow paths'' rather than a ''containment leak rate.'' Light-water reactor designs would continue to use fission product release paths from the core into the containment and containment leak rates. The proposed rule would also revise footnotes 3 and

6—which provide additional information on the fission product release to be used in the analyses described in 10 CFR 50.34(a)(1)(ii)(D) and in several items in 10 CFR 50.34(f)(1)—to be more technology-inclusive and allow for evaluation of designs with mechanistic source terms and functional containments. In addition, the proposed rule would revise footnote 4, which discusses the use of 25 roentgen equivalent man (rem) (0.25 sieverts (Sv)) total effective dose equivalent (TEDE) in 10 CFR 50.34(a)(1)(ii)(D)(*1*) as a reference value to remove outdated information regarding recommendations included in a 1959 National Bureau of Standards handbook.

Conforming changes would be made to the similar regulatory text and footnotes in each subpart of 10 CFR part 52 to ensure consistency between the power reactor licensing and approval pathways. Specifically, these proposed changes would be made in 10 CFR 52.17, which applies to ESPs, 10 CFR 52.47, 52.79, 52.137, and 52.157. These changes would reflect a more technology-inclusive approach, eliminate unnecessary exemptions that may otherwise be needed for some designs, and ensure consistency in power reactor applications.

XIX. Background—Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

A. Need for Regulatory Flexibility

Many existing NRC regulations include prescriptive acceptance criteria expressed as specific numerical limits (*e.g.,* temperature, pressure, dose). These criteria were developed based on the state of knowledge and technology at the time the rules were promulgated and do not always reflect the significant advancements in nuclear safety analysis, PRA, and reactor design that have occurred in the decades since. Additionally, the codification of these criteria has limited the ability of licensees and applicants to propose alternative approaches without seeking exemptions, which can introduce cost and regulatory uncertainty.

Licensees and applicants have consistently identified unduly prescriptive requirements as a deterrent to innovation. This has been particularly challenging for U.S. companies developing new reactor designs and seeking to compete in global markets. Nonetheless, the NRC has determined that a top-down approach—modifying individual prescriptive requirements throughout 10 CFR parts 50 and 52—would be resource-intensive and could have unintended consequences, especially for the licensing bases of currently operating reactors. Therefore, instead of a top-down approach, the NRC is proposing to expand the use of risk-informed and performance-based alternatives to existing prescriptive requirements.

B. Enabling Risk-Informed and Performance-Based Alternatives

The NRC has long supported the use of risk-informed and performance-based approaches in its regulatory decision-making, as reflected in the Commission's policy statements and strategic goals, particularly, SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk-Informed and Performance-Based Regulation,'' dated March 1, 1999. Since then, the agency has encouraged the use of such approaches to improve regulatory decision-making, enhance safety, and reduce unnecessary regulatory burden.

The proposed rule would build on this foundation by providing a structured pathway for licensees and applicants to propose alternative acceptance criteria that would be tailored to demonstrate the safety of their specific technologies without the need for exemptions. Additionally, the proposed rule would further utilize risk-informed and performance-based methodologies to update appendix A to 10 CFR part 50 to clarify the application of general design criteria (GDCs) during the licensing of new LWR designs.

XX. Discussion—Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

The NRC is proposing to add new, standalone regulations, 10 CFR 50.220 and 10 CFR 52.220, entitled ''Use of risk-informed and performance-based alternatives to acceptance criteria,'' to allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed, or performance-based acceptance criteria as alternatives to existing prescriptive requirements. These new provisions would support the expanded and accelerated use of acceptance criteria reflective of innovative nuclear technologies without the need for exemptions, while continuing to ensure reasonable assurance of adequate protection of public health and safety.

In addition, the NRC is proposing to update appendix A to 10 CFR part 50 to clarify that (1) deviations from GDCs could be identified and justified within licensing submittals, with no need for a separate exemption request; and (2) demonstrating compliance with Criterion 28, ''Reactivity limits'' (GDC 28), of appendix A to 10 CFR part 50 could be based on a different design basis accident than the control rod ejection or control rod drop accident.

The proposed 10 CFR 50.220 and 10 CFR 52.220 would address regulatory inefficiencies and foster innovation by offering a flexible, voluntary alternative to the current approach, which in many instances relies on prescriptive requirements that applicants must seek exemptions from when proposing to adopt innovative methodologies. The NRC has identified several cases in which this type of framework could have enabled more timely and efficient regulatory decisions. These experiences highlight the value of reducing the number of exemptions and rulemakings required, thereby improving efficiency and supporting the deployment of new technologies. The proposed rule would also provide opportunities for increased operational flexibility at existing facilities that choose to propose and adopt alternative criteria.

The proposed approach would enhance regulatory flexibility, efficiency, and reliability by providing a voluntary pathway for the use of alternative criteria. This approach would maintain the existing licensing basis for currently operating reactors and potential restart units, thereby avoiding unintended impacts associated with a broad, top-down revision of regulatory requirements. Additionally, the proposed rule would establish a more transparent and structured process for NRC review and acceptance of alternative criteria.

This approach would be consistent with the NRC's commitment to enabling the safe use of nuclear technology for the benefit of society, while maintaining reasonable assurance of adequate protection of public health and safety. It would also be consistent with the approach of previous NRC rulemakings that provided voluntary pathways for risk-informed and performance-based alternatives to existing requirements, such as the promulgation of 10 CFR 50.69, ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors'' (69 FR 68008; November 22, 2004) and 10 CFR part 53 (91 FR 15696; March 30, 2026).

The NRC recognizes that successful implementation of this proposed approach would require broad and flexible guidance to accommodate the range of potential alternative criteria. As a result, NRC encourages the increased use of pre-application engagement by applicants and licensees who would wish to exercise the flexibility provided by the proposed 10 CFR 50.220 and 52.220. Draft guidance on the content of applications submitted under this proposed rule is provided in DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' which accompanies this rulemaking.

Looking forward, the NRC would maintain a record of NRC-approved alternative acceptance criteria, along with references to the associated bases for approval to support streamlined use of approved alternative acceptance criteria by potential applicants and serve as a means of regulatory recordkeeping for the agency.

The proposed changes would include revising appendix A to 10 CFR part 50 to clarify that exemptions are not required for deviations from the GDCs. Instead, such deviations could be identified and justified directly within the licensing application. While this clarification would not change the NRC's review of the justification itself, it would reduce regulatory burden for applicants proposing innovative designs in which certain GDCs may be tailored to be better risk-informed.

In addition, the NRC is proposing to revise GDC 28 of appendix A to 10 CFR part 50 to allow applicants to propose and justify alternative design basis accidents for reactivity control, rather than prescriptively requiring evaluation of control rod ejection or control rod drop accidents. Although applicants and licensees may be able to accomplish this through the flexibilities in the proposed 10 CFR 50.220 and 52.220, this change would more explicitly enable the use of design-specific accident scenarios and support removal of unnecessary conservatism in safety analyses without the need to provide the information that would be required in proposed 10 CFR 50.220(b) and 52.220. The NRC is issuing, for public comment along with this proposed rule, DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' which would be used to support applicants in determining appropriate design basis accidents based on credible, realistic risks.

XXI. Background—Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

Section 5(f) of E.O. 14300 directs the NRC to establish stringent thresholds for circumstances in which the NRC may demand changes to a reactor design once construction of the reactor is underway. In response, the NRC is proposing to raise the threshold for changes required during construction by eliminating ''increased standardization'' as a criterion for Commission-directed modification of design certification information on either a plant-specific or generic basis. In addition, this proposed rule would provide additional flexibility and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes during construction under 10 CFR parts 52 and 53. The NRC is also proposing changes to 10 CFR parts 52 and 53 to provide flexibility and efficiencies for licensee-requested changes during operation.

A. Development of Tiers of Information and Processes for Changes and Departures in Design Certification Rules

In 1987, the NRC issued a policy statement on nuclear power plant standardization (52 FR 34884; September 15, 1987). In 1989, 10 CFR part 52 was issued (54 FR 15372; April 18, 1989), which established that design certification would be accomplished by rulemaking. The NRC ultimately adopted a two-tiered system for design information. These tiers are designated in a design control document (DCD), which the NRC incorporates by reference into its regulations, and each information tier is subject to a specified process for changes and departures from design certification information.

Tier 1 information is the portion of the DCD that is approved and certified. It includes definitions and general provisions; design descriptions; inspections, tests, analyses, and acceptance criteria (ITAAC); significant site parameters; and significant interface requirements. Tier 1 design descriptions were intended to be applicable for the life of the facility. Tier 2 and Tier 2* information is the portion of the DCD that is approved but not certified. Tier 2 includes information like that found in a final safety analysis report (FSAR) for 10 CFR part 50 licenses. Tier 2* was created to minimize information in Tier 1 while requiring that this information could not be changed without prior NRC approval. If the Tier 2* designation were not available, this information would have been designated Tier 1. While the Tier 2* category was used in the first five design certifications, from the U.S. Advanced Boiling Water Reactor (ABWR) to the Economic Simplified Boiling-Water Reactor (ESBWR), the later APR1400 and NuScale DCDs did not designate any information as Tier 2*.

Each design certification 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,'' appendix F, ''Design Certification Rule for the APR1400 Design,'' and appendix G, ''Design Certification Rule for NuScale,'' of 10 CFR part 52 includes a section VIII, ''Processes for Changes and Departures,'' that specifies processes to change Tier 1, Tier 2, and, where applicable, Tier 2* information. The requirements in section VIII of these appendices are essentially identical except for certain certified designs that do not have information designated as Tier 2*. Under these section VIII requirements, plant-specific changes or departures from Tier 1 require an exemption. Plant-specific departures from Tier 2* require NRC approval by license amendment. Changes or departures from Tier 2 information are evaluated using a process like the one provided for 10 CFR part 50 licensees in 10 CFR 50.59, which provides criteria for determining whether a licensee-initiated change requires prior NRC approval. This similar departure process for Tier 2 information is, therefore, often described as a 10 CFR 50.59-like process for COL holders referencing a design certification. The change processes in section VIII sought to balance standardization with flexibility and apply during both construction and operation.

For currently certified designs, Tier 2* is defined in section II.F of appendices A, D, and E to 10 CFR part 52. Appendices F and G to 10 CFR part 52 do not contain Tier 2* information. Tier 2* is the portion of Tier 2 information designated with brackets, italicized text, and an asterisk in the generic DCD. Per sections VIII.B.6.b and VIII.B.6.c of appendices A, D, and E to 10 CFR part 52, any licensee who references these appendices may not depart from Tier 2* matters without prior NRC approval and any request for such a departure will be treated as a request for a license amendment under 10 CFR 50.90. Sections VIII.B.6.b and VIII.B.6.c of appendices A, D, and E to 10 CFR part 52 list all of the Tier 2* matters for the respective designs. The Tier 2* matters listed in section

VIII.B.6.b of appendices A, D, and E to 10 CFR part 52 retain this Tier 2* designation for the lifetime of the facility, while the Tier 2* matters listed in section VIII.B.6.c of these appendices revert to Tier 2 after the plant first achieves full power.

Another key aspect of the standard design certification is finality. Issuance of the design certification rule allows the design to be incorporated by reference into a COL application. Issue finality rules limit the types of changes that may be imposed on the certification information. During the COL application review, design information codified by rule is not subject to NRC review, but the NRC staff would review applicant-requested departures from the certified design that require NRC approval. The scope of a hearing for a COL application that references a certified design does not include the design certified by NRC rule but would encompass any departures from the certified design requiring NRC approval.

The final rule promulgating 10 CFR part 53 established a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants, including advanced reactor designs. Part 53 of 10 CFR dispensed with the Tier 1 and Tier 2 terminology. Rather, 10 CFR 53.1525, ''Revising certification information within a design certification rule,'' uses the term ''certification information'' in place of Tier 1. Information that is ''not certification information'' is equivalent to Tier 2 information under 10 CFR part 52. The change control processes for ''certification information'' and ''not certification information'' in 10 CFR part 53 are similar to those for Tier 1 and Tier 2 in 10 CFR part 52.

B. Licensing Experience and Improvement Initiatives Regarding Information Designation and Change Processes for Design Certifications

The NRC has periodically considered improvements to the effectiveness and efficiency of information designations for standard design certifications and associated change processes. Many of these improvements, developed through internal and external reviews and interactions, are addressed in this proposed rule.

The NRC staff internally reviewed and considered improvements to the content of Tier 2* and Tier 1 information. In SECY–17–0075, ''Planned Improvements in Design Certification Tiered Information Designations,'' dated July 24, 2017, the NRC staff examined license amendment requests (LARs) affecting Tier 2* information from AP1000 COL licensees to assess the effectiveness of the Tier 2* designation and the 10 CFR 50.59-like change process. While the NRC staff concluded that there was a benefit to maintaining the use of Tier 2* information in certified designs, it noted that for the AP1000 there were several non-safety significant Tier 2* changes requested in LARs that probably would not have triggered the 10 CFR 50.59-like criteria requiring prior NRC approval of the change. In SECY–19–0034, ''Improving Design Certification Content,'' dated April 8, 2019, the NRC staff refined the general principles for Tier 1 content so that in future design certifications, NRC approval would not be required for design changes of minimal safety significance. These refinements also apply to Tier 2*.

Through the experience from Vogtle Units 3 and 4, the NRC staff has gained insights into the Tier 2* information for the AP1000 design referenced in appendix D to 10 CFR part 52. These insights were summarized in the ''10 CFR part 52 Construction Lessons Learned Report,'' issued January 16, 2024.

The AP1000 design certification contained a significant amount of Tier 2* information, more than would be identified should the process be repeated today. The construction experience at Vogtle Units 3 and 4 showed that, in some cases, LARs were needed to change Tier 2* information that had minimal if any safety significance (*e.g.,* to make edits to a bibliography in a document that was identified as Tier 2* information in its entirety). In these cases, submittal of an LAR to change the information resulted in an inefficient use of resources for both the licensee and the NRC. The use of Tier 2* designations should be consistent with the approaches described in SECY–17–0075 and SECY–19–0034. When this designation is used in future licensing applications, the Tier 2* information should be carefully selected to minimize the potential to require LARs for non-safety-significant changes to this information.

Following the issuance of several 10 CFR part 52 COLs, the NRC engaged with industry representatives and members of the public to consider their perspectives while developing guidance for standardized ITAAC and corresponding Tier 1 information. The NRC considered a draft industry guideline developed by the Nuclear Energy Institute (NEI), dated May 27, 2015, which discussed ''first principles'' for developing Tier 1 information and a set of standard ITAAC that could be used in future design certification applications. While discussions between the NRC and the NEI continued, a final version of the guideline was never endorsed.

The NRC issued COLs to Southern Nuclear Operating Company (SNC) for Vogtle Units 3 and 4 on February 10, 2012. Vogtle Units 3 and 4 are currently the only two nuclear plants to be licensed and constructed and to enter into commercial operation using the 10 CFR part 52 licensing process. In the years following the issuance of the COLs, the NRC and SNC had a series of interactions regarding exemptions related to Tier 1 and Tier 2* information for Vogtle Units 3 and 4, including the challenges, lessons learned, and experience gained during licensing and construction.

During construction, SNC sought adjustments to the Tier 2* process on several occasions. By letter dated August 7, 2014, SNC submitted an amendment and exemption request to apply the existing departure evaluation process for Tier 2 changes to Tier 2* changes. SNC withdrew that request by letter dated December 15, 2014. Subsequently, on February 1, 2016, the NRC granted amendment and exemption requests to reclassify fire-protection related Tier 2* information as Tier 2. On December 21, 2017, SNC submitted LAR–17–037, and an associated exemption request, seeking changes to the Vogtle Units 3 and 4 COLs to add a license condition that would apply the change process for Tier 2 information for a proposed departure from Tier 2* information provided that specific criteria are not met. If one of the criteria were met for the proposed departure, then the proposed departure would continue to require prior NRC approval. In this request, SNC noted that LAR–17–037 ''arises from SNC's nearly six years' experience with the departure evaluation processes outlined in 10 CFR part 52, Appendix D'' and that ''SNC has identified an approach to alleviate some of the administrative burden for both the NRC and the Licensee.'' In addition, SNC stated that this proposal was intended to be in line with the Tier 2* lessons learned in SECY–17–0075. On September 20, 2018, the NRC granted the amendments and exemptions to Vogtle Units 3 and 4 that effectively replaced the Tier 2* change process with an alternative process (reflected in a license condition) that applied the Tier 2 change process along with nine additional criteria to determine whether a license amendment was required.

SNC submitted LARs, both during construction and after the start of commercial operation, proposing to change the contents of Tier 2 and Tier

2* information, and, where applicable, requested exemptions from Tier 1 information in accordance with the change processes specified in the design certification appendix. During construction, there were nearly 200 license amendments, some with related exemptions, and various ASME Code alternatives that required NRC review and approval. For each of the numerous Tier 1 exemption requests approved for Vogtle Units 3 and 4, the NRC determined that the special circumstances outweighed any decrease in safety from the reduction in standardization. Lessons learned from these licensing activities indicate that the need for the submittal and an evaluation of how standardization is maintained do not result in significant insights that support the implementation of the standardization policy; rather, experience shows that the requirement for maintaining standardization as a criterion for allowing changes is often burdensome to a licensee without significant benefit. The NRC has not imposed these changes on the certification information in appendix D of 10 CFR part 52 via rulemaking under 10 CFR 52.63, because these deviations from standardization are not significant reductions in safety. In addition, the NRC never found an exemption request submitted by SNC to be unacceptable based solely on the criterion that the special circumstances did not outweigh the decrease in safety from the reduction in standardization. During construction, SNC also sought efficiencies in the content of both Tier 1 and Tier 2* information. Specifically, SNC requested an amendment to consolidate several ITAAC, with corresponding changes to related Tier 1 information, in the plant-specific DCD to improve the efficiency of the ITAAC completion and closure process.

During a September 20, 2023, public meeting, SNC staff acknowledged that the ''existing Tier 2* requirements are not overly burdensome, but SNC would benefit from being able to implement a similar change process across its fleet of plants.''

After the start of commercial operation, SNC submitted a license amendment and exemption request dated July 25, 2024, for Vogtle Units 3 and 4 to remove all Tier 1 and Tier 2* information and associated requirements from its license. SNC proposed, in part, to convert Tier 1 and Tier 2* information to Tier 2, so that the Tier 2 change process would apply to all this information. At that time, the NRC communicated to SNC that the request contained significant questions of policy more appropriately addressed through the petition for rulemaking process and that revisions to the licensing documents SNC proposed were significant licensing changes that raised policy implications appropriate for Commission consideration. Subsequently, SNC withdrew the license amendment and exemption request on September 25, 2024. This proposed rulemaking would address the issue raised by SNC's request to convert Tier 1 and Tier 2* information to Tier 2.

On January 15, 2025, the NRC held another public meeting to seek feedback on preliminary options to provide regulatory flexibility in 10 CFR part 52 during construction and operational phases, including a change process for Tier 1 and Tier 2* information and the adjustment of tier designations. Members of the public who spoke at the meeting provided no adverse feedback and supported the NRC's approaches presented at the meeting.

In its rulemaking efforts to align the 10 CFR parts 50 and 52 licensing processes, the NRC staff proposed various changes regarding standardization and Tier 1 principles in SECY–22–0052, ''Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150–AI66),'' dated June 6, 2022. In SRM–SECY–22–0052, ''Staff Requirements—SECY–22–0052—Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150–AI66),'' dated November 20, 2024, the Commission approved publication of a revised proposed rule in the **Federal Register** that would eliminate requirements for evaluating the impact on standardization when approving departures from information in a design certification or ML. This proposed rule would incorporate that change.

In SECY–22–0052, the NRC staff also proposed to add a definition in 10 CFR part 52 for Tier 1 information that would have defined Tier 1 information as the qualitative and functional level portion of the design-related information in the generic DCD. This proposed rule also incorporates this change and would further include ITAAC in the definition of Tier 1. Relevant guidance documents would be updated to clarify that Tier 1 information should not include detail that could necessitate NRC approval for departures from certified designs that have minimal safety significance.

This proposed rule would also revise regulations governing licensee-requested changes during construction and operation under 10 CFR part 52 to provide additional flexibility and reduce unnecessary regulatory burden. This would be accomplished through changes in each of the certified designs described in appendices A, D, E, F, and G of 10 CFR part 52. Appendix B (System 80+) and appendix C (AP600) to 10 CFR part 52 have expired.

C. Severe Accidents

In SECY–12–0081, ''Risk-Informed Regulatory Framework for New Reactors,'' dated June 6, 2012, the NRC staff described a potential ''gap'' in the Tier 2 change process regarding severe accident features that are not related to ex-vessel severe accident prevention and mitigation. Unless such non-ex-vessel severe accident design features also happen to have a dual function such as also addressing design basis accidents or aircraft impacts, risk-significant Tier 2 changes (*e.g.,* information in Chapter 19 of Tier 2 of the DCD and FSAR related to prevention and mitigation of severe accidents other than those considered ''ex-vessel'') could be screened out altogether and not receive prior NRC approval. In SECY–12–0081, the NRC staff observed that Tier 1 descriptions usually have sufficient detail that necessitates prior NRC review for major changes to severe accident design features. However, the NRC staff also noted that (1) changes may be screened out or less appropriate criteria applied when determining if prior NRC approval is needed and (2) whether prior NRC approval is obtained may be highly dependent on the degree of detail in Tier 1, if any. The current change process does not address all of the severe accidents defined in 10 CFR 52.47(a)(23) and 52.79(a)(38). The current regulation and its implementation through the guidance in NEI 96–07, Appendix C, ''Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed under 10 CFR part 52,'' Revision 0-Corrected, issued March 2014, could result in the licensee screening out changes in Chapter 19 (and other sections) of Tier 2 of the DCD and FSAR that do not affect ex-vessel severe accident design features. In a worst-case scenario, significant Tier 2 changes to non-ex-vessel severe accident features, up to and including permanent removal from service, could be made without prior NRC approval.

In SRM–SECY–12–0081, ''Staff Requirements—SECY–12–0081—Risk-Informed Regulatory Framework for New Reactors,'' dated October 22, 2012, the Commission approved the NRC staff's plan to address the potential gap in the Tier 2 change process by (a) ensuring that there are sufficient details on all key severe accident features in Tier 1 and (b) including a change process in future design certification rulemaking for non-ex-vessel severe accident features similar to the process for ex-vessel severe accident features. While no current certified designs include a change process for non-ex-vessel severe accident features, reverting Tier 1 information to Tier 2 information once the plant first achieves full power (a proposed change discussed in section XXII.B. of this document) may introduce a gap regarding changes to non-ex-vessel severe accident features. To address this potential gap, the proposed rule would revise the 10 CFR 50.59-like process in section VIII of appendices A, D, E, F, and G of 10 CFR part 52 to consider all severe accidents and not just ex-vessel severe accidents.

XXII. Discussion—Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

To respond to the direction in E.O. 14300 to ''establish stringent thresholds'' for changes required during construction, this proposed rule would revise the finality provisions for design certifications in 10 CFR 52.63, ''Finality of standard design certifications,'' and 10 CFR 53.1263, ''Finality of standard design certifications,'' to (1) eliminate ''increased standardization'' as a criterion for modifying design certification information on either a generic or plant-specific basis, and (2) eliminate whether special circumstances outweigh any decrease in safety that may result from a reduction in standardization as considerations for plant-specific orders and licensee requests for exemptions. Similarly, the proposed rule would revise finality provisions for MLs in 10 CFR 52.171, ''Finality of manufacturing licenses; information requests,'' and 10 CFR 53.1437, ''Exemptions, departures, and variances,'' to eliminate whether ''special circumstances outweigh any decrease in safety that may result from the reduction in standardization'' as a consideration for requests for departures from the applicant referencing or using the manufactured reactor. Further, the proposed rule would include other rule changes to provide additional flexibility and reduce unnecessary regulatory burden for licensee-initiated changes.

A. Standardization

The NRC is proposing to amend its regulations to remove unnecessary requirements to consider standardization as a criterion to justify generic changes to certified designs, plant-specific orders regarding information from a referenced standard design certification, or requested departures from a standard design certification or ML.

As explained in section XXI.B. of this document, recent reactor licensing experience with Vogtle Units 3 and 4 has shown that the requirement for maintaining standardization as a criterion for allowing requested changes is often burdensome to a licensee without significant offsetting benefit. With regard to changes imposed by the NRC, 10 CFR 52.63(a)(1), 52.63(a)(4), 53.1263(a)(1), and 53.1263(a)(4) set out criteria that must be met before the Commission modifies, rescinds, or imposes new requirements on certification information by rulemaking or plant-specific order. Sections 52.63(a)(1)(vii) and 53.1263(a)(1)(vii) of 10 CFR, which provide that changes contributing to increased standardization of certification information is an exception to finality that the Commission may use as a basis to impose new requirements on the certification information, would be deleted from the NRC's regulations. Before imposing new requirements by plant-specific order, 10 CFR 52.63(a)(4)(ii) and 53.1263(a)(4)(ii) require that special circumstances be present and the Commission consider whether these special circumstances outweigh any decrease in safety that results from the effects of decreased standardization. The criterion of whether the special circumstances outweigh any decrease in safety that results from a reduction in standardization, which apply to the Commission, would be deleted from the NRC's regulations. The criterion that special circumstances are present would remain in the regulations.

With regard to changes proposed by licensees and applicants, 10 CFR 52.63(b)(1) and 53.1263(b) permit an applicant or licensee that references a design certification rule to request an exemption from one or more elements of the certification information. These regulations require the Commission to consider whether the special circumstances that the exemption regulation requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. However, as described in section XXI.B. of this document, experience has shown that for all cases, the required special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the requested exemption. Therefore, the NRC is proposing to revise 10 CFR 52.63(b)(1) and 53.1263(b) to eliminate the requirements for the NRC to review the impact of the requested exemption on standardization.

For similar reasons, the NRC is also proposing to revise 10 CFR 52.93(c), 52.171(b)(2), and 53.1437(c) to remove the requirement to discuss the impact of the change on standardization as a criterion for the justification for departures from ML information.

On September 15, 1987, the NRC issued a revised policy statement on nuclear power plant standardization (52 FR 34884). The purpose of this policy statement was for the Commission to encourage standardization by providing a regulatory framework for the certification of nuclear power plant designs that can be referenced in individual plant applications. As stated in this policy, ''[t]he Commission believes that the use of certified standardized designs can benefit the public health and safety by concentrating resources on specific design approaches without stifling ingenuity; by stimulating standardized programs of construction practice, quality assurance, and personnel training; and by fostering more effective maintenance and improved operation.'' The use of certified designs would also improve the efficiency of NRC reviews and reduce uncertainty in the regulatory process.

The proposed rule changes would not be contrary to this policy goal. The policy goal of standardization along with the efficiencies and safety benefits associated with it would be maintained because the overall regulatory framework would still allow for certified designs to be referenced by applicants and licensees in CP applications or COL applications. The deletion of 10 CFR 52.63(a)(1)(vii) and 53.1263(a)(1)(vii) would ensure that changes to certified designs could not be imposed on licensees for the sole purpose of establishing or maintaining standardization among reactors referencing the same design. However, the Commission could still impose new requirements on certification information using one of the six other criteria that would remain in 10 CFR 52.63(a)(1) and 53.1263(a)(1). Since the design certification changes imposed by the NRC for reasons that meet these other criteria would apply to all plants referencing the certified design, standardization would still be achieved.

Regarding the proposed changes to the requirements in 10 CFR 52.63(b)(1), 52.93(c), 52.171(b)(2), 53.1263(b), and 53.1437(c) requiring an analysis of the effects of a change on standardization, experience has shown that it is challenging for an applicant or the NRC to evaluate whether any one change proposed would decrease safety solely as a result of a reduction in standardization. The NRC recognizes that increased standardization remains a policy goal of 10 CFR parts 52 and 53, and requirements supporting that goal should be maintained when there is an appropriate benefit to doing so. The proposed changes to the NRC's regulations that remove the requirement to justify requested changes to the design, based on the changes' effects on standardization, would eliminate unnecessary burden on applicants and licensees while maintaining beneficial aspects of the NRC's policy on standardization. The proposed changes to 10 CFR 52.63(a)(4) and 53.1263(a)(4) would eliminate similar requirements for the NRC to consider whether special circumstances outweigh any decrease in safety that results from a reduction in standardization before issuing a plant-specific order.

Even though the proposed rule revisions described in section XXII.C, ''Processes for Changes and Departures,'' of this document would provide licensees with additional flexibility to make plant-specific changes to certified designs, the NRC does not expect the scope and extent of plant-specific changes to result in such drastic and significant differences that would negate the advantages and safety benefits of standardization. The regulatory structure and change control processes in 10 CFR parts 52 and 53 would continue to support the policy goal of standardization.

B. Definitions

The NRC is proposing to change its regulations to add the definitions of tier information to 10 CFR 52.1, ''Definitions,'' and to make the definitions consistent with the principles in SECY–19–0034. The terms ''Tier 1,'' ''Tier 2,'' and ''Tier 2*'' are defined in section II, ''Definitions,'' of each design certification in appendices A, D, E, F and G to 10 CFR 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 10 CFR part 52 design certification appendices. This flexibility can lead to inconsistencies and increased burden for design certification and COL applicants in preparing applications and increased burden to the NRC in reviewing applications. Recent 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 has resulted in the need for licensees to request NRC review and approval of Tier 1 departures from information that, because of its minimal safety significance, could more appropriately have been handled under the 10 CFR 50.59-like change process currently applicable to Tier 2 information.

To address these problems, the NRC is proposing to change its regulations to add a definition of ''Tier 1'' to 10 CFR 52.1 that would state that Tier 1 information is the qualitative and functional-level portion of the design-related information in the generic DCD and also includes ITAAC. Relevant guidance documents would be updated to clarify that 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 proposed 10 CFR 52.1 definition of Tier 2* information because information should be designated as Tier 2* only if it qualifies for inclusion in Tier 1.

The NRC also notes the following regarding the definitions of ''Tier 2'' and ''Tier 2*'' proposed to be added to 10 CFR 52.1:

- The definition of ''Tier 2'' in section II of appendices A, D, E, F and G to 10 CFR part 52 goes on to list specific information that is included in Tier 2. The proposed definition of ''Tier 2'' in 10 CFR 52.1 would not contain this listed information.
- The definition of ''Tier 2*'' in section II of appendices A, D, E, F and G to 10 CFR part 52 states, ''This designation expires for some Tier 2* information under paragraph VIII.B.6.'' The proposed definition of ''Tier 2*'' in 10 CFR 52.1 would state, in part, that after the plant first achieves full power, the Tier 2* designation reverts to Tier 2 status for all Tier 2* matters.

These proposed 10 CFR 52.1 definitions of Tier 1, Tier 2, and Tier 2* would apply to design certifications issued after the effective date of the final rule.

For currently certified designs, the NRC is proposing to clarify its definitions of Tier 1 information in section II.D of appendices A, D, E, F, and G to 10 CFR part 52. Currently, section II.D in each of these appendices states that Tier 1 is the portion of the design-related information in the generic DCD that is approved and certified and includes: definitions and general provisions; design descriptions; ITAAC; significant site parameters; and significant interface requirements. The proposed revisions to section II.D would provide further clarification by identifying specific sections and tables within the generic DCD that correspond to each of these categories of Tier 1 information. Since the proposed rule would implement different change control processes for these various categories of Tier 1 information, there would be a need to clearly identify what Tier 1 information in the generic DCD corresponds to each category. For definitions and general provisions (section II.D.1), significant site parameters (section II.D.4), and significant interface requirements (section II.D.5), the specific sections in the generic DCD would be identified. For ITAAC (section II.D.3), the specific tables in the generic DCD would be listed. The proposed rule would also specify that only the inspections, tests, and analyses column and the acceptance criteria column of these tables would be considered ITAAC information. For design descriptions (section II.D.2), the proposed rule would identify the specific sections in the generic DCD and would clarify that figures and non-ITAAC tables referenced in these sections would also be considered design description information. Non-ITAAC tables would be any tables not specifically listed as an ITAAC table in the definition.

C. Processes for Changes and Departures

(i) Tier 1 Design Description Information

The NRC is proposing to change its regulations regarding licensee-requested changes during construction for COL holders referencing a certified design. Several of these proposed rule changes would impact the 10 CFR 50.59-like criteria in the appendices of 10 CFR part 52. These include proposed changes to the 10 CFR 50.59-like criteria themselves as well as their application to design information. The NRC acknowledges that section XII, ''Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods,'' of this document describes proposed changes to 10 CFR 50.59 that would allow consideration of risk insights from PRAs and provide increased flexibility for changes to methods of evaluation. As part of the development of the final rule, the NRC will consider the rule revisions to 10 CFR 50.59 and their applicability to the 10 CFR 50.59-like process in 10 CFR part 52.

The NRC proposes to amend section VIII.A, ''Tier 1 Information,'' of appendices A, D, E, F, and G to 10 CFR part 52 regarding licensee-requested changes to Tier 1 design description information. Currently, exemptions from all Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The proposed rule would revise the change process for Tier 1 design descriptions and provide a conforming change in 10 CFR 52.63(b)(1) reflecting that some Tier 1 design description changes within the scope of the new change process would not require an exemption. Licensee-requested exemptions from definitions and general provisions, significant site parameters, and significant interface requirements would be unchanged and any departure from this Tier 1 information would continue to require an exemption. The NRC recognizes that some of the change requests for Tier 1 information based on construction experience from Vogtle Units 3 and 4 may not have been important to safety. Providing flexibility in determining which changes to Tier 1 design description information require NRC approval would reduce burden on licensees and minimize possible construction delays due to licensing reviews without impacting safety.

The NRC proposes to add section VIII.A.5 to appendices A, D, E, F, and G to 10 CFR part 52 to allow an applicant or licensee to depart from Tier 1 design description information without NRC approval if certain criteria are met. The criteria for determining whether a proposed departure from Tier 1 design description information requires an exemption would be listed in the proposed new section VIII.A.6 of appendices A, D, E, F, and G of 10 CFR part 52. These criteria are based upon the 10 CFR 50.59-like criteria currently listed in sections VIII.B.5.b and VIII.B.5.c in appendices A, D, E, F, and G of 10 CFR part 52 for determining whether changes to Tier 2 information require NRC approval. Since Tier 1 design description information is based on Tier 2 information, these criteria would also be appropriate to use for changes to Tier 1 design description information. The criteria in the proposed new section VIII.A.6 would be identical to those in section VIII.B.5.b. The criteria in the proposed new section VIII.A.6 would also include criteria similar to those in current section VIII.B.5.c but these criteria would be revised to consider all severe accident design features and not just ex-vessel severe accident design features, consistent with proposed changes to section VIII.B.5.c that would be made by this proposed rule. Additional discussion for this change is in section XXII.C.(iii), ''Severe Accidents,'' of this document. If any of the criteria in the proposed section VIII.A.6 were met, then the proposed departure from the Tier 1 design description would require an exemption request for NRC approval.

Section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 states that generic changes to Tier 1 information are applicable to all applicants or licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant by plant-specific actions under paragraphs VIII.A.3 or VIII.A.4. Because the NRC proposes to add paragraphs VIII.A.5 and VIII.A.6 as means for making plant-specific changes to Tier 1 design descriptions, the NRC also proposes a conforming change that would amend section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 to add the new paragraphs VIII.A.5 and VIII.A.6 to the list of plant-specific actions that can render a generic change to Tier 1 information technically irrelevant.

Section VI.B of appendices A, D, E, F, and G to 10 CFR part 52 lists matters the Commission considers resolved in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing the applicable appendix. Section VI.B.4 of these appendices identifies one resolved matter as all exemptions under and in compliance with the change processes in paragraphs VIII.A.4 and VIII.B.4 of the applicable appendix. Section VI.B.6 of these appendices identifies another resolved matter as all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of the applicable appendix that do not require prior NRC approval. Because the NRC proposes to add paragraphs VIII.A.5 and VIII.A.6 as means for making plant-specific changes to Tier 1 design descriptions, the NRC also proposes a conforming change that would amend section VI.B.4 of appendices A, D, E, F, and G to 10 CFR part 52 to add exemptions under and in compliance with section VIII.A.6 to the list of resolved matters. Another conforming change would amend section VI.B.6 of appendices A, D, E, F, and G to 10 CFR part 52 to add departures from Tier 1 under and in compliance with section VIII.A.5 that do not require NRC approval to the list of resolved matters. In addition, the NRC proposes to make a correction in section VI.B.6 of appendices A and F to 10 CFR part 52 by changing the reference, ''paragraph VIII.B.5.f,'' to ''paragraph VIII.B.5.g,'' of the applicable appendix.

Analogous changes are proposed for 10 CFR part 53. Specifically, the NRC proposes to revise 10 CFR 53.1525(b) to allow a holder of a license that references a design certification issued under 10 CFR part 53 to make changes to certification information that has not been incorporated into the license without requesting an exemption if certain criteria are met. Additional changes are proposed for 10 CFR 53.1535, ''Amendments and exemptions during construction,'' and 10 CFR 53.1550 to reflect the proposed change to 10 CFR 53.1525(b). Paragraph (a) of 10 CFR 53.1535 would be revised to add provisions that holders of a CP or LWA may also request an exemption, if an exemption is required. Paragraph (b) of 10 CFR 53.1535 would be revised to require any COL holders for which the 10 CFR 53.1452(g) finding has not yet been made to submit an exemption request within 45 days from the date the licensee begins the construction to implement a change requiring NRC approval. This requirement currently applies to requested license amendments, and the NRC is proposing to also apply it to exemptions to reflect the proposed change to 10 CFR 53.1525(b) under which certain departures from certification information would require an exemption but not an amendment. The proposed changes to 10 CFR 53.1550 would clarify that the evaluation of changes to the facility applies to certification information as well as FSARs. Finally, the NRC proposes to delete the current requirement in 10 CFR 53.1525(b) that a request for an exemption be included with a LAR since departures under proposed 10 CFR 53.1525(b) that require NRC approval would be subject to exemption requests and not require a license amendment unless the departure would change the license itself. A conforming change is proposed to 10 CFR 53.1530, ''Revising information within a Final Safety Analysis Report associated with a manufacturing license,'' to eliminate the requirement that a holder of an ML referencing a design certification request an exemption from the design certification rule as part of an amendment application. The proposed 10 CFR 53.1530 would state that, in these cases, the provisions of 10 CFR 53.1525 would apply.

(ii) Tier 1 ITAAC and Certification Information

The NRC proposes to amend section VIII.A of appendices A, D, E, F, and G to 10 CFR part 52 regarding licensee-requested changes to Tier 1 ITAAC information. Under the current change control requirements, any change to generic ITAAC in a COL application referencing a certified design requires the COL holder to submit both an exemption request and a LAR to the NRC for approval. An exemption request is required to modify generic ITAAC because, like other Tier 1 information, ITAAC are certified information. Changes to either generic or plant-specific ITAAC also require a license amendment because section 185b. of the AEA requires the Commission to include the ITAAC within the COL.

The proposed rule would add a new section VIII.A.7 to appendices A, D, E, F, and G to 10 CFR part 52. Proposed section VIII.A.7 in each appendix would require licensees who reference that appendix to request a license amendment under 10 CFR 50.90 for any change to Tier 1 ITAAC information. However, unlike current requirements, licensees requesting a departure from Tier 1 ITAAC information would no longer be required to submit an exemption request in addition to the LAR due to the proposed requirements in section VIII.A.7 of appendices A, D, E, F, and G to 10 CFR part 52. Removing the requirement to submit an exemption request would reduce the unnecessary burden on licensees by eliminating the need to submit both an exemption request and a LAR for the same change. The NRC would still be required to review and approve any ITAAC changes to ensure that the requirements of 10 CFR 52.97(b)—namely, that the COL contains the ITAAC that are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the AEA, and the Commission's regulations—continue to be met. Experience from construction of Vogtle Units 3 and 4 demonstrated that there is no enhanced assurance of safety by evaluating these same ITAAC changes against the exemption criteria specified in 10 CFR 52.7 (which reference 10 CFR 50.12), 10 CFR 52.63(b), and section VIII.A.4 of the applicable appendix to 10 CFR part 52. The need for the exemption request for ITAAC information was simply due to the designation of ITAAC as Tier 1 (*e.g.,* certified) information.

Section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 states that generic changes to Tier 1 information are applicable to all applicants or licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant by plant-specific actions under paragraphs VIII.A.3 or VIII.A.4. In a conforming change, the NRC proposes to amend section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 to add the new paragraph VIII.A.7 to the list of plant-specific actions that can render a generic change to Tier 1 information technically irrelevant.

Analogous changes are proposed for 10 CFR part 53. Specifically, the NRC proposes to amend 10 CFR 53.1525(a) to allow a holder of an OL or COL that references a design certification issued under 10 CFR part 53 to request a license amendment, in lieu of an exemption, if proposing changes to certification information that has been incorporated into the license. A conforming change is also proposed to 10 CFR 53.1550(a)(1) to clarify that changes could be made without a license amendment if the change to certification information incorporated into the license is not required.

The requirements for licensee-requested changes to Tier 1 information in the appendices of 10 CFR part 52 are not identical to those for certified information in 10 CFR part 53 because the Tier 1 definition in the appendices of 10 CFR part 52 states that Tier 1 information includes definitions and general provisions; design descriptions; ITAAC; significant site parameters; and significant interface requirements, whereas 10 CFR part 53 does not specify certification information. The 10 CFR part 52 change control process for Tier 1 ITAAC is similar to that for 10 CFR part 53 certified information that has been incorporated into the license. The 10 CFR part 52 change control process for Tier 1 design descriptions is similar to that for 10 CFR part 53 certified information that has not been incorporated into the license. The NRC proposes to amend section VIII.A.4 of the appendices of 10 CFR part 52 to state that licensee-requested departures from definitions and general provisions, significant site parameters, and significant interface requirements would continue to require an exemption from Tier 1 information. 10 CFR part 53 does not and would not have a similar requirement because it does not define this type of information. Despite this difference, the proposed requirements in 10 CFR parts 52 and 53 would establish appropriate thresholds for licensee-requested changes. During a review of a design certification under 10 CFR part 53, if the NRC determined that certain certification information always warranted prior NRC approval, this information could be designated as information required to be incorporated into a license referencing the certified design.

(iii) Severe Accidents

The NRC proposes to amend the criteria described in section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 used to determine if a proposed departure from Tier 2 information affecting the resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD requires a license amendment.

The proposed rule would address the gap described in SECY–12–0081 and section XXI.C. of this document by revising section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 by removing the phrase "ex-vessel" from the description of severe accidents considered. This change would allow the revised criteria to consider all severe accident design features identified in the DCD, not just ex-vessel severe accident design features.

As discussed in section XXII.C.(i) of this document, another change proposed in this rulemaking would be to add a new section VIII.A.5 to appendices A, D, E, F, and G to 10 CFR part 52. Proposed section VIII.A.5 would allow an applicant or licensee to depart from Tier 1 design description information without NRC approval if certain criteria are met. The criteria for determining whether a proposed departure from Tier 1 design description information requires an exemption would be listed in the proposed section VIII.A.6. These criteria were based upon the 10 CFR 50.59-like criteria currently listed in sections VIII.B.5.b and VIII.B.5.c of appendices A, D, E, F, and G of 10 CFR part 52 for determining whether changes to Tier 2 information require NRC approval. The criteria in the proposed section VIII.A.6 would also include criteria similar to those in current section VIII.B.5.c but these criteria would be revised to consider all severe accident design features and not just ex-vessel severe accident design features.

(iv) Process for Changes and Departures During Commercial Operation

The NRC proposes to amend section VIII.A in appendices A, D, E, F, and G to 10 CFR part 52 regarding the treatment of Tier 1 information during commercial operation. A proposed section VIII.A.8 would be added to each appendix stating that after the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information would be subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information. Per 10 CFR 52.103(h), after the Commission has made the 10 CFR 52.103(g) finding, ITAAC do not constitute regulatory requirements except for any specific ITAAC for which the Commission has granted a hearing under 10 CFR 52.103(a). Also, all ITAAC expire upon final Commission action in the proceeding under 10 CFR 52.103(a). Therefore, after the 10 CFR 52.103(g) finding and any proceedings held under 10 CFR 52.103(a), the only remaining Tier 1 requirements are the definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements. As discussed in section XXII.C.(i) of this document, proposed section VIII.A.5 would allow an applicant or licensee, even during construction, to depart from Tier 1 design description information without NRC approval if certain criteria are met. Thus, the criteria for determining whether a proposed departure from Tier 1 design description information would require an exemption would be the 10 CFR 50.59-like criteria that apply to departures from Tier 2 information. With the NRC's additional proposal to treat licensee-initiated departures from Tier 1 the same as licensee-initiated departures from Tier 2 after first achieving full power, an exemption would be needed for a plant-specific departure from Tier 1 design description information during construction and start-up testing up to full power if the 10 CFR 50.59-like criteria are met, but a license amendment would be needed for such departures after full power operation is first achieved. The criteria for determining whether the change would need NRC approval would remain the same.

Since plant-specific departures from Tier 2 information are governed by the 10 CFR 50.59-like criteria, the proposed section VIII.A.8 would allow licensees, after first achieving full power, to use the 10 CFR 50.59-like process to determine if changes to definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements would require prior NRC approval. Tier 1 definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements would still remain requirements for the lifetime of the facility, but the proposed rule would provide additional flexibility to 10 CFR part 52 licensees by allowing them to use the 10 CFR 50.59-like process to determine if changes to this information would require prior NRC approval.

(v) Tier 2* Information

The NRC proposes to amend sections II.F and VIII.B of appendices A and E to 10 CFR part 52 to revert all Tier 2* information to Tier 2 status after the plant first achieves full power. Proposed amendments to section II.F of appendices A and E to 10 CFR part 52 would clarify that the Tier 2* designation expires for all Tier 2* matters, not just for those listed in section VIII.B.6.c. In addition, the proposed rule would modify section VIII.B.6.b of appendices A and E to 10 CFR part 52 to add the Tier 2* matters listed in section VIII.B.6.c and correspondingly remove those items from section VIII.B.6.c. Finally, section VIII.B.6.c of appendices A and E to 10 CFR part 52 would be revised to state that after the plant first achieves full power, all Tier 2* matters would revert to Tier 2 status and would thereafter be subject to the departure provisions in section VIII.B.5. These proposed changes would reduce the regulatory burden during operation for COL holders who reference appendix A or E to 10 CFR part 52 by allowing them to use the 10 CFR 50.59-like criteria to determine if a departure from Tier 2* information would require a LAR. This would also provide COL licensees under 10 CFR part 52 the same flexibility afforded to OL licensees under 10 CFR part 50 during plant operation.

The NRC also proposes to amend sections II.F and VIII.B of appendix D to 10 CFR part 52 regarding Tier 2* information. These changes would allow the use of the 10 CFR 50.59-like criteria in sections VIII.B.5.b and B.5.c to determine if licensees who reference appendix D to 10 CFR part 52 may depart from Tier 2* information without prior NRC approval. The proposed rule would revise sections VIII.B.5.a, VIII.B.5.b, and VIII.B.5.c to apply to both Tier 2* information as well as Tier 2 information. Section VIII.B.6 would be deleted in its entirety, along with cross-references to section VIII.B.6 elsewhere in appendix D to 10 CFR part 52. With these proposed changes, the Tier 2* information for the AP1000 design would effectively be treated as Tier 2 information during construction as well as operation. The bases for these proposed rule changes are as follows. First, SNC's experience with the Tier 2* departure evaluation process for Vogtle 3 and 4 during the first six years of construction demonstrated that the Tier 2* change process for the AP1000 design imposed an administrative burden to both the licensee and the NRC because LARs were needed to change Tier 2* information that had minimal safety significance. This was also documented in SECY–17–0075 and the ''10 CFR part 52 Construction Lessons Learned Report,'' issued after the completion of construction of Vogtle units 3 and 4. Second, the 10 CFR 59.59-like process is an acceptable approach to determine which changes are safety significant and require prior NRC approval. The 10 CFR 50.59 process is used successfully by the operating fleet of plants licensed under 10 CFR part 50. In addition, as part of this proposed rule, the NRC is proposing to apply the 10 CFR 59.59-like process to the Tier 1 design description information for existing certified designs.

Section VI.B of appendix D to 10 CFR part 52 lists matters the Commission considers resolved in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing appendix D. Section VI.B.6 of appendix D identifies one resolved matter as all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of appendix D that do not require prior NRC approval. Because the NRC proposes to amend section VIII.B of appendix D to 10 CFR part 52 to apply the change process in paragraph VIII.B.5 to Tier 2* information, the NRC also proposes a conforming change that would amend section VI.B.6 of appendix D to 10 CFR part 52 to add departures from Tier 2* under and in compliance with section VIII.B.5 that do not require NRC approval to the list of resolved matters.

At this time, the NRC is not proposing that Tier 2* information for the ABWR and ESBWR designs be treated as Tier 2 information during construction. The NRC acknowledges some inconsistency in the treatment of Tier 1 design description and Tier 2* information but wants to provide considerations for the construction and licensing experience from COLs referencing the AP1000. However, the NRC has posed a specific question in section XXXVI, ''Specific Questions,'' of this document asking if the flexibility afforded the AP1000 design should include the ABWR and ESBWR designs and for the basis of a response to that question.

Section VIII.B.2 of appendix A to 10 CFR part 52 states, in part, that generic changes to Tier 2* information are applicable to all applicants or licensees who reference that appendix, except those for which the change has been rendered technically irrelevant by certain plant-specific actions. The NRC proposes to amend section VIII.B.2 of appendix A to 10 CFR part 52 to add paragraph VIII.B.6 to the list of plant-specific actions that can render a generic change to Tier 2* information technically irrelevant. This proposed addition would make appendix A to 10 CFR part 52 similar in this regard to other appendices in 10 CFR part 52 and avoid an unnecessary imposition of a generic change to a plant for which the underlying issue has already been addressed.

(vi) Section IX of Appendix D to 10 CFR Part 52

The NRC proposes to delete the requirements in section IX, ''Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC),'' of appendix D to 10 CFR part 52 and reserve this section for future use. The ITAAC requirements currently listed in this section were incorporated into 10 CFR 52.99 and 52.103 in a 2007 rulemaking (72 FR 49352; August 28, 2007). Therefore, the language in this section is no longer needed, and removal of it is consistent with previous Commission direction. As stated in the rulemaking for the ESBWR design certification (79 FR 61944; October 15, 2014), ''The language of the ESBWR design certification rule differs from the rule language of other DCRs in two substantive areas. First, paragraph IX was reserved for future use because the substantive requirements in this paragraph (for other DCRs) has since been incorporated into 10 CFR part 52 in a 2007 rulemaking (72 FR 49352; August 28, 2007) and thus are no longer needed in the four existing DCR appendices. The NRC intends to remove these requirements from Section IX of the four existing DCR appendices in future amendment(s) separate from this rulemaking.''

This change would also make appendix D to 10 CFR part 52 similar in this regard to the other appendices in 10 CFR part 52.

(vii) Manufacturing Licenses

The NRC proposes to revise 10 CFR 52.171(b)(1) to allow the holder of an ML to use the regulations in 10 CFR 50.59 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval of an amendment to the ML. If prior Commission approval is required, then the change would need to be submitted in the form of a license amendment per 10 CFR 50.90, 50.91, and 50.92. The NRC also proposes a conforming change to 10 CFR 50.71(f) regarding FSAR updates for ML holders. Instead of requiring FSAR updates that reflect only design modifications approved by the Commission, the revised 10 CFR 50.71(f) would require that FSAR updates reflect safety analyses and evaluations that support approved amendments to the ML or support conclusions that changes did not require a license amendment. This revision would be consistent with the requirements in 10 CFR 53.1530 and would provide additional flexibility to licensees and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes.

(viii) Applicants and Licensees That Reference Manufacturing Licenses

The NRC proposes to revise its regulations to allow licensees who reference an ML license to use the applicable change processes in 10 CFR part 50 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval. This would be accomplished with two proposed revisions to 10 CFR 52.98. The first proposed change would be to delete 10 CFR 52.98(d), which establishes requirements for changes or departures for COLs that reference an ML under subpart F of 10 CFR part 52. The second proposed change would be to revise 10 CFR 52.98(b). The current requirement in 10 CFR 52.98(b) is that only COLs that do not reference either a design certification or an ML may make changes to the facility using the applicable 10 CFR part 50 change processes. The NRC proposes to eliminate the restriction for COLs that reference a reactor manufactured under an ML by deleting the phrase ''or a reactor manufactured under a manufacturing license issued under subpart F of this part.'' The NRC also proposes to modify 10 CFR 52.171(b)(2) so that it would not apply to licensees referencing an ML. These proposed changes would allow a COL that references an ML to make changes to the facility using the applicable 10 CFR part 50 change processes.

The NRC proposes to add a new 10 CFR 50.59(f) that would allow the holder of an OL or COL that references a reactor manufactured under an ML to make changes in the facility or procedures as described in the FSAR without requesting a license amendment if the changes would be the same as changes approved by amendment to the ML and upon a determination that implementing the changes would be consistent with the basis for the Commission's approval of the amendment to the ML and would not involve any additional changes that would require an amendment to the OL or COL. The NRC proposes to add a similar provision as 10 CFR 53.1550(c) for holders of OLs or COLs that reference an ML. These proposed requirements would prevent OL and COL holders and the NRC from having to duplicate the amendment process for each manufactured reactor.

Sections 50.59(d)(1) and 53.1550(d) of 10 CFR would also be revised to require that the licensee maintain records of these changes.

The NRC proposes to amend 10 CFR 52.93(c), 52.171(b)(2), 53.1288(b), and 53.1437(c) to eliminate requirements that the Commission determine that departures from MLs by an applicant referencing the ML comply with the requirements for specific exemptions. Applicants that reference an ML would still request departures from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The NRC would review these proposed departures as part of its review of the application. Removing the requirement that approval of these departures also meets the requirements for exemptions would eliminate an unnecessary regulatory burden for applicants.

All of these proposed revisions would provide additional flexibility to licensees and applicants and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes.

XXIII. Background—Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

A. Existing Emergency Preparedness Frameworks for Nuclear Power Reactors

Before December 18, 2023, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' to 10 CFR part 50 identified the minimum requirements for emergency plans. Additionally, the regulations in 10 CFR 50.47, ''Emergency plans,'' provided emergency preparedness (EP) requirements for nuclear power reactors, including planning standards for onsite and offsite emergency response plans. Other relevant regulations included paragraphs (q), (s), and (t) of 10 CFR 50.54, ''Conditions of licenses.''

Efforts to develop a performance-based approach for EP have been ongoing for over two decades. In SECY–06–0200, ''Results of the Review of Emergency Preparedness Regulations and Guidance,'' dated September 20, 2006, the staff sought Commission approval to begin activities to develop a new voluntary performance-based EP regulatory regimen. On November 16, 2023, the NRC published a final rule creating 10 CFR 50.160, ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities'' (88 FR 80050) (referred to herein as the ''2023 EP final rule''). Section 50.160 of 10 CFR provides a performance-based, technology-inclusive, risk-informed, and consequence-oriented EP framework as an alternative to 10 CFR 50.47 and appendix E to 10 CFR part 50. The alternative EP framework recognizes advances in reactor design and technology and credits the potential benefits of smaller sized reactors and non-light-water reactors (non-LWRs) associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products, as compared to large LWRs. The regulations in 10 CFR 50.160 are applicable to small modular reactors (SMRs) of rated power less than 1000 megawatts thermal (MWt), non-LWRs, and certain non-power production or utilization facilities. The NRC did not include large LWRs in the scope of 10 CFR 50.160 because an EP licensing framework already existed for those reactors, and licensees for those plants had not expressed a clear interest in changing that framework during development of the 2023 EP final rule. However, the work underpinning 10 CFR 50.160, originating from the motivations of SECY–06–0200, included considerations of large LWRs. Consistent with Commission direction in SRM–SECY–14–0038, ''Staff Requirements—SECY–14–0038—Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight,'' dated August 2, 2015, which directed the staff to ''be vigilant in continuing to assess the NRC's emergency preparedness program and should not rule out the possibility of moving to a performance-based framework in the future,'' the changes in this proposed rulemaking would expand the voluntary applicability of 10 CFR 50.160 to large LWRs. Part 53 of 10 CFR provided another opportunity to increase the use of performance-based regulation. The regulations in 10 CFR 53.855, ''Emergency preparedness,'' require each holder of an OL or COL under 10 CFR part 53 to have an emergency plan that complies with either the requirements in 10 CFR 50.160 or the requirements in appendix E to 10 CFR part 50 and the planning standards of 10 CFR 50.47(b).

B. Protective Actions and Emergency Planning Zones

EP is an operational safety program that provides reasonable assurance that adequate protective measures can and will be taken in the unlikely event of a radiological emergency. For radiological emergencies, protective actions should be carefully planned to balance protection with other important factors and ensure that actions result in more benefit than harm. The use of precautionary protective action strategies that rely on predetermined, prompt protective measures, including prompt evacuation, should be reserved for only the most severe incidents as protective actions are not without risk (see, for example, NUREG/CR–7285, ''Nonradiological Health Consequences from Evacuation and Relocation,'' issued September 2021). To balance these risks, the NRC applies a graded approach to EP in which the requirements and criteria are based on the relative radiological risks and hazards of the facility, among other considerations. The most detailed level of planning is associated with the implementation of predetermined, prompt protective actions and is reserved for only the most severe events. For less severe events, the level of planning can be scaled commensurately.

The emergency planning zone (EPZ) is a planning tool for implementing predetermined, prompt protective actions. It simplifies decision-making, particularly when such decisions may be time-constrained or require coordination across a large area involving multiple jurisdictions. Currently, protective actions within the EPZ are initiated promptly at the declaration of a General Emergency (*i.e.,* the highest emergency classification level that indicates that events are occurring or have occurred at the facility with the potential for an offsite release) as a precaution. However, a precautionary approach is not the only strategy that can be used for implementing protective measures. Risk-informed strategies, which make use of the best available information in a robust, transparent, and repeatable process to arrive at a decision can also be used to respond to radiological emergencies. Risk-informed protection strategies are particularly useful to reduce or avoid the risk of stochastic effects from radiation or when there is ample time to make a decision based on the actual conditions associated with the emergency event.

Under 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g), the plume exposure pathway EPZ for a nuclear power reactor consists of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ for such facilities consists of an area about 50 miles (80 km) in radius. These regulations also provide that the size of plume exposure pathway and ingestion pathway EPZs for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt may be determined on a ''case-by-case basis.''

For small modular reactors, non-LWRs, and other non-power production or utilization facilities, the size of the EPZ can be determined on a case-by-case basis under 10 CFR 50.33(g)(2). Specifically, 10 CFR 50.33(g)(2)(i) provides two criteria for determining whether an EPZ is needed, and if so, the size of the EPZ. The first criterion, located in 10 CFR 50.33(g)(2)(i)(A), is that the plume exposure pathway EPZ is the area within which public dose, as defined in 10 CFR 20.1003, ''Definitions,'' is projected to exceed 1 rem (10 millisieverts (mSv)) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion, located in 10 CFR 50.33(g)(2)(i)(B), is that the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. These criteria were added in the 2023 EP final rule and were based, in part, on the methodology 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,'' dated December 1978. Similar provisions for a case-by-case EPZ determination are contained in 10 CFR 53.1109(g)(2).

The EPZ is one element of the emergency planning basis, which is operational in nature. The EPZ is not a design feature of the reactor or a part of the ''design bases'' as defined in 10 CFR 50.2 (*i.e.,* the EPZ is not a plant structure, system, or component). The purpose of the EPZ analysis required by 10 CFR 50.33(g)(2) is to arrive at a robust and resilient protection strategy for managing radiological emergencies. The EPZs are scalable in size and commensurate with the planning needs for the facility. However, the EPZ size does not change the requirements for emergency planning; it only sets bounds on the planning for a predetermined, prompt response. The capabilities within the emergency plan can support expanding the response beyond the EPZ during an actual emergency, should that prove necessary.

When an EPZ extends beyond the site boundary, the NRC requires additional findings and determinations on the adequacy of offsite plans to implement a prompt response. In such cases, the

NRC considers Federal Emergency Management Agency (FEMA) findings and determinations on the adequacy of the offsite planning in its overall reasonable assurance determination. FEMA maintains a voluntary offsite radiological emergency preparedness (REP) program to administer EP for the areas surrounding commercial nuclear power plants. The EP rule changes in this proposed rule would not impact the ability of State, local, and Tribal governments to receive support from FEMA or any other Federal agency regardless of whether the NRC requires reasonable assurance of the offsite plans. For current facilities without offsite EPZs (*e.g.,* non-power reactors, decommissioning power reactors, independent spent fuel storage installations), the NRC does not require findings and determinations of the adequacy of the offsite plans as the risks from radiation exposure are manageable under comprehensive emergency management plans and local emergency response. Emergency plans for these types of facilities provide reasonable assurance that adequate protective measures can and will be taken in coordination with offsite response organizations.

XXIV. Discussion—Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

A. Emergency Plan Licensing Flexibility

(i) Flexible EP Licensing Paths

The proposed rule would provide all applicants and licensees under 10 CFR parts 50, 52, and 53, including power reactor applicants and licensees, with the option to use the performance-based requirements in 10 CFR 50.160. Specifically, the proposed rule would remove the provision in the current rule limiting the applicability of 10 CFR 50.160 to only small modular reactors, non-LWRs, and non-power production or utilization facilities. This proposed change would reduce the need for exemptions to use the performance-based EP regulations. For example, a reactor would not be limited in power to 1000 MWt to meet the definition of ''small modular reactor'' as defined in 10 CFR 50.2 and utilize 10 CFR 50.160. In addition, the proposed rule would revise paragraph I.5 of appendix E to 10 CFR part 50 to provide for a scalable approach for power reactors that choose to comply with the planning standards of 10 CFR 50.47(b). The proposed changes would ensure applicants are not restricted in licensing options for EP and would provide the appropriate regulatory flexibility to support the various licensing pathways.

The planning standards in 10 CFR 50.47(b) and the requirements in appendix E to 10 CFR part 50 were originally developed for the hazards and emergency planning needs of large LWRs. Additionally, the prescriptive planning elements of appendix E to 10 CFR part 50 can be applied to non-power production or utilization facilities on a case-by-case basis. Basic emergency planning functions are similar across NRC licensed facilities, as the operational aspects of EP are well established in regulation and in practice across all hazards. There is no technology-specific language used in the planning standards for required EP functions that limit application to a particular technology. Therefore, the proposed rule would revise the section heading of 10 CFR 50.160 from ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,'' to ''Performance-based emergency preparedness standards,'' to be applicable to all reactor types. In addition, the proposed rule would amend 10 CFR 50.33(g), 50.34(b)(6), 50.54(q)(2), 50.54(q)(3), 52.79(a)(21), 53.1109(g), and 53.1565(d)(3) to remove the distinction among applicants and licensees of small modular reactors, non-LWRs, and non-power production or utilization facilities in complying with 10 CFR 50.160. The proposed rule would not change the definition of ''small modular reactor'' in 10 CFR 50.2 and 53.020 because the definition would no longer have specific relevance to EP regulations.

The proposed rule would amend paragraph I.5 of appendix E to 10 CFR part 50 to determine the degree to which compliance with the requirements in certain sections of appendix E is necessary on a case-by-case basis for power reactors with a site-boundary EPZ or no EPZ. The proposed revision would reduce the need for exemptions and would provide applicants with the flexibility to propose the planning elements appropriate to their facility. For licensing efficiency, the NRC and specific applicants could achieve agreement on applicable planning elements in pre-application interactions. Alternatively, generic guidelines could be developed and endorsed by the NRC to support the rapid deployment of similar reactor types that wish to apply appendix E to 10 CFR part 50 in lieu of 10 CFR 50.160.

The proposed rule would add new 10 CFR 50.47(h) to allow a licensee to submit a license amendment to comply with the requirements of 10 CFR 50.160 in lieu of 10 CFR 50.47 and appendix E to 10 CFR part 50. Similarly, the proposed rule would add new 10 CFR 50.160(c)(4) to allow a licensee to submit a license amendment to comply with the requirements of appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the requirements of 10 CFR 50.47 in lieu of 10 CFR 50.160. The proposed rule would also add new 10 CFR 53.855(d) to provide provisions for complying with alternative EP requirements.

(ii) Preoperational Exercises

The NRC is proposing to remove specific time requirements and add flexibility in the performance of preoperational exercises. Prior to initial loading of fuel, or power operations, successful completion of a preoperational exercise is required to ensure that the licensee staff is ready to implement the emergency plan and that the emergency plan, as written, is acceptable. The proposed rule would amend paragraphs IV.F.2.a.(i) through (iii) of appendix E to 10 CFR part 50 and 10 CFR 50.160(c)(1) and (c)(2) by removing the requirement to demonstrate compliance within 2 years before issuance of an OL or the scheduled date of initial loading of fuel. Regulatory flexibility in the performance of this exercise may be desirable for applicants and holders of a COL that are co-located on, or adjacent to, an existing site and that may be able to subsume this demonstration requirement within the emergency plan exercise program that already exists, up to and including offsite exercise requirements. The specificity of the requirement to conduct the initial exercise within 2 years of certain milestones creates the potential to repeat the demonstration if schedules change. The proposed rule would ensure that the initial exercise need only be performed one time. The proposed rule would also provide flexibility to applicants and holders of a COL in the performance of preoperational exercises if they have preexisting licensed power reactors at the same site with similar onsite and offsite emergency plan elements in place. In such cases, the applicant or holder of a COL and the licensee may credit the same exercise as both the preoperational exercise required under proposed paragraphs IV.F.2.a.(i) and IV.F.2.a.(iii) and the onsite exercise required under paragraph IV.F.2.b of appendix E to 10 CFR part 50.

(iii) Alert and Notification System

The proposed rule would provide clarity for when backup alert and notification system (ANS) methods are required. Traditional ANS strategies typically consist of a single primary method based upon fixed sirens and a single backup method using route-alerting strategies, but alternative methods are available. For example, the Integrated Public Alert & Warning System (IPAWS) is FEMA's national system for local alerting that includes parallel methods of providing authenticated emergency and life-saving information to the public typically through mobile phones using Wireless Emergency Alerts, to radio and television via the Emergency Alert System, and on the National Oceanic and Atmospheric Administration's Weather Radio among others. IPAWS typically provides multiple, simultaneous, primary methods of alerting the public implemented in parallel, and as such, does not require a designated backup. Because of technologies like IPAWS, the proposed rule would amend paragraph IV.D.3 of appendix E to 10 CFR part 50 to provide flexibility in meeting the requirements based upon the ANS chosen by the applicable State as approved in the ANS Design Report.

(iv) Use of Modern Terminology

Certain terminology used in the current regulations is no longer common or does not align with advances in technology. The NRC proposes to revise 10 CFR 50.160(b)(1)(iv)(A)(*2*) to provide clarity and to simplify the language for the requirement to implement the emergency plan in response to a security event. The NRC also proposes to revise paragraph IV.D.2 of appendix E to 10 CFR part 50 to replace ''local broadcast services'' with ''media sources.''

B. Emergency Planning Zone Certainty

The proposed rule would provide greater certainty and a streamlined approach to EPZ determinations for all applicants and licensees. The NRC is proposing to amend the requirements in 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) to simplify EPZ determinations for new reactors and to ensure the plume exposure pathway EPZ is no larger than needed to implement predetermined, prompt protective measures. Specifically, the proposed rule would (1) establish the bounds of an EPZ to generally be about 2 to 10 miles (3.2 km to 16 km) in radius; (2) provide certainty for a site-boundary EPZ for facilities with an authorized power level less than 300 MWt; and (3) allow for case-by-case determinations for all facilities. The proposed rule would make conforming changes to 10 CFR 50.160(b)(3) in referring to the requirements in proposed 10 CFR 50.33(g)(1) and 53.1109(g)(1) to determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.

The recommended 10-mile (16-km) plume exposure pathway EPZ is a generic planning distance for pressurized water reactor (PWR) and boiling water reactor (BWR) technologies based on the analyses in NUREG–0396. In the decades since, many studies have provided additional risk insights and analyses that demonstrate the conservatism in the NUREG–0396 analyses. These analyses include insights from the NRC's State-of-the-Art Reactor Consequence Analyses (SOARCA) regarding the magnitude and timing of severe accidents; insights from the NRC's Level 3 Probabilistic Risk Assessment (PRA) Project regarding the margin to quantitative health objectives, multi-unit events, and integrated plant risks; and specific studies to inform NRC's EP program including: (1) NUREG/CR–7160, ''Emergency Preparedness Significance Quantification Process: Proof of Concept,'' dated June 2013; (2) Task 1.5–1.6 Report to User Need Request NSIR–2017–002, ''Analyses Informing Emergency Planning Zone Size Determinations: Identification of Parameter Sensitivities,'' dated December 2019; (3) SAND2022–3706, ''Scoping Analysis of MACCS Modeling Improvements for the Study of Protective Action Recommendations, dated March 2022; and (4) SAND2025–08913, ''Dose Exceedance Distance Sensitivity Based on Parametric Uncertainty,'' dated July 2025. Combined, these analyses support the use of an EPZ that is generally no less than 2 miles (3.2 km) and no more than 10 miles (16 km) for implementing predetermined, prompt protective measures. Certain analyses were also based, in part, on conservative source terms for designs with an authorized power level less than 300 MWt, which suggest that there is a very low risk of exceeding acute doses offsite requiring a predetermined, prompt response. Additionally, numerous research reports from national laboratories, peer-reviewed published articles, and studies on small modular reactors, microreactors, and advanced reactor designs consistently demonstrate these designs would not require extensive plume exposure pathway EPZs. Combined, these analyses support the proposed changes to 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) to reduce the conservatism in the current 10-mile (16-km) EPZ size and provide certainty for a smaller EPZ or a site-boundary EPZ without requiring extensive analyses on the part of the applicant or licensee.

The proposed rule would also simplify the case-by-case EPZ determination under 10 CFR 50.33(g)(1) and (g)(2) and 53.1109(g)(1) and (g)(2). The EPZ determination should be a simple evaluation of the consequences of a spectrum of accidents to inform protective action strategies. Tools like PRA are useful to help inform EPZ determinations and the risk insights can be used to produce a robust and resilient emergency plan to deal with the residual risk of the facility and to account for uncertainty and unknowns in the design and operation of the facility. While a risk-informed design can provide valuable information to develop a risk-informed EP program, including sizing the EPZ, the EP program is not part of the design and the EPZ determination is not an analysis to reiterate the safety case of the design, demonstrate compliance with the Licensing Modernization Project (LMP) process, or enforce design changes on an applicant or licensee to ensure that no accident will ever exceed 1 rem (10 mSv) at the EPZ boundary. Accordingly, the EPZ criteria for the case-by-case analysis are not design criteria or dose limits. The 1 rem (10 mSv) TEDE value in 10 CFR 50.33(g)(2)(i)(A) is a threshold dose quantity below which it may be demonstrated that no EPZ is needed to manage the radiological risks and hazards of the facility. The EPZ criteria does not require an applicant to demonstrate that doses cannot exceed 1 rem (10 mSv) TEDE over 96 hours beyond the EPZ boundary for all accidents. When doses can exceed 1 rem (10 mSv) TEDE, it is generally necessary to risk-inform the EPZ size by considering additional factors as specified in 10 CFR 50.33(g)(2)(i)(A) and by considering the need for predetermined, prompt protective measures as specified in 10 CFR 50.33(g)(2)(i)(B). The EPZ criteria in 10 CFR 53.1109(g)(2) are applied in the same way. For analysis purposes, the dose criteria is applied to a reference individual, as is done with other dose criteria (*e.g.,* 10 CFR 50.34(a)(1)(ii)(D)(*1*) and (*2*)) and with the Environmental Protection Agency (EPA) protective action guides (PAGs) (see EPA, ''PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents,'' issued in 2017). Therefore, the proposed rule would amend 10 CFR 50.33(g)(2)(i)(A) and 53.1109(g)(2)(i)(A) to remove the reference to public dose as defined in 10 CFR 20.1003 and to apply the dose to a reference individual. The EPZ dose criteria is not a limit, so the term ''public dose'' would be removed to avoid confusion.

When the radiological consequences can exceed 1 rem (10 mSv), dose criteria should not be strictly imposed at an EPZ boundary. There is significant inherent variability in any consequence analysis. For dose quantities less than 25 rem (250 mSv), this inherent variability can be on the order of kilometers. This creates a significant challenge for defining an EPZ boundary based on low dose, especially for EPZs less than 2 miles (3.2 km) in radius as the inherent variability in the consequence analysis could be as large or larger than the defined EPZ. In developing the 2023 EP final rule, the NRC extensively reviewed available studies and performed additional sensitivity analyses to understand the inherent variability of consequence analyses that inform the EPZ determination. The NRC is issuing, for public comment along with this proposed rule, DG–1430, ''Performance-Based Emergency Preparedness,'' which would be Revision 1 to the existing RG 1.242, with an updated methodology for a case-by-case EPZ determination. The revised guidance would provide applicants with clarification on the spectrum of accidents, including the consideration of security-related events and severe seismic events; additional guidance on risk-informing dose-distance evaluations to account for uncertainty and inherent variability in the calculation; and additional guidance for assessing the need for predetermined, prompt protective measures. These guidance updates, based on NRC analyses of parameter uncertainty and NRC staff experience with the review of EPZ methodologies, would provide simple methods to make better risk-informed EPZ determinations.

The proposed rule would reinforce the purpose of the EPZ as a planning tool and encourage the use of risk-informed protection strategies for situations that do not rely on EPZs. The proposed rule would amend 10 CFR 50.47(b)(10) by removing the word ''EPZ'' wherever it appears to ensure protection strategies are developed for the potential pathways of exposure and are not limited to a predefined zone. The proposed rule would also amend 10 CFR 50.33(g)(1), 50.47(c)(2), and 53.1109(g)(1) to state that emergency plans would need to describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary. The EPZ concept is not limited to protective actions for the public, but applies to anyone within the EPZ, including emergency workers and onsite personnel. The proposed rule would ensure that the planning necessary to implement predetermined, prompt protective measures would be focused within the area most at-risk surrounding a nuclear power reactor, including areas within the site boundary. Consistent with the historical planning basis for the EPZ, this is an area where there is potential for acute doses or early health effects from the accidental release of radioactive material in addition to the risk of stochastic effects from radiation exposure. An EPZ may also be defined for purposes of managing the risk of stochastic effects, but the proposed rule would encourage the use of risk-informed protection strategies to make informed protective action decisions for the management of such risks, rather than rely on a predetermined, prompt response that could do more harm than benefit. The NRC proposes to clarify the requirements for use of evacuation time estimates (ETE) to inform protective action recommendations and protective action strategies to distinguish between the level of planning required for predetermined, prompt protective actions, as opposed to taking action as conditions warrant. Specifically, the proposed rule would amend the requirements in paragraphs IV.3 and IV.4 in appendix E to 10 CFR part 50 by adding the phrase, ''predetermined, prompt'' to clarify which protective action recommendations and strategies within the EPZ are informed by the ETE.

Consistent with the rationale for revision of the EPZ criteria, the proposed rule would amend 10 CFR 50.33(g)(1) and 53.1109(g)(1) by eliminating the requirement to submit response plans of State, local, and participating Tribal governmental entities. The proposed change to 10 CFR 50.33(g)(1) and 53.1109(g)(1) would require applicants to coordinate with offsite organizations with responsibilities for coping with emergencies, including State, local, and Tribal governmental agencies, as applicable. This coordination would ensure that response organizations are aware of potential radiological consequences of the facility and have been consulted on appropriate protective measures, including the extent of any EPZ. The proposed rule would require applicants to include information that describes the extent of interaction with these agencies. The NRC would not require FEMA findings and determinations on the extent of interaction between the applicant and offsite response organizations because this proposed change is not part of the FEMA review of offsite plans under FEMA's regulations in 44 CFR part 350, ''Review and Approval of State and Local Radiological Emergency Plans and Preparedness.''

The proposed rule changes to the plume exposure pathway EPZ would be consistent with Federal guidance and international standards. Section 2.2.4 of the EPA PAG Manual discusses the relation between PAGs and EPZs and states, ''The pre-designated areas for immediate protective action may be reserved for use only in the most severe incidents and in cases when the facility operator cannot provide a quick estimate of projected dose based on actual releases. For lesser incidents, or if the facility operator is able to provide prompt off-site dose projections, the area for immediate protective action may be specified at the time of the incident instead of using a pre-designated area.'' Similarly, the International Atomic Energy Agency (IAEA) Safety Standards in General Safety Requirements (GSR) No. 7, ''Preparedness and Response for a Nuclear or Radiological Emergency,'' specify use of a precautionary action zone (PAZ) for taking urgent protective actions before any significant release occurs on the basis of conditions at the facility in order to avoid or to minimize severe deterministic effects. The recommended size for the PAZ within IAEA standards is 1.9 to 3.1 miles (3 to 5 km) for reactors greater than 1000 MWt and 0.3 to 1.9 miles (0.5 to 3 km) for reactors 100 to 1000 MWt. The proposed change to 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) would establish EPZs that remain aligned with EPA guidelines and international standards to meet the purpose of the EPZ as a planning tool for implementation of predetermined, prompt protective actions. Consistent with the PAG Manual, the zones for response could also be specified at the time of the emergency, rather than predesignated.

The proposed rule would add new 10 CFR 50.47(g), 50.160(c)(3), and 53.855(c) to allow a licensee to submit a license amendment to change its plume exposure pathway EPZ. The proposed rule would require the change to be agreed on by the applicable State, local, and Tribal governmental authorities before submission to the NRC. The FEMA REP Program Manual provides a process for offsite response organizations to follow for changes to the EPZ boundary in accordance with FEMA regulations in 44 CFR 350.14.

Consistent with the 2023 EP final rule, the proposed rule would remove the requirement to define an ingestion pathway EPZ. The proposed rule would remove reference to the ingestion pathway EPZ in 10 CFR 50.33(g)(1) and 53.1109(g)(1), 50.47(b)(10), 50.47(c)(2), and paragraph IV.F.2.a.(i) and footnote 1 of appendix E to 10 CFR part 50. In lieu of a defined zone, the proposed rule would amend 10 CFR 50.33(g)(1), 50.47(c)(2), and 53.1109(g)(1) to require emergency plans to describe such actions as are appropriate to protect the ingestion pathway. The capabilities described in the emergency plan would need to address major exposure pathways associated with the ingestion of contaminated food and water. The duration of any exposure to contaminated food or water could range from weeks to months and represents a long-term response need. The current 50-mile ingestion pathway EPZ is based on the planning assumptions in NUREG–0396 and does not reflect technology advancements and modern response capabilities for interdicting to prevent ingestion of contaminated food and water, such as the use of Geographic Information System (GIS) tools and unmanned aerial vehicles for monitoring.

Currently, paragraph IV.E.8.b of appendix E to 10 CFR part 50 requires the licensee's emergency operation facility (EOF) to be located between 10 miles and 25 miles of the nuclear power reactor site(s), or a primary facility located less than 10 miles from the nuclear power reactor site(s) and a backup facility located between 10 miles and 25 miles of the nuclear power reactor site. The 10 miles is based on the current 10-mile EPZ requirement and does not account for scalable EPZs under current and proposed 10 CFR 50.33(g) and 53.1109(g). The proposed rule would amend paragraph IV.E.8.b of appendix E to 10 CFR part 50 to specify the location of the emergency operations facility in relation to the EPZ boundary. The proposed rule would not change the requirement for a licensee to request Commission approval to locate an EOF more than 25 miles from a nuclear power reactor site.

C. Eliminating Redundant Requirements

(i) Preliminary Emergency Plans

The NRC proposes to eliminate the requirements for applicants to submit preliminary plans for coping with emergencies because these submittals do not significantly enhance licensing efficiency. Many details of the emergency plan depend on conditions of the as-built facility and site-specific parameters, including agreements with offsite emergency response organizations. These details are often not available early in the licensing process. The NRC reviewed the content of CPs and ESPs and found that the level of information contained in the associated preliminary emergency plans or major features of emergency plans was very limited, often nothing more than a general structure and placeholder for more detailed information. The proposed rule would eliminate 10 CFR 50.34(a)(10) and 53.1309(a)(4) that require applicants to submit the preliminary plans for coping with emergencies as part of the preliminary safety analysis report for a CP application. The proposed change would reduce the burden on applicants to provide preliminary plans of limited benefit in licensing. The proposed rule would not change 10 CFR 52.17(b)(2)(i) because applicants may choose not to submit major features of the emergency plan in the ESP site safety analysis report if such details are not available. Instead, the NRC encourages applicants to engage the NRC in pre-application activities in preparation for submission of emergency plans as part of the FSAR or in preparation for submission of major features of the emergency plan as part of the ESP site safety analysis report. As a conforming change, the proposed rule would amend paragraphs I.1 and I.2 of appendix E to 10 CFR part 50 to remove the requirements to submit emergency plan information in the preliminary safety analysis report and would eliminate section II, ''The Preliminary Safety Analysis Report,'' of appendix E to 10 CFR part 50. Many of the elements in section II of appendix E to 10 CFR part 50 are redundant to other criteria or would be considered as part of the development of emergency plans in coordination with offsite response organizations under proposed 10 CFR 50.33(g) and 53.1109(g).

(ii) Independent Program Element Reviews

The proposed rule would amend 10 CFR 50.54(t) and 53.1565(d)(3)(vii) to eliminate the requirement for licensees to ensure that all program elements are reviewed by people who have no direct responsibility for implementation of the EP program. Since the implementation of this regulation, the NRC's oversight program has evolved such that this regulation is redundant to the NRC Reactor Oversight Program and adds no additional oversight benefit to the EP program. However, the proposed rule would retain the requirement in 10 CFR 50.54(t)(2) and 53.1565(d)(3)(vii)(B) for an annual review of the interface between licensee and offsite response organizations to ensure the adequacy of the interface with State and local governments.

(iii) Evacuation Time Estimate Updates

The NRC is proposing to eliminate requirements related to updates of the ETE that have limited utility in ensuring effective implementation of protective action recommendations. The proposed rule would eliminate the requirement to estimate EPZ permanent resident population changes during the years between decennial censuses and to update the ETE based on the criteria of paragraphs IV.5 and IV.6 of appendix E to 10 CFR part 50. This proposed change is based, in part, on an analysis of the limited number of licensees over the past decennial periods that met the criteria to perform the ETE update and an analysis of the impact of updated ETEs on protective action strategies, following the guidance in Supplement 3, ''Guidance for Protective Action Strategies,'' to NUREG–0654/FEMA–REP–1. Decennial ETE updates include sensitivity analyses that provide the expected change to the ETE as the permanent resident population changes. In addition, section 5.4.1, ''Extreme Conditions,'' of NUREG/CR–7002, ''Criteria for Development of Evacuation Time Estimate Studies,'' Revision 1, contains guidance for updating the ETE if conditions within the EPZ change significantly. The NRC has determined that the sensitivity analyses and the ETE guidance would ensure that ETEs remain adequate for use in protective action recommendations and in developing offsite protective action strategies in the years between decennial censuses. For similar reasons, a review of changes in the EPZ population under paragraph IV.7 of appendix E to 10 CFR part 50 would not be required for parts 52 and 53 licensees. As such, the proposed rule would eliminate paragraphs IV.5, IV.6, and IV.7 of appendix E to 10 CFR part 50.

(iv) Periodic Communication Tests With NRC

The proposed rule would eliminate the requirement to test each NRC Regional Office Operations Center under paragraph IV.E.9.d of appendix E to 10 CFR part 50. A monthly test between each licensee and the appropriate Regional Office Operations Center would not be required because the regional Operations Centers are not typically staffed by the NRC unless it is warranted by the escalation of an emergency event. Monthly testing of communication between the licensee's primary response location and the NRC

Headquarters Operations Center would be sufficient.

D. Risk-Informing the Emergency Plan Change Process

The NRC proposes to revise and risk-inform the emergency plan change process in 10 CFR 50.54(q) and 53.1565(d)(3) regarding which proposed changes would need to receive prior approval from the NRC. Licensees would be required to evaluate a reduction in effectiveness for only changes to the emergency plan involving risk-significant planning standards. Under the proposed rule, the licensee would analyze changes related to the other planning standards and applicable requirements in appendix E to 10 CFR part 50, or 10 CFR 50.160 only to ensure they continue to meet the regulatory requirements.

The proposed rule would add new 10 CFR 50.54(q)(1)(v) and 53.1565(d)(3)(i)(E) to define risk-significant planning standards as those providing the most essential functions of EP to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency, including classification, notification, assessment, and protective actions. The proposed definition would also include the standards for providing adequate staffing and facilities as risk-significant for the purposes of evaluating changes to the emergency plan as these standards have a direct impact on the ability to effectively implement the risk-significant planning standards. The proposed definition would apply to the standards of 10 CFR 50.160 or 50.47 and applicable requirements in appendix E to 10 CFR part 50.

Consistent with the proposed changes to allow licensees the option to comply with either the requirements in appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards of 10 CFR 50.47(b), or the requirements in 10 CFR 50.160, the proposed rule would combine 10 CFR 50.54(q)(2)(i) and (ii) into a single paragraph (q)(2) and would revise (q)(3)(i) and (ii) for the evaluation of changes to the emergency plan. The proposed rule would similarly combine 10 CFR 53.1595(d)(3)(ii)(A) and (B) and revise 10 CFR 53.1595(d)(3)(iii).

XXV. Background—Optional Submittal of Operational Programs

For several years, stakeholders have expressed growing interest in the rapid, widespread deployment of reactors of a standard design (*e.g.,* July 31, 2024, letter from NEI to the NRC, ''Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors,'' followed by a July 14, 2025, supplement to that letter). At the same time, the NRC staff developed strategies to provide for the predictable and efficient licensing and regulation of microreactors that would use standard designs. The staff sought Commission approval for some of these proposals in SECY–24–0008, ''Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory,'' dated January 24, 2024, and SECY–25–0052, ''Nth-of-a-Kind Microreactor Licensing and Deployment Consideration,'' dated June 18, 2025. The latter paper recommended a change in Commission policy to allow the NRC to review, approve, and afford finality to, as appropriate, standard operational programs submitted to the NRC in connection with a design certification or ML application. These agency actions would support the rapid licensing and high-volume deployment of new microreactors and other low consequence reactors and the direction in E.O. 14300 to adopt shorter timeframes tailored to particular licensing pathways.

The Commission approved the staff's recommendations in SRM–SECY–0008, ''Staff Requirements—SECY–24–0008—Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory,'' dated June 17, 2025, and SRM–SECY–25–0052, ''Staff Requirements—SECY–25–0052—Nth-of-a-Kind Microreactor Licensing and Deployment Consideration,'' dated November 13, 2025. The NRC included many of these proposals, including the proposal to allow an ML applicant to include standard operational program information in its application, in the ''Licensing Requirements for Microreactors and Other Reactors With Comparable Risk Profiles'' proposed rule (91 FR 23628; May 1, 2026). The NRC is proposing conforming changes to 10 CFR parts 52 and 53 in this rulemaking to allow microreactor and other developers the option to submit essentially complete programmatic controls, operational programs, or operational requirements with an ML application under 10 CFR part 52 or 53.

XXVI. Discussion—Optional Submittal of Operational Programs

The NRC proposes to modify 10 CFR 52.158, ''Contents of application; additional technical information,'' to allow ML applicants the option to submit essentially complete operational program information with their applications and 10 CFR 52.171, ''Finality of manufacturing license; information requests,'' to provide finality to such program information that is reviewed and approved by the NRC as part of the ML review. As stated in proposed 10 CFR 52.158(c), this optional program information would be submitted ''to satisfy requirements for license applications that may reference a manufacturing license,'' and this program information submitted with the ML application would be assessed against the pertinent requirements for these other license applications.

The appropriate change control mechanism for changes to this information by an ML holder would be established through the issuance of the ML. Under current regulations, the change control requirements in 10 CFR 52.171(b)(1) for changes sought by the holder of an ML apply to design information, not operational program information. Elsewhere in this proposed rule, the NRC proposes to modify 10 CFR 52.171(b)(1), but as modified, the change control provision would apply to information in the FSAR submitted under 10 CFR 52.157 and not to non-FSAR information submitted under 10 CFR 52.158. Moreover, the change control process in proposed 10 CFR 52.171(b)(1) relies on the change control criteria in 10 CFR 50.59, whereas some operational programs are subject to other change control provisions (*e.g.,* 10 CFR 50.54(a), (p), and (q)). Therefore, the NRC would establish the appropriate change control process for the optionally submitted operational program information as part of issuing the ML.

An applicant or licensee who references or uses a nuclear power reactor manufactured under an ML who wishes to depart from or omit (in whole or part) the optional operational program information approved in the ML would not be subject to the process in 10 CFR 52.171(b)(2) because this optional operational program information would not constitute design characteristics, site parameters, terms and conditions, or approved design information subject to 10 CFR 52.171(b)(2). Departures from, or omissions of, the optional operational program information approved in the ML would be reviewed in accordance with the applicable operational program requirements for the license being applied for (*e.g.,* OL or COL).

This proposed change would enhance regulatory certainty and expedite review timelines for CP/OL and COL applicants wishing to reference operational programs approved with an ML but would still allow flexibility for these applicants to submit their own programs. There would be no additional obligations imposed on license applicants as this would be optional information for a developer to provide and optional for a CP/OL or COL applicant to reference. Additionally, the hearing opportunity provided as part of the ML review process would allow for public engagement on the program information included in the ML application. For licensing efficiency, agreement on operational programs being considered to be essentially complete could be achieved between the NRC and applicants through pre-application interactions.

The NRC is proposing a similar change to 10 CFR part 53 to allow for the optional submittal with the ML application of operational program information not material to the design. The NRC is proposing to modify 10 CFR 53.1282, ''Contents of applications for manufacturing licenses; other application content,'' to allow for the submittal of such program information and 10 CFR 53.1288, ''Finality of manufacturing licenses,'' to provide finality to the information that would be reviewed and approved by the NRC.

XXVII. Background—Early Site Permit for Nuclear Power Plants

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' In response, the NRC is proposing to amend its regulations to remove the ESP fixed term requirement.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to provide procedures for the early resolution of safety and environmental issues in commercial power reactor licensing proceedings and to provide for the standardization of the design of nuclear power plants. To further those ends, the Commission issued 10 CFR part 52 to add alternative licensing processes for early site permits (ESP), standard design certifications, and COLs. These alternatives in 10 CFR part 52 were in addition to the two-step licensing process that already existed in 10 CFR part 50. The processes in 10 CFR part 52 allow for resolving safety and environmental issues early in licensing proceedings, which would result in regulatory stability, and were intended to enhance the safety and reliability of nuclear power plants through standardization. Part 53 of 10 CFR also provides for ESPs.

In particular, ESPs provide a process for applicants to resolve the majority of site-specific safety and environmental issues prior to applying for a CP or COL. Subsequent to promulgating 10 CFR part 52, the NRC has issued six ESPs,—the Exelon Generation Company, LLC ESP Site, ESP–001, March 15, 2007; System Energy Resources, Inc., Grand Gulf ESP Site, ESP–002, April 5, 2007; Dominion Nuclear North Anna, LLC, North Anna ESP Site, ESP–003, November 27, 2007; Southern Nuclear Operating Company Vogtle Electric Generating Plant ESP Site, ESP–004, August 26, 2009; PSEG Power, LLC and PSEG Nuclear, LLC PSEG Site Early Site Permit, ESP–005, May 5, 2016; and Tennessee Valley Authority, Clinch River Nuclear Site Early Site Permit, ESP–006, December 19, 2019.

XXVIII. Discussion—Early Site Permit for Nuclear Power Plants

Under the current regulations in 10 CFR 52.26, ''Duration of permit,'' the NRC may issue an ESP with a term no longer than 20 years. Upon the elapse of 20 years, the ESP expires, but an ESP holder has the option to renew it for an additional term under current 10 CFR 52.29, ''Application for amendment to update an early site permit.'' The term for an ESP is similarly limited in 10 CFR 53.1164, ''Duration of permit.''

This proposed rule would remove the requirement in 10 CFR 52.26 and 53.1164 for an ESP to include a fixed term. Because each ESP would be issued without a fixed term, renewal would no longer be needed. Nonetheless, the revised regulations in 10 CFR 52.29 would provide an option by which an ESP holder may choose to update its ESP, which could maintain the preclusive effect of the ESP if the ESP is referenced in a COL or CP application. The proposed rule would similarly revise 10 CFR 53.1173, ''Application for renewal.'' The requirements specific to renewal at 10 CFR 52.33, ''Duration of renewal,'' and 10 CFR 53.1179, ''Duration of renewal,'' would be removed and reserved.

As noted in the 1989 10 CFR part 52 final rule, the ESP provides for early resolution of site-related issues, making possible the ''banking'' of the site, to enable more efficient licensing of a future nuclear power plant. The current rule mandates renewal of the ESP at a set point in time, not to exceed 20 years after issuance, and therefore requires the holder of the ESP to undertake updating the ESP to retain the benefits of issue finality. However, there are a number of factors that may influence the time that elapses between NRC's issuance of an ESP and a determination by the ESP holder to reference the ESP in a CP or COL application. Indeed, two of the issued ESPs are nearing 20 years since issuance without having been referenced in a CP or COL application. Therefore, this maximum 20-year duration of an ESP and the associated renewal requirement may artificially constrain the ESP holder's development planning because the renewal-requirement lacks a direct linkage to either a change in the ESP identified by the holder or the holder's plans to reference the ESP in a CP or COL application.

By removing the fixed term duration and providing a process for the permit holder to update the ESP through an amendment, the proposed rule would provide permit holders with flexibility to retain the site as ''banked,'' rather than referencing the ESP in a CP or COL application in a shorter time frame, and determine when or if the ESP will be updated. Removing the fixed term, however, would necessitate a change to the finality provisions in 10 CFR 52.39, ''Finality of early site permit determinations,'' to provide clarity regarding the limited duration of finality for site-specific characteristics of the initial ESP application and to account for stale environmental evaluations. Accordingly, the proposed rule would establish a 20-year timeframe for information in the ESP to retain finality, which would account for the limited time for which site data remains valid and the potential for environmental evaluations to become stale. The proposed rule would similarly revise 10 CFR 53.1188, ''Finality of early site permit determinations.''

The proposed 20-year timeframe would provide a boundary for both preparing a CP or COL application that references an ESP and NRC review, to avoid the level of uncertainty that would exist with providing analyses without a fixed term. However, ESP holders would have the option to update the information in the ESP to refresh the site data and environmental evaluations and thereby extend the 20-year timeframe at their discretion. Thus, when developing an ESP application, applicants for future ESPs should consider the 20-year expected duration for potentially time sensitive information, such as seismic, meteorological, hydrologic, and geologic characteristics; the presence of nearby facilities such as industrial, military, or transportation; the population profile; and environmental data and evaluations.

Under this proposed rule, the ESP holder may choose to update the ESP by submitting an amendment to update the potentially time sensitive information, which would provide an additional 20 years of finality for the updated safety and environmental information if the NRC grants the amendment. Alternatively, an ESP holder could forgo finality and address those issues directly in a CP or COL application that references the ESP. The request for amendment of the ESP could be made by the ESP holder at any time. Unlike the current regulatory framework, where information must be updated prior to expiration of the ESP at year 20 through renewal to maintain issue resolution, the proposed changes would enable the ESP holder to retain the ESP for as long as desired and identify needed updates only when and if the holder determines the update would be advantageous to support a future CP or COL application. The proposed rule would allow the ESP holder to submit an amendment to update the time-sensitive information and request an extension for an already extended permit, providing flexibility for the ESP holder to update the ESP at such time and as many times as needed. To support the removal of a fixed term, a provision would be added to enable the ESP holder to request termination of an ESP at any time, with consideration for the status of any required redress for authorized activities. The changes would enhance flexibility for the ESP holder and reduce the effort associated with ESP renewal at year 20. NRC resources, likewise, would not be expended for review of ESP renewal applications. To be sure, some portions of an ESP, such as design parameters specified in the permit, are not time-sensitive and would continue in effect unless the ESP holder seeks to amend them or an applicant for a CP or COL referencing the ESP proposes to change them.

This proposed rule would remove and reserve paragraph (c) of 10 CFR 2.109, ''Effect of timely renewal application,'' which provides for timely renewal of the ESP.

This proposed rule would revise 10 CFR 52.15, ''Filing of applications,'' to remove the reference to ''renewal'' and replace it with ''amendment,'' reflecting that the permit would be issued with no fixed term and would not expire.

This proposed rule would revise 10 CFR 52.18, ''Standards for review of applications,'' to clarify its applicability to the initial issuance of the ESP. This proposed rule would revise 10 CFR 52.25, ''Extent of activities permitted,'' to remove the reference to the duration of the permit, reflecting that an ESP would no longer have a fixed term. The requirement for an ESP to remain in effect for site redress by the ESP holder if any activities authorized by 10 CFR 52.24(c) are performed would be unchanged. The proposed rule would similarly revise 10 CFR 53.1161, ''Extent of activities permitted.''

This proposed rule would revise 10 CFR 52.26(a) to remove the current duration, identifying that the permit would be issued with no fixed duration. The proposed rule would similarly revise 10 CFR 53.1164. Removal of the expiration date from the ESP would enable the permit holder to retain the site as banked until such time as either the permit is subsumed into another application or a decision is made to terminate the ESP. Because some site-specific characteristics are potentially time dependent, 10 CFR 52.39 and 53.1188 would limit finality for safety issues to 20 years from issuance of the ESP or an amendment to update the information for those items. Finality for environmental issues would also be limited to 20 years from issuance of the ESP or an amendment. Because the ESP would be issued with no fixed term, this proposed rule would revise 10 CFR 52.35, ''Use of site for other purposes,'' to provide a provision for the permit holder to request termination and to ensure the ESP holder identifies site redress activities to the Commission as part of the termination request. The ESP would not be terminated until site redress activities have been performed in accordance with 10 CFR 52.25. Termination of the ESP would not preclude the same or another applicant from submitting another application for an ESP or another license for the same site at a future time. The proposed rule would similarly revise 10 CFR 53.1182, ''Use of site for other purposes.''

This proposed rule would rename 10 CFR 52.29 and 53.1173 to, ''Application for amendment to update an early site permit,'' and revise these sections to provide the requirements for submitting an amendment. Following NRC review and completion of the hearing process, issuance of the amended ESP would extend finality for future use of the ESP for reference in a CP or COL application. The specific information limited to a 20-year duration for finality would be specified in 10 CFR 52.39 and 53.1188.

This proposed rule would rename 10 CFR 52.31, ''Criteria for renewal,'' as ''Issuance of amendment to update an early site permit,'' and revise it to include specific provisions for the Commission's issuance of an amended ESP. An application for amendment would be reviewed against similar criteria to that previously identified for renewal, which reflect the AEA, the Commission's regulations, and orders applicable and in effect at the time the ESP was originally issued. New requirements to be imposed during the amendment would be limited to those necessary for adequate protection to public health and safety or common defense and security. Additionally, for the purpose of site characteristic data and environmental data and evaluations which may be time dependent, the proposed rule would limit finality for those issues to 20 years while providing flexibility for the ESP holder to update that information through an amendment at any time. Therefore, the NRC's review of those potentially time-dependent characteristics would encompass the 20-year timeframe that aligns with the finality that would be afforded to that information. The proposed rule would similarly revise 10 CFR 53.1176, ''Criteria for renewal,'' and rename it as, ''Issuance of amendment to update an early site permit.''

This proposed rule would revise 10 CFR 52.39 to remove reference to a renewed ESP and replace it with an amended ESP. The site characteristic data on which an ESP is based, however, is valid for only a limited duration. Accordingly, the finality provisions in 10 CFR 52.39 would be revised to reflect that an ESP does not resolve siting issues in 10 CFR part 100, ''Reactor Site Criteria,'' specifically including site characteristics in the ESP, in a proceeding on a referencing application submitted more than 20 years after the date of issuance of the ESP or the date of an update to the ESP in which a matter has been resolved, whichever is later. This revised provision would not affect the finality of the source term included in the ESP. The duration limitation on finality of safety issues would be updated by revising 10 CFR 52.39(c)(1)(v) and finality of environmental issues would be updated by revising 10 CFR 52.39(c)(1)(vi). The proposed rule would similarly revise 10 CFR 53.1188.

The new provisions in 10 CFR 52.29 would provide for amendments to update ESPs in paragraph (e) of 10 CFR 52.39. The proposed rule would similarly revise 10 CFR 53.1188(e) to add 10 CFR 53.1173 as a requirement.

This proposed rule would amend 10 CFR 52.79 by redesignating paragraphs (b)(3) through (5) as paragraphs (b)(4) through (6) and revising paragraph (3) to add a requirement for a referencing COL application to confirm whether the potentially time-dependent site characteristics were updated in the ESP within the 20 years prior to filing the COL application and thus resolved under 10 CFR 52.39. If not, the COL applicant would need to evaluate and update that information in the FSAR. The information to be evaluated would be that information in the site safety analysis report required by paragraphs

10 CFR 52.17(a)(1)(vi) through (ix), which includes seismic, meteorological, hydrologic, and geologic characteristics; the presence of nearby facilities such as industrial, military, or transportation; and the population profile. The safety assessment based on these characteristics would also require evaluation and update, except that the referencing COL application would not need to update the postulated source term stated in the ESP if it fell within the source term derived from the design. If the postulated source term stated in the ESP did not fall within the source term derived from the design, then the referencing application would need to propose a variance from the ESP in accordance with 10 CFR 52.39 and 10 CFR 52.93. The proposed rule would similarly revise 10 CFR 53.1416.

This provision parallels the requirement in 10 CFR 52.39 and 53.1188 that specifies the 20-year limitation for finality on this type of potentially time-dependent information and recognizes that the holder of an ESP may choose not to update the ESP to retain finality once the ESP is 20 years past issuance. Together, the proposed revised provisions of 10 CFR 52.39 and 52.79, as well as 10 CFR 53.1188 and 53.1416, would provide flexibility for an ESP holder to determine when and what information to update while retaining the ESP for reference until such time as the holder chooses to terminate, and for a referencing COL applicant to have clarity regarding which aspects of the ESP would need to be evaluated and updated in the FSAR submitted as part of the application.

XXIX. Background—Manufacturing License Term Extension

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' In response, the NRC is proposing to amend its regulations to extend the term for initial issuance and the renewal of an ML to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. This change would align the term of MLs with the current term of design certifications.

On August 28, 2007, the NRC revised the provisions applicable to the licensing and approval processes for nuclear power plants with the final rule, ''Licenses, Certifications, and Approvals for Nuclear Power Plants'' (72 FR 49352). In that final rule, a new subpart F, ''Manufacturing Licenses,'' of 10 CFR part 52 replaced former appendix M of 10 CFR parts 50 and 52 that previously governed MLs. Under subpart F, an ML would be issued upon the submission of an acceptable final reactor design, equivalent to that required for a design certification under 10 CFR part 52, and certain information on the manufacturing process. The term for an ML was set to be for not less than 5, nor more than 15 years from the date of issuance, and was established to be consistent with the maximum term for a standard design certification in 2007. The Commission's stated intent was ''to encourage the use of a manufacturing license for the manufacture of more than one nuclear power reactor.'' However, no ML has been issued under subpart F of 10 CFR part 52.

In the July 2, 2025, direct final rule, ''Revising the Duration of Design Certifications'' (90 FR 28869), the NRC replaced the 15-year duration for design certifications with a 40-year duration period, both for certifications currently in effect and generically for future certifications, including renewals. As explained in that direct final rule, extending the term of design certifications reduces unnecessary regulatory burden on applicants and saves NRC resources without any reduction in safety or security.

XXX. Discussion—Manufacturing License Term Extension

The proposed amendments to the regulations in 10 CFR 52.173, ''Duration of manufacturing license,'' and 52.181, ''Duration of renewal,'' would change the duration of an ML to a maximum of 40 years and the duration of the renewed ML to a maximum of 40 years. The minimum terms of initial and renewed MLs would remain at 5 years. Amending the regulations to extend the term of an ML would make the duration of the ML consistent with the current durations of design certifications. The current landscape for nuclear power reactors designs, which encompasses potential microreactors and small modular reactors in addition to traditional large LWRs, may significantly benefit from the regulatory stability afforded by a longer ML term. This proposed change would allow ML holders to significantly decrease the burden associated with license renewal as the frequency of renewals would decrease. No other impact on licensees or other stakeholders is expected.

The NRC proposes to align the maximum term for an ML with the maximum term for a design certification because of the similarities between the scope of the two approvals. Most of the required information for an ML pertains to the same final design information required for a design certification. While part of an ML application pertains to organizational and QA information on manufacturing activities, this information is similar in kind to the organizational and QA information required for reactor COLs, which are also subject to a 40-year license term. Finally, consistent with the explanation provided by the NRC when it extended the term of a design certification to 40 years, the proposed extension to the term of MLs would not lead to any reduction in safety or security. If a safety or security issue is discovered during the term of an ML, the issue finality provisions in 10 CFR 52.171 allow the NRC to impose requirements to address the issue, as well as allow the holder of an ML or the applicant or licensee who references or uses a nuclear power reactor manufactured under an ML to seek a change to address the issue.

XXXI. Background—Nuclear Power Plant License Renewal

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Also, as set forth in section 2 of the E.O., it is the policy of the United States to facilitate appropriate operational extensions of the current nuclear fleet. In response, the NRC is proposing to make several amendments to its nuclear power reactor license renewal regulations.

The NRC first issued the license renewal rule (10 CFR part 54) on December 13, 1991 (56 FR 64943) and later revised it on May 8, 1995 (60 FR 22461). The rule establishes the procedures, criteria, and standards governing the renewal of nuclear power plant OLs. It also references the environmental protection requirements in 10 CFR part 51 for the evaluation of the environmental effects of the extended plant operation.

Since publishing the 1995 rule, the NRC has issued renewed licenses for nearly all currently operating plants, extending their operation from 40 to 60 years. The NRC has also issued second, subsequent renewed licenses for several plants, allowing them to operate for up to 80 years. Based on the experience gained through these renewals, the NRC has identified several opportunities to revise the regulations to make the process more flexible, efficient, and better able to support operational extensions.

XXXII. Discussion—Nuclear Power Plant License Renewal

This rulemaking proposes revising requirements in the following areas:

A. Extension of the Renewal Time Period

When the NRC issued the 1991 license renewal rule, it noted that the 40-year limit on licenses in section 103 of the AEA was not based on safety or security reasons; rather, it ''was adopted for antitrust and financial reasons'' (56 FR 64960; December 13, 1991). Section 103 of the AEA also provides that OLs may be renewed. However, the NRC noted that, because existing plants were licensed for 40-year periods, some aging-related issues expected to arise beyond 40 years of operation may not have been fully considered. (Id. at 64946, 64954). Therefore, while the NRC determined that there was no reason to assess all aspects of a plant's licensing basis during license renewal, the NRC should ensure that aging will be effectively managed during the period of extended operation. Moreover, this aging management does not ensure that a plant will operate until the end of its period of extended operation; rather it ensures that aging-related degradation will be identified and addressed before it becomes a safety issue.

The current regulation in 10 CFR 54.31(b) limits a renewed license to no more than 20 years beyond the existing license expiration. The NRC explained that the intent of the 20-year limit was to provide ''a useful opportunity to validate and reassess, if necessary, the current understanding of age-related degradation effects.'' (Id. at 64964). At that time, the NRC also noted that it might revisit the limit once additional experience is acquired and the NRC gains confidence in licensee programs that manage age-related degradation.

The NRC has examined its experience with aging management and in light of that experience is proposing to revise 10 CFR 54.31(b) to extend the maximum renewal term to 40 years, consistent with the maximum license period in section 103 of the AEA. Most U.S. reactors are already operating beyond 40 years under renewed licenses and are following their approved aging management programs. The NRC's oversight has confirmed that licensees are effectively detecting and resolving aging issues in a timely manner. The NRC has not identified any fundamental gaps in the understanding of aging that licensees have not been able to adequately address through the current renewal process or other existing regulatory processes.

The NRC has long recognized that issuing a renewed license for a full 40-year term is legally consistent with the terms of the AEA. When the NRC issued the 1991 rule, it considered two approaches to renewing licenses: (1) a ''tack-on'' license, which would take effect at the end of the current OL term, and (2) a ''supersession'' license, which would be immediately effective upon renewal and would add a number of years, at the time up to 20, to the existing license. The NRC chose to use the supersession approach. At that time, the NRC also noted that future efforts to extend the 20-year limit closer to the 40-year maximum would require a reappraisal of the use of supersession licensing. The supersession license approach that the Commission currently uses never results in a license greater than 40 years because the renewal term is 20 years and licensees currently may not apply for renewal until there are 20 years or less remaining on the license. In contrast, a renewed license that includes any number of years remaining on the existing license plus a 40-year extension would necessarily extend the term of the renewed license past the limit in section 103 of the AEA. Therefore, the NRC concludes that granting a 40-year extension would require the use of a tack-on license. Moreover, as the NRC noted when it initially promulgated its license renewal rules, a tack-on license may be more compatible with the terms of the AEA that state that licenses ''may be renewed upon the expiration'' of the license term. (Id. at 64964).

Maintaining a tack-on license may require additional administrative steps, particularly if it is issued well before the beginning of the period of extended operation. Therefore, these amendments to 10 CFR part 54 would also include a requirement that the licensee take steps to ensure the renewed license remains up to date, consistent with the current licensing basis as defined in 10 CFR 54.3, prior to the period of extended operation. Also, currently, certain activities are implemented prior to the period of extended operation in accordance with the conditions of the renewed license that is immediately in effect upon issuance, such as implementing new aging management programs and enhancing existing programs. The NRC's oversight program verifies that these activities are completed, including taking advantage of the plant's refueling outage prior to the period of extended operation to observe licensee activities that take place at reduced power levels. The NRC is considering alternative means of conditioning these activities, given that a tack-on license would not be in effect until the start of the period of extended operation, and the NRC is seeking the public's input on this topic.

With the change to a longer renewal term, applicants may need to address potential gaps in the current safety and environmental review guidance until the guidance is updated. For example, the current revision of NUREG–2191, ''Generic Aging Lessons Learned for Subsequent License Renewal (GALL–SLR) Report,'' was based on evaluations of up to one term of subsequent license renewal under the current regulation, or 80 total years of plant operation. Likewise, NRC regulations at subpart A of appendix B to 10 CFR part 51 codify the conclusions of NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants,'' (LR GEIS) for one initial term of renewal and one term of subsequent renewal. However, the NRC staff noted in SECY–22–0109, ''Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review,'' dated December 6, 2022, that, when it provided the draft LR GEIS to the Commission, the underlying analysis of environmental issues in that document ''could apply to any license renewal term,'' even one beyond the first subsequent license renewal term.

However, with the proposed change to allow license extensions of 40 years, plants currently operating in their initial renewal period (40 to 60 years) could apply for a 40-year subsequent renewal that would bring the plant to a total of 100 years of operation. Similarly, licensees that will be operating in their approved subsequent renewal period (60 to 80 years under existing regulations) could apply for a third 40-year renewal that would bring the plant to a total of 120 years of operation. As a result, applicants seeking to operate beyond 80 years would need to consider whether to supplement the guidance to address any aging and environmental effects specific to the longer operating life. No such gap analysis would be needed for applicants for an initial renewal, extending operation from 40 to 80 years, as the current subsequent renewal guidance readily applies to 80 total years of plant operation. For environmental effects, because the analysis in the LR GEIS is term neutral, licensees could consider using the LR GEIS as a starting point for that environmental analysis (although for environmental impacts past year 80, that analysis is not codified in 10 CFR part 51). The NRC has prepared draft interim staff guidance, LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' on this topic as part of this rulemaking. The NRC is also seeking the public's input on this topic.

B. Alternative Risk-Informed and Performance-Based Criteria

The current license renewal rule is often described as a deterministic rule because it prescribes the specific structures and components whose function must be demonstrated to be maintained. Under 10 CFR 54.21(a)(1), in-scope structures and components are included in the aging management review if they perform their function without moving parts or without a change in configuration or properties (*i.e.,* they are ''passive'') and if they are long-lived. In addition, 10 CFR 54.21(a)(3) requires applicants to demonstrate that the effects of aging will be adequately managed so that intended function(s) will be maintained for ''each structure and component identified in'' 10 CFR 54.21(a)(1). These regulations do not explicitly allow applicants to use risk insights to weigh the importance of the need to evaluate aging for license renewal.

When the NRC issued the 1995 license renewal rule, it considered allowing risk-informed methods, specifically PRA. The NRC decided against it due to concerns about the quality of risk data and models at that time. However, in SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk Informed and Performance-Based Regulation,'' dated March 1, 1999, the Commission defined its expectations for risk-informed and performance-based regulation. Since then, the agency has encouraged the use of such approaches to improve regulatory decision-making, enhance safety, and reduce unnecessary regulatory burden. There has since been widescale adoption of risk initiatives such as 10 CFR 50.69 and risk-informed technical specification completion times and surveillance frequencies that require PRAs to have a high level of acceptability. Since 1995, PRA standards have matured, data collection has improved, and NRC reviews of these activities have strengthened.

As a result, the NRC is proposing to add 10 CFR 54.21(a)(4) to allow applicants to voluntarily propose risk-informed and performance-based alternatives to the current prescriptive requirements of the aging management review. Applicants could use these alternative criteria to decide which structures and components need an aging management review and how to show that aging effects will be managed. Similarly, the NRC is also proposing to revise 10 CFR 54.29, ''Standards for issuance of a renewed license,'' to clarify that the NRC's safety finding could rely on risk insights in assessing the adequacy of an applicant's actions, or lack thereof, to maintain the functionality of structures and components.

The purpose of the license renewal rule is to ensure the preservation of intended functions during long-term operations for which the understanding of aging is more limited. The NRC focused the aging management requirements on passive structures and components because they generally lack performance and condition indicators that can be easily monitored. Although operating experience shows that passive components are typically more reliable than active ones, and PRA often assigns them a low contribution to plant risk, this does not guarantee their future performance over extended operating periods. New degradation mechanisms may emerge, existing mechanisms may progress faster than expected, or safety margins may be reduced. In addition, common cause aging issues that impact overall system function may emerge.

For these reasons, alternative risk-informed or performance-based criteria could not inappropriately weaken the capability of aging management programs to preserve intended functions over long-term operations. These criteria could not be used to eliminate aging management review requirements solely because past operating experience suggests passive structures and components are reliable. The criteria would need to be applied carefully to preserve the intent of 10 CFR part 54. The NRC has prepared draft interim staff guidance, LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' on this topic as part of this rulemaking.

C. Eliminate the Limitation on Early Application Submittal

The current regulation in 10 CFR 54.17(c) states that a licensee cannot apply for renewal more than 20 years before its current license expires. When the NRC issued the 1995 license renewal rule, it stated that the purpose of this limitation was to ensure that plants had sufficient operating experience to reveal any aging concerns before applying for renewal. At the same time, this 20-year limit was also intended to give utilities enough time to plan for alternatives, like replacing a plant, if the license was not renewed.

The NRC is proposing to remove the 20-year limit. Instead, the proposed regulations in 10 CFR 54.17(c) would permit licensees to apply for a renewed license anytime within their current operating period. For example, licensees could apply for initial renewal anytime within their initial 40-year license, and they could apply for subsequent renewal anytime within the period of extended operation. Removing the 20-year limit would give licensees more flexibility, such as coordinating their renewal applications with other licensing actions at the same plant or across their fleet to make the process more efficient. This change would not change the timely renewal provisions in 10 CFR 2.109.

The NRC has already granted exemptions from this regulation to several plants, based on the availability of operating experience from similar facilities (*i.e.,* similar materials and service environments) to inform the renewal decision. At this time, most U.S. plants have been operating past 40 years, and many for more than 50 years. As a result, there is a large amount of industry-wide operating experience to inform the NRC's renewal reviews, even if a specific plant has been operating for a short time. Also, the regulatory process will continue to provide the NRC with the means to verify that plants are effectively addressing emergent aging issues after a license is renewed. As described in NUREG–2191, Appendix B, ''Operating Experience for Aging Management Programs,'' holders of renewed licenses should have processes to capture and review operating experience to assess the need to enhance their aging management programs, as appropriate.

The NRC understands that newer reactor designs might use unique materials in new service environments, so they may not immediately have a complete base of operating experience. If licensees with newer designs request a renewed license early in plant life, the NRC's review guidance (*e.g.,* GALL Report) might not fully apply in some areas. In those cases, applicants would be expected to explain how they will address any unique issues and uncertainties in their demonstration of adequate aging management.

D. Eliminate the Required Application Content on Exemptions

The current regulation in 10 CFR 54.21(c)(2) requires that the application for a renewed license include a list of plant-specific exemptions granted under 10 CFR 50.12 that are based on time-limited aging analyses (TLAAs), along with a justification for continuing those exemptions during the extended operating period. When the NRC issued the 1995 rule, it explained that this requirement was important because it was necessary to make an independent assessment that all exemptions based on TLAAs had been evaluated as part of the license renewal process.

However, the NRC's experience in reviewing applications has found that this requirement leads to duplication of submitted information and adds unnecessary burden for applicants in their preparations to support the NRC's application review. The regulation in 10 CFR 54.21(c)(1) already requires applicants to identify and evaluate all TLAAs, whether or not they involve an exemption. Repeating the same information to meet the separate 10 CFR 54.21(c)(2) requirement does not aid the NRC's review. As a result, the NRC is proposing to remove 10 CFR 54.21(c)(2) to streamline the process and reduce the burden on applicants.

E. Eliminate the Required Application Content on Technical Specifications

The current regulation in 10 CFR 54.22, ''Contents of application—technical specifications,'' requires that applicants include and justify any technical specification changes needed to manage the effects of aging. However, based on its experience in reviewing renewal applications, the NRC has found that this requirement is not necessary. As the renewal process is meant to maintain a plant's current licensing basis (not change it), technical specification changes are very rarely needed. Also, even without this explicit application content requirement, the review process is capable of ensuring that any needed technical specification changes are identified. As a result, the NRC is proposing to remove 10 CFR 54.22. In addition, this regulation would no longer be cited in 10 CFR 54.9, ''Information collection requirements: OMB approval,'' and 10 CFR 54.43, ''Criminal penalties.''

F. Reduce Ongoing, Post-Renewal Updates to the Final Safety Analysis Report

The license renewal rule requires applicants to include a supplement to the plant's final safety analysis report (FSAR). This supplement must provide a summary description of the programs and activities credited for managing the effects of aging and the evaluation of TLAAs. In addition, after the NRC issues a renewed license, the regulation in 10 CFR 54.37(b) requires a licensee to keep the FSAR updated. These required updates are to ''include systems, structures, and components newly identified'' and ''describe how the effects of aging will be managed.'' The NRC Regulatory Issue Summary (RIS) 2007–16, Revision 1, ''Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses,'' dated April 28, 2010, explained the definition of ''newly identified'' systems, structures, and components (SSCs) as those that are either related to a change to the plant's licensing basis or were already installed during the original license renewal review but were not included in that review.

When the NRC issued the 1995 license renewal rule, some commenters pointed out that 10 CFR 54.37(b) requires more detail in the ongoing FSAR updates than the summary description provided in the original renewal application. At that time, the NRC justified the discrepancy on the grounds that, after a renewed license is issued, the ongoing FSAR updates serve dual purposes. They function as both the renewal application (in that they describe how the licensee evaluated the effects of aging for newly identified SSCs) and the FSAR supplement (establishing appropriate regulatory controls on aging management programs).

However, based on its oversight experience, the NRC believes the current level of detail in the required FSAR update is not necessary, provided that licensees keep details of their evaluation of newly identified SSCs available for NRC inspection. As a result, the NRC is proposing to revise 10 CFR 54.37(b) to only require a summary description of aging management activities, consistent with what is required in the renewal application. Under this change, a newly identified SSC would trigger an FSAR update only if it affects the summary description of aging management programs or TLAAs. However, regardless of whether an FSAR update is needed, the licensee would be required to keep the full evaluation of newly identified SSCs available in a form that could be audited and retrieved.

Finally, the other currently proposed revisions to 10 CFR part 54 (described in sections XXXII.A. and C. of this document) would change how licensees would need to address some physical plant additions or modifications made prior to the start of the period of extended operation. To date, newly installed SSCs have not been considered to be subject to 10 CFR 54.37(b), based on the idea that they would not be in service for more than 40 years during the extended license period. In its responses to comments on draft RIS–2007–16, Revision 1, ''Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses'' dated May 27, 2009, the NRC explained that plant operating programs and NRC regulatory activities are adequate to address aging during the first 40 years of service, and aging management is only necessary when that service life is exceeded. However, with the other proposed changes to 10 CFR part 54—extending the renewal term from 20 to 40 years with a tack-on license and removing the 20-year limit on early applications—SSCs newly installed after the NRC completes its license renewal review, but prior to start of the period of extended operation, could significantly exceed 40 years of service during the period of extended operation. Because of that, any of these SSCs that are installed before the start of the period of extended operation would be subject to the provisions of 10 CFR 54.37(b).

XXXIII. Background—Enhancing Flexibility of Reactor Site Criteria

The NRC acknowledges the importance of site characterization in the determination of site suitability to demonstrate reasonable assurance of adequate protection of public health and safety, particularly as it relates to external hazards with broad impacts and the potential to cause failure of all preventative and mitigative controls with one initiating event. Site investigations performed to determine the site-specific external hazards and to adequately characterize the geology, seismology, meteorology, and hydrology of a proposed power reactor site can be time consuming and expensive. The NRC further recognizes that the emergence of new reactor technologies, including non-stationary reactors, and alternate fuels may justify greater flexibility within the siting requirements, and site investigations performed to meet those requirements.

In the current regulatory framework, 10 CFR part 100, ''Reactor Site Criteria,'' consists of two subparts: subpart A, ''Evaluation Factors for Stationary Power Reactor Site Applications Before January 10, 1997 and for Testing Reactors,'' and subpart B, ''Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997.'' The requirements in subpart B to 10 CFR part 100 are more prescriptive than the requirements of subpart A to 10 CFR part 100 and impose an increased burden to obtain the required information. For example, subpart A of 10 CFR part 100 requires an applicant to consider the seismology, meteorology, geology, and hydrology of a site, but the requirements in subpart B of 10 CFR part 100 demand greater specificity, such as maximum probability wind speed, data on site foundation materials, earthquake recurrence rates, and groundwater velocity. Within the current framework, all power reactor applicants, even those for new reactor designs with smaller physical footprints, potentially lower radiological risk, and enhanced safety features, would perform the same site characterization and hazard analysis under the requirements in subpart B to 10 CFR part 100.

Subpart B to 10 CFR part 100 and the supporting guidance on acceptable site characterization methods impose a higher burden because they were developed primarily with large LWR sites in mind and were informed by the scale and potential radiological consequences of these facilities. Conversely, subpart A to 10 CFR part 100, including appendix A, contains less prescriptive requirements applicable to older LWR sites not reflective of updated method of external hazards analysis or testing reactors with a lower potential radiological consequence. Applying this regulatory framework and associated site characterization guidance as it currently exists to new reactor designs may not reflect a risk-informed, performance-based approach to site characterization that fully considers the site, design, and hazard-specific conditions at a prospective site.

Therefore, the NRC is proposing changes to these criteria to introduce a more risk-informed, performance-based approach to siting. The proposed changes to the regulations would clearly define a graded approach to site characterization for nuclear power reactor applicants, including non-stationary reactors, by introducing a tiered approach in the regulatory framework that would allow a lower consequence power reactor applicant to demonstrate site suitability through an appropriately scaled site investigation rather than the potentially more burdensome requirements in the current subpart B to 10 CFR part 100. Further, the draft guidance documents issued for public comment along with this proposed rule would provide a risk-informed approach that could be leveraged by reactor applicants under any licensing pathway to optimize their site characterization to achieve an acceptable level of risk for external hazards. This proposed approach is consistent with other recent rulemaking actions, such as the 10 CFR part 53 rulemaking, and would provide similar requirements for applicants across licensing frameworks.

The NRC has a long-standing preference to site reactors in areas of low population density but recognizes that safety, environmental, economic, or other factors may justify siting nuclear plants in areas with greater population densities. Therefore, the NRC proposes to revise its regulations in subparts A and B of 10 CFR part 100 to allow reactors to be sited in areas with greater population densities when justified by an assessment that compares the societal risks and societal benefits of siting reactors in those areas. This proposed change is consistent with the recent 10 CFR part 53 rulemaking and would provide similar requirements for applicants across licensing frameworks.

XXXIV. Discussion—Enhancing Flexibility of Reactor Site Criteria

The proposed changes to 10 CFR part 100 would allow power reactor applicants under 10 CFR part 50 or 52 to have greater flexibility to determine the appropriate level of site characterization. Specifically, these proposed changes would utilize existing flexibility in the regulatory framework for licensing testing and power reactors, including non-stationary reactors, by allowing certain lower consequence power reactor applicants to use the same siting criteria used for testing reactors under subpart A to 10 CFR part 100. Additionally, these proposed changes would remove outdated information on a deterministic approach to seismic hazards analysis in appendix A to 10 CFR part 100 that no longer applies to new reactor applications. The proposed changes to 10 CFR 100.10, ''Factors to be considered when evaluating sites,'' would streamline the regulation and be accompanied by guidance on how to meet the regulatory requirements for subpart A to 10 CFR part 100. The proposed title change to subpart B to 10 CFR part 100 would retain the more prescriptive regulatory requirements that would remain applicable to higher consequence power reactor applicants. These more prescriptive regulatory requirements would continue to ensure appropriate siting criteria for this class of applications. The existing titles of subparts A and B to 10 CFR part 100 are currently reflected in 10 CFR 50.34(a) and (b). Accordingly, conforming changes to those sections would be needed to align the proposed changes in 10 CFR part 100 with the requirements for content of applications described in 10 CFR 50.34(a) and (b). These conforming changes include updating 10 CFR 50.34(a) and (b) to remove references to applications on or after January 10, 1997, and stationary power reactors.

Specific proposed changes to 10 CFR part 100 implementing this approach are described below. The title of subpart A to 10 CFR part 100 would be changed to ''Subpart A—Evaluation Factors for Tier 1 Power and Testing Reactors.'' Appendix A to 10 CFR part 100 would be deleted in its entirety as it provides a description of an approach to determine the safe shutdown earthquake that is outdated and is not consistent with the current practice for performing a probabilistic seismic hazards analysis at nuclear power plant sites. The information necessary to perform an acceptable probabilistic seismic hazards analysis would be included in guidance. The proposed revisions to 10 CFR 100.3, ''Definitions,'' would be conforming changes to define the new terms introduced in proposed revisions to 10 CFR part 100: ''Tier 1 reactor'' and ''Tier 2 reactor.'' These terms would be defined based on an unmitigated consequence. The proposed revision to 10 CFR 100.8, ''Information collection requirements: OMB approval,'' would be a conforming change to remove the mention of appendix A, which would be deleted. The proposed revisions to 10 CFR 100.10 would remove the references to appendix A to 10 CFR part 100 and delete explanatory text. That explanatory text would instead be contained in the draft guidance documents issued for public comment along with this proposed rule. With the deletion of appendix A to 10 CFR part 100, a new reference to appendix S to 10 CFR part 50 would be added to 10 CFR 100.10(b) to provide earthquake engineering criteria for applicants pursuing siting under subpart A to 10 CFR part 100. Additional changes to 10 CFR 100.11, ''Determination of exclusion area, low population zone, and population center distance,'' related to the exclusion area, low population zone, and population center distance are being proposed to align with the dose reference values in subpart B to 10 CFR part 100, which references 10 CFR 50.34(a)(1). Other proposed changes to the text describing the consequence analysis in 10 CFR 100.11 would align with proposed revisions to the text in 10 CFR 50.34(a)(1)(ii)(D) to be more technology-inclusive and meaningful for designs with functional containments. The proposed rule would also revise footnote 1 to 10 CFR 100.11, which provides additional information on the fission product release, to be more technology inclusive and allow for the evaluation of designs with mechanistic source terms and functional containments. In addition, the proposed rule would remove outdated information from footnote 2 to 10 CFR

100.11, which discusses the use of 25 rem (0.25 Sv) TEDE as a reference value.

These proposed changes to subpart A to 10 CFR part 100 would enable power reactor applicants that meet the Tier 1 entry criterion for subpart A to 10 CFR part 100 to develop the appropriate level of site characterization information to support the permit or license application. The proposed entry criterion for a Tier 1 reactor would be to demonstrate an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary. The draft guidance documents issued for public comment along with these proposed rule changes would provide guidance on how to determine the unmitigated consequence, select the site parameters to include when defining a site parameter envelope and apply graded approaches for seismic and other external hazard characterization for any power reactor applicant. The draft guidance documents also would describe appropriate uses of existing site characterization information and alternative site investigation techniques, which would increase regulatory clarity and review efficiency.

Proposed entry criteria for subpart A to 10 CFR part 100 and guidance on graded approaches for external hazards with the potential to impact all safety controls with a single initiating event (*e.g.,* seismic) would be based on an unmitigated consequence analysis. The unmitigated consequence analysis would be necessary to account for the common-cause failure aspect of external hazards and to determine the appropriate target performance criteria for acceptable risk. Information on appropriate methods for performing unmitigated consequence analyses will be provided in the draft guidance documents being issued for public comment along with this proposed rule.

Additionally, an appendix within the draft guidance would provide considerations for optimizing seismic design bases using the unmitigated consequence analysis. The NRC recognizes that the seismic design basis for a nuclear facility often has a significant impact on cost and schedule. This appendix would enable applicants to optimize the seismic design basis, reducing the burden of seismic design while still ensuring safety.

With the proposed introduction of the concept of a Tier 1 reactor in subpart A to 10 CFR part 100, the title to subpart B to 10 CFR part 100 would be changed to ''Subpart B—Evaluation Factors for Tier 2 Power Reactor Site Applications.'' The NRC proposes to make additional changes to 10 CFR 100.20, ''Factors to be considered when evaluating sites,'' and 100.23, ''Geologic and seismic siting criteria,'' to reflect the new ''Tier 2'' terminology. Tier 2 reactors would be power reactors that have not been demonstrated to meet the Tier 1 entry criterion. This would include power reactors with an unmitigated consequence of greater than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary or where the unmitigated consequence is undetermined. No other changes are proposed to subpart B as part of this rulemaking, and the framework would be maintained to accommodate higher consequence reactor applications.

The NRC proposes to maintain its long-standing preference for siting reactors in areas of low population density, while providing flexibility to allow siting reactors in areas of greater population density when warranted. The NRC recognizes that safety, environmental, economic, or other factors may justify siting nuclear plants in areas with higher population densities or within a densely populated center containing more than about 25,000 residents. Therefore, the NRC is proposing to revise 10 CFR 100.10, 100.11(a)(3), 100.21(b), and 100.21(h) to allow applicants to justify siting reactors at such sites by performing assessments of additional societal risks associated with siting a reactor in areas of higher population density (*e.g.,* potential increases in population dose or economic consequences from reactor accidents) and comparing those risks to the societal benefits of a specific proposed site (*e.g.,* ability to use existing infrastructure for a retired fossil fuel power plant). Implementing guidance for these assessments will be developed.

The proposed changes to 10 CFR part 100 and the explanations provided in the draft guidance documents issued for public comment along with this rulemaking could result in timelier and more efficient site investigations, more appropriate seismic design bases, and more streamlined reviews for new power reactor applications.

XXXV. Background—Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

A. Accident Tolerant Fuels

Accident tolerant fuels (ATFs) are advanced nuclear fuel technologies that have the potential to enhance safety at U.S. nuclear power plants by offering better performance during normal operation, transient conditions, and accident scenarios. Section 107, ''Commission Report on Accident Tolerant Fuel,'' of the Nuclear Energy Innovation and Modernization Act defines ATF as a new technology that makes an existing commercial nuclear reactor more resistant to a nuclear incident (as defined in section 11 of the AEA (42 U.S.C. 2014)) and lowers the cost of electricity over the licensed lifetime of an existing commercial nuclear reactor.

While this proposed rule would not make any fuel-design-specific conclusions, it would facilitate the adoption of increased enrichment and higher burnup to enable entities, licensed to use conventional or ATF designs, to use LWR fuel containing uranium enriched to greater than 5.0 weight percent uranium-235 (U-235), in most cases, without the use of exemptions.

B. Rulemaking Development

(i) Early Considerations of Increased Enrichment

From interactions with stakeholders, the NRC is aware that licensees and applicants plan to request to deploy ATF concepts and operate fuel to extract more energy from each fuel rod (*i.e.,* operate fuel at higher burnups). Specifically, the NRC expects requests to raise fuel burnup limits to higher than the 62 gigawatt-days per metric ton of uranium (GWd/MTU) rod-average burnup limit set by the NRC in most safety analysis methodologies. To achieve higher burnup limits, licensees and applicants would need to request increases in fuel enrichment from the current standard of 5.0 weight percent U–235 up to approximately 10.0 weight percent U-235. Additionally, in February 2019, nuclear power industry representatives identified potential advantages of increased enrichment fuel for LWRs in the NEI white paper, ''The Economic Benefits and Challenges with Utilizing Increased Enrichment and Fuel Burnup for Light-Water Reactors.''

In September 2021, the NRC issued version 1.2 of the ''Project Plan to Prepare the U.S. Nuclear Regulatory Commission for Efficient and Effective Licensing of Accident Tolerant Fuels,'' which describes the pursuit of higher burnup and increased enrichment as key components of nuclear power industry ATF efforts. Currently, the industry plans to deploy batch loads of fuels enriched to levels greater than the current standard of 5.0 weight percent U-235 by the mid-to-late 2020s. Paragraph (b)(7) of 10 CFR 50.68, ''Criticality accident requirements,'' requires that U-235 enrichment levels in power reactor fuel be no more than 5.0

percent by weight, unless the NRC approves exemptions from this limit. The development of the current regulatory framework did not foresee use of enrichments greater than 5.0 weight percent U-235. The NRC established the current weight percent limits as reasonable bounding assumptions for its safety analysis methodologies. As part of this rulemaking, the NRC evaluated the framework and considered whether the current weight percent limits can be adjusted while maintaining reasonable assurance of adequate protection of public health and safety. In addition, the NRC considered whether rulemaking would support a more efficient review of licensing actions.

In response to industry interest in LWR fuels enriched to between 5.0 to 10.0 weight percent U-235, the NRC staff submitted to the Commission a rulemaking plan in SECY–21–0109, ''Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors,'' dated December 20, 2021. The staff requested Commission approval to initiate rulemaking to amend NRC requirements to facilitate the use of LWR fuel containing uranium enriched to greater than 5.0 weight percent U-235. In SECY–21–0109, the staff recommended rulemaking to reduce the number of exemption requests and facilitate increased regulatory efficiency and consistency. The staff explained that rulemaking on this topic would allow the staff to thoroughly review the potential regulatory implications of fuels enriched to greater than 5.0 weight percent U-235 and identify and assess the potential costs and benefits of changing regulatory requirements that impact the use of these fuels. Rulemaking also would provide options for a generic resolution of these issues and invite stakeholder participation in decisions affecting this regulatory area, rather than deciding issues on a case-by-case basis as in the current regulatory framework.

In SRM–SECY–21–0109, ''Staff Requirements—SECY–21–0109—Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors,'' dated March 16, 2022, the Commission approved the staff's plan to initiate rulemaking to amend requirements for the use of LWR fuel containing uranium enriched to greater than 5.0 weight percent U-235. The Commission stated that the provisions of the rule should apply only to high-assay, low-enriched uranium (HALEU) fuel, both for nonproliferation and safeguards reasons, and that the staff's analysis should focus on the range of enrichment most likely to be contemplated in future applications.

In addition, the Commission directed that (1) fuel fragmentation, relocation, and dispersal (FFRD) issues relevant to fuels of higher enrichment and burnup levels should be appropriately addressed and analyzed in the regulatory basis for this rulemaking; and (2) staff should take a risk-informed approach when developing this rule and the associated regulatory basis and guidance.

(ii) Other Considerations

On April 11, 2024, the Commission returned the 10 CFR 50.46c draft final rule to the staff in SRM–SECY–16–0033, ''Staff Requirements—SECY–16–0033—Draft Final Rule—Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria.'' As a result, this rulemaking proposes to leverage the previously proposed performance-based approach to emergency core cooling system (ECCS) requirements, including the expanded applicability to advanced fuels, and incorporate the embrittlement research findings from the 10 CFR 50.46c draft final rule into the new voluntary 10 CFR 50.46a proposed rule. This is discussed in sections XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' and XXXVI.F.(v), ''Alternative ECCS Analysis Requirements and Acceptance Criteria,'' of this document.

C. Background and History of Affected Regulations

This section provides the regulatory history and the background of each of the affected regulatory areas and its relationship to fuel enrichment.

(i) 10 CFR 70.24 and 10 CFR 50.68 Criticality Accident Requirements

One regulation initially evaluated by the NRC for its relationship to fuel enrichment is 10 CFR 70.24, ''Criticality accident requirements.'' This regulation was established as part of the rulemaking for 10 CFR part 70, ''Domestic Licensing of Special Nuclear Material,'' in 1974 (39 FR 39020; November 5, 1974). Section 70.24 ensures that licensees handling special nuclear material (SNM) have the appropriate monitoring systems in place for detecting a criticality accident and establish an emergency plan.

During the 1980s and 1990s, nuclear power reactor licensees sought exemptions from several requirements in 10 CFR 70.24, including those related to active criticality monitoring alarm capabilities, criticality emergency drills, and plans for evacuations, decontamination, medical treatment for radiation exposure, and reentry protocols, which must also be demonstrated through the regular criticality safety drills. As discussed in SECY–97–155, ''Staff's Action Regarding Exemptions from 10 CFR 70.24 for Commercial Nuclear Power Plants,'' dated July 21, 1997, in response to these numerous exemption requests, the staff evaluated the likelihood of an inadvertent criticality accident during fuel handling operations at nuclear power plants and concluded that such events would be unlikely for power reactor facilities because existing administrative and design controls were based on no more than 5.0 weight percent U-235 fuel enrichment. As a result, in 1998 the NRC issued 10 CFR 50.68 to offer these licensees an alternative to 10 CFR 70.24, provided that they meet certain criteria (63 FR 63127; November 12, 1998).

Under 10 CFR 50.68, licensees may decide not to comply with the requirements of 10 CFR 70.24 and, instead, must comply with the requirements in 10 CFR 50.68(b), if they can demonstrate appropriate subcriticality margins that are expressed in terms of k-effective (keff), the estimated ratio of neutron production to neutron absorption and leakage, for new and fresh fuel storage facilities. Section 50.68(b) specifies the following keff limits:

- *10 CFR 50.68(b)(2):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for fresh fuel wet storage racks in unborated water.
- *10 CFR 50.68(b)(3):* keff ≤ 0.98 at 95 percent probability and 95 percent confidence level for fresh fuel storage in low-density hydrogenous fluid (fog). This keff limit is only applicable to the current fleet of operating LWRs if they use a dry new fuel storage vault that is susceptible to moderation by natural weather or fire suppression fogging conditions. If new fuel is stored submerged in the fuel pool (*i.e.,* 10 CFR 50.68(b)(2) wet storage conditions), then 10 CFR 50.68(b)(3) does not apply.
- *10 CFR 50.68(b)(4):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for spent fuel wet storage racks in unborated water.
- *10 CFR 50.68(b)(4):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for spent fuel wet storage racks in borated water; furthermore, keff must remain < 1.0 at 95 percent probability and 95 percent confidence level without soluble boron credit taken.

In addition to the keff requirements, 10 CFR 50.68(b)(6) requires radiation monitoring only during fuel handling and movement. Finally, 10 CFR 50.68(b)(7) limits current applications to 5.0 weight percent U–235 for fresh fuels. The NRC added 10 CFR 50.68(c) in 2006 (71 FR 66648; November 16, 2006) to delineate independent spent fuel storage installation dry storage cask loading applicability.

Most operating reactors currently adhere to 10 CFR 50.68(b) requirements in lieu of the criticality monitoring requirements in 10 CFR 70.24. When fuel transition changes are made, if enrichments are being increased, the licensee must perform a safety analysis of spent fuel pool criticality as part of the fuel transition because increasing enrichments may cause a decrease in margin to the applicable keff safety limits of 10 CFR 50.68(b)(4). There is also a plant-specific criticality safety limit for the new and spent fuel storage areas listed in Standard Technical Specification Design Feature 4.3, ''Fuel Storage,'' in NUREG–1430, ''Standard Technical Specifications—Babcock and Wilcox Plants''; NUREG–1431, ''Standard Technical Specifications—Westinghouse Plants''; NUREG–1432, ''Standard Technical Specifications—Combustion Engineering Plants''; NUREG–1433, ''Standard Technical Specifications—General Electric Plants (BWR/4)''; NUREG–1434, ''Standard Technical Specifications—General Electric Plants BWR/6''; and NUREG–2194, ''Standard Technical Specifications—Westinghouse Advanced Passive 1000 (AP1000) Plants.'' The guidance in these NUREGs assists the NRC's review of any proposed fuel changes that could affect 10 CFR 50.68 compliance.

Nonetheless, given that 10 CFR 50.68(b)(7) limits current applications to 5.0 weight percent U-235, if reactor licensees transition to using fuel enriched above 5.0 weight percent U-235, then 10 CFR 50.68 would not be available as an alternative to 10 CFR 70.24. Absent rulemaking, the NRC expects that reactor licensees seeking to transition to fuel enriched above 5.0 weight percent U-235 would likely request exemptions from 10 CFR 50.68.

Unlike 10 CFR 50.68, 10 CFR 70.24 does not have an enrichment limit, so a licensee or applicant could comply with 10 CFR 70.24 and implement enrichments beyond 5.0 weight percent U-235. Licensees or applicants complying with 10 CFR 70.24 that seek exemption from that section's active criticality monitoring and emergency planning requirements could not justify the exemptions with the subcriticality margin approach methodology used in 10 CFR 50.68. Furthermore, under 10 CFR 70.24(d)(2), any exemption from 10 CFR 70.24 held by a licensee becomes ineffective once that licensee elects to comply with 10 CFR 50.68. Industry stakeholders have also acknowledged the greater regulatory flexibility of the 10 CFR 50.68 subcriticality margin approach, and licensees have expressed interest in applying the 10 CFR 50.68 methodology to higher enrichments in lieu of meeting the 10 CFR 70.24 criticality safety approach. Proposed amendments to address this issue are discussed in section XXXVI.A., ''Criticality Accident Requirements in 10 CFR 50.68,'' of this document.

(ii) Environmental Requirements in 10 CFR 51.51 and 51.52

In 10 CFR 51.51, table S–3, ''Table of Uranium Fuel Cycle Environmental Data,'' references the original environmental assessments in WASH–1248, ''Environmental Survey of the Uranium Fuel Cycle,'' issued April 1974, and NUREG–0116, ''Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle: A Task Force Report,'' Supplement 1 to WASH–1248, issued October 1976.

In 10 CFR 51.52, summary table S–4, ''Environmental Impact of Transportation of Fuel and Waste to and From One Light-Water-Cooled Nuclear Power Reactor,'' references the environmental assessments in WASH–1238, ''Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants,'' issued December 1972, and Supplement 1 to NUREG–75/038, ''Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants,'' issued April 1975.

The aforementioned environmental surveys were based on enrichments up to 4.0 weight percent U-235. Subsequent analysis by the NRC, incorporated into section 4.12.1.1 of NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Final Report,'' Revision 1, issued June 2013, confirmed that table S–3 of 10 CFR 51.51 and table S–4 of 10 CFR 51.52 are also bounding for enrichments up to 5.0 weight percent U-235. The NRC does not have an approved assessment of environmental impacts related to the uranium fuel cycle in current 10 CFR 51.51, or to transportation of enriched fresh, nonirradiated fuel to a reactor in current 10 CFR 51.52, for enrichments greater than 5.0 weight percent U-235.

Under 10 CFR 51.51 and related to 10 CFR 51.50, ''Environmental report—construction permit, early site permit, or combined license stage,'' the environmental data of table S–3 apply for enrichments up to 5.0 weight percent U-235 and apply to the environmental report for the CP stage, ESP stage, or COL stage of an LWR. Also, as required in 10 CFR 51.50, an applicant for a CP, ESP, or COL must submit an environmental report that contains information specified in 10 CFR 51.45, ''Environmental report,'' 10 CFR 51.51, and 10 CFR 51.52.

Under 10 CFR 51.52, an environmental report prepared for the CP stage, ESP stage, or COL stage of an LWR must contain a statement concerning the environmental impacts of transportation of fuel and radioactive waste to and from the LWR. If the conditions in 10 CFR 51.52(a) as extended to 5.0 weight percent U-235 are met, then table S–4 gives these environmental impacts and can be so stated in the applicant's environmental report. If an LWR applicant for a CP, ESP, or COL cannot meet the conditions for using table S–4 (for example, the plant has enrichments greater than 5.0 weight percent U-235), then the environmental report must contain a full description and detailed analysis of the environmental effects of transportation of fuel and radioactive waste to and from the reactor, including values for the environmental impact under normal conditions of transport and for the environmental risk from accidents in transport.

For licensing actions other than CP, ESP, and COL applications, which may not require submission of an environmental report (*e.g.,* license amendment requests), the uranium fuel cycle and the transportation of the fuel and waste could be considered necessary to support the operation of the plant. In such situations, the NRC would assess the environmental effects of the licensing action with respect to the uranium fuel cycle or transportation of fuel and waste or both.

Sections XXXVI.B., ''Uranium Fuel Cycle Environmental Data—Table S–3 in 10 CFR 51.51,'' and XXXVI.C., ''Environmental Effects of Transportation of Fuel and Waste—Table S–4 in 10 CFR 51.52,'' of this document include discussions of proposed amendments to support the use of fuel with enrichments greater than 5.0 weight percent U-235 for the uranium fuel cycle in 10 CFR 51.51 and transportation and waste requirements in 10 CFR 51.52. In a separate rulemaking, the NRC is considering changing the types of environmental impacts considered in tables S–3 and S–4.

(iii) Fissile Packaging Requirements

In an effort to fully utilize ATF capabilities, licensees and applicants are expected to seek approval for the transport of fissile material with enrichments that range between 5.0 and 10.0 weight percent U-235. The fuel cycle for commercial LWR fuel includes enrichment of uranium hexafluoride (UF_6) and shipment of the enriched UF_6 to a fuel fabricator for deconversion to uranium dioxide (UO_2). The enriched UF_6 is transported in NRC-approved packages that incorporate 30-inch cylinders.

The regulation in paragraph (b) of 10 CFR 71.55, ''General requirements for fissile material packages,'' requires that a transportation package be designed and constructed, and its contents limited, so that it would be subcritical if water were to leak into the containment system. This criticality analysis with moderation ensures criticality safety in transport in the unanticipated event that water leaks into the containment vessel and provides moderating materials for the fissile contents.

In the 2004 amendments to 10 CFR part 71 (69 FR 3698; January 26, 2004), the NRC implemented an exception to 10 CFR 71.55(b) in 10 CFR 71.55(g), which codified a longstanding NRC and worldwide practice for evaluating the leakage of water into UF_6 packages. This exception for UF_6 transportation packages can be used if all of the following conditions are met:

- The UF_6 cylinder remains leak tight following the tests specified for hypothetical accident conditions.
- The valve body of the cylinder does not impact any other part of the package, other than where it is attached to the cylinder.
- There is adequate quality control in the manufacture, maintenance, and repair of packagings.
- Each package is tested to demonstrate closure before each shipment.
- The uranium is enriched to not more than 5.0 weight percent U-235.

This exception is a performance-based assessment of the structural and containment integrity of the UF_6 cylinder, which is independent of the enrichment level of the contents.

Similarly, 10 CFR 71.55(c) also provides for an exception to the requirements in 10 CFR 71.55(b) if the applicant specifies that the package incorporates special design features that ensure that no single packaging error would permit leakage and that appropriate measures are taken before each shipment to ensure that the containment system does not leak. This exception does not limit the enrichment of the package contents.

In the 2004 amendments to 10 CFR part 71, the NRC explained the basis for the specific exception in 10 CFR 71.55(g) and its enrichment limit of 5.0 weight percent U-235 as follows: (1) it would maintain consistency with worldwide practice, (2) operation experience and history demonstrate safe shipment of fuel enriched to less than or equal to 5.0 weight percent U-235, and (3) it is necessary to transport an essential commodity (UF_6 feed material).

Currently, the regulations in 10 CFR part 71 are sufficiently performance-based and, except for 10 CFR 71.55(g), do not directly reference or limit the enrichment level of the radioactive contents. The regulatory issue with 10 CFR 71.55(g) is that it specifies an enrichment limit (5.0 weight percent U-235) for UF_6 that does not bound the range of enrichment that applicants may choose to ship in their UF_6 transportation packages in the future.

Section XXXVI.D., ''Fissile Material Packaging Requirements in 10 CFR 71.55,'' of this document includes a discussion of proposed amendments to the fissile packaging requirements in 10 CFR 71.55 to support the use of fuel with enrichments greater than 5.0 weight percent U-235.

(iv) Appendix A to 10 CFR Part 50 (General Design Criterion 19) and 10 CFR 50.67(b)(2)(iii)

The general design criteria (GDC) in appendix A to 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' Criterion 19, ''Control room'' (GDC 19), provide minimum design, fabrication, construction, testing, and performance requirements for structures, systems, and components (SSCs) that provide reasonable assurance that the facility can be operated without undue risk to public health and safety. Additionally, 10 CFR 50.67, ''Accident source term,'' allows applicable licensees to voluntarily revise the accident source term used in design basis radiological consequences analyses if certain requirements in 10 CFR 50.67(b)(2) are met.

Both GDC 19 and 10 CFR 50.67(b)(2)(iii) provide a specific dose-based criterion of 5 rem (0.05 Sv) TEDE for demonstrating the acceptability of the control room design. They represent a distinct layer of defense-in-depth that assumes a major accident that results in substantial meltdown of the reactor core with subsequent release of appreciable quantities of fission products. In application, GDC 19 and 10 CFR 50.67(b)(2)(iii) are performance based and require that a licensee or applicant provide a control room habitability design using traditional deterministic radiological consequence analyses methods to judge the acceptability of the design.

An acceptable level of control room habitability for design basis events (DBEs) is necessary to provide reasonable assurance that the control room would continue to be staffed and operated effectively to mitigate the effects of the postulated accident and protect public health and safety. GDC 19 and 10 CFR 50.67(b)(2)(iii) are *design* criteria and should not be construed as operational *limits.* While the design criteria are computed in terms of dose, they are figures of merit used to characterize the minimum requirements for design, fabrication, construction, testing, and performance for SSCs. The design criteria do not represent actual occupational exposures received during normal and emergency conditions, which are primarily controlled by 10 CFR part 20, ''Standards for Protection Against Radiation.''

The preamble for the 1971 final rule (36 FR 3255; February 20, 1971) that first published the GDC addressed the criteria only in the aggregate; the individual criteria were not discussed. However, there is a record of a change made to the proposed GDC 11 (32 FR 10213; July 11, 1967), which became the final GDC 19. The proposed GDC 11 referred to the occupational exposure limits of 10 CFR part 20 rather than specifying a numeric dose criterion. Industry comments on that proposal generally recommended deletion of the reference to 10 CFR part 20 (see SECY–R–143, ''Amendment to 10 CFR 50—General Design Criteria for Nuclear Power Plants,'' dated January 28, 1971). The Commission resolved these comments by deleting the reference to 10 CFR part 20 occupational exposure limits and providing the current ''5 rem whole-body, or its equivalent to any part of the body, for the duration of the accident'' in its place.

Section 50.67 of 10 CFR was established shortly after a revision to 10 CFR part 20 was issued in 1991, providing the voluntary regulatory mechanism for licensees to replace the original design criteria of whole body and thyroid with the new TEDE criteria. The preamble for the 10 CFR 50.67 final rule included the Commission's rationale for establishing 5 rem (0.05 Sv) TEDE as the GDC 19 numeric design criterion for licensees using an alternative source term. That rationale was composed of the following:

• The criteria in GDC 19 were based on a primary occupational exposure limit.

• The use of 5 rem (0.05 Sv) TEDE as the control room criterion did not imply that this value would be an acceptable exposure during emergency conditions, or that other radiation protection standards of 10 CFR part 20, including individual organ dose limits, might not apply. This criterion was provided only to assess the acceptability of design provisions for protecting control room operators under postulated design-basis accident (DBA) conditions. The DBA conditions assumed in these analyses, although credible, generally did not represent actual accident sequences but were specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.

• The regulations at 10 CFR 20.1206, ''Planned special exposures,'' permitted a planned special dose of five times the annual dose limits. Also, the pertinent U.S. Environmental Protection Agency (EPA) guidance at that time, ''Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,'' EPA–400/R–92–001, issued May 1992, set a limit of five times the annual dose limits for workers performing emergency services such as lifesaving or protection of large populations. The Commission did not suggest that control room dose during an accident can be treated as a planned special exposure or that the EPA emergency worker dose limits are an alternative to GDC 19. However, the Commission stated that these provisions offer a useful perspective that supports the conclusion that the organ doses implied by the 5 rem (0.05 Sv) criterion can be considered to be acceptable due to the relatively low probability of the events that could result in doses of this magnitude.

Development of the current control room design criterion did not foresee how licensees are currently operating their facilities and managing their fuel or considering fuel enrichments up to but less than 20.0 weight percent U-235. The history of fuel utilization for the current large LWR fleet has seen a gradual progression toward higher fuel burnups and increased enrichments. The original control room design criteria were developed during the late 1960s when burnup rates and enrichments were relatively low. During that time, there was enough margin in the facilities' design bases to accommodate the control room design criteria, even for power uprates of up to 120 percent of the originally licensed steady-state thermal power level. Today, vendors, licensees, and other members of the nuclear power industry have indicated to the NRC that they are looking for further power uprates using fuel enrichments up to 10.0 weight percent U-235 with fuel burnup limits higher than the 62 GWd/MTU rod-average burnup.

Depending on how the reactor core is designed with increased U-235 enrichment fuel elements and operation at higher burnup levels to reach longer cycle time, the results of a licensee's DBA radiological consequence analysis results would increase. The impact of this increase would decrease the retained margin maintained by the licensee to provide operational flexibility. An unjustifiably low design criteria can unnecessarily burden licensees for seeking increased enrichments with extensive analyses to preserve margin for operational flexibility purposes. These additional analyses may not result in safety benefits and can increase actual operational exposure to workers due to increased maintenance activities.

Under the current definition of ''safety-related structures, systems and components'' in 10 CFR 50.2, ''Definitions,'' any SSCs credited with providing mitigation functions during a DBE (or accident) must be designated as ''safety-related.'' The traditional radiological consequence analyses performed to demonstrate compliance with the control room design criterion assess the performance of safety-related SSCs because they are relied upon to remain functional during and following DBAs to ensure the capability to prevent or mitigate the consequences of accidents that could result in potential exposure. The analyses are not intended to be actual event sequences but, rather, are intended to be surrogates to enable deterministic evaluation of the response of the plant-engineered safety features. These accident analyses are intentionally conservative in order to address uncertainties in accident progression, fission product transport, and atmospheric dispersion. With few exceptions, these analyses do not credit non-safety-related SSCs or operator actions that would otherwise lower the radiological consequence results. This analysis approach can ensure conservative results, but the results can also have large uncertainties. Due to the modeling approach and inherent uncertainty, overly conservative results can lead licensees to perform extensive re-analyses to preserve margin for operational flexibility purposes that do not necessarily enhance safety.

The radiological consequence analyses also confirm several aspects of the facility's design- and licensing-basis when safety-related SSCs are credited as input parameters. These input parameters are often specific values and limits found in the facility's updated FSAR and technical specifications, pursuant to 10 CFR 50.36, ''Technical specifications.'' Deviations from the Technical Specification identified during maintenance or testing (*e.g.,* higher leakage rates or lower filter efficiencies) indicate a non-conformance issue with the facility's licensing basis. In such cases, additional maintenance must be performed to correct the discrepancy to bring the facility back into compliance with established licensing requirements. The degree of maintenance necessary to ensure the facility is in compliance can significantly influence the amount of radiation exposure incurred by workers. The numerical value of the control room design criteria, through the radiological consequence analyses that utilize specific values and limits found in the facility's technical specifications, factors into the licensee's decisions when performing maintenance activities and thus directly impacts the amount of workers' exposure to ionizing radiation. A very low design criteria value can result in an excessive amount of maintenance, leading to potentially avoidable occupational exposure and unnecessary operational disturbances. Conversely, a very high value may allow for unacceptable degradation, potentially compromising overall safety and performance over time. Adequate protection of public health and safety and occupational radiological safety can still be achieved at a higher and safe control room design criteria performance level while balancing both dose-savings to workers and providing some regulatory relief to maintain operational flexibilities. As discussed in section XXXVI.E., ''Control Room Requirements in 10 CFR 50.67 and GDC 19,'' of this document, the NRC proposes to address these issues so licensees would not need to perform potentially extensive re-analyses or excessive maintenance activities, or possibly request exemptions, to demonstrate compliance without a commensurate increase in safety.

The NRC's Radiation Protection and Emergency Response Framework

The NRC's comprehensive radiation protection and emergency response framework, which covers both normal operations and accident conditions, is another important aspect of the control room design criteria rulemaking efforts. This framework helps to protect occupational workers from ionizing radiation as well as prepare the licensee to respond to abnormal and emergency conditions to protect the public health and safety.

At the time that GDC 19 was established in 1971, 10 CFR part 20 limited occupational radiation exposure to 3 rem (0.03 Sv) whole body dose per calendar quarter, provided the total lifetime dose was verified not to exceed 5 rem (0.05 Sv) times the individual's age in years minus 18. Thus, a worker could receive a radiation exposure of up to 12 rem (0.12 Sv) in a given year.

The current annual limit on occupational radiation dose exposure in 10 CFR 20.1201, ''Occupational dose limits for adults,'' is 5 rem (0.05 Sv) TEDE. Under 10 CFR 20.1201, an adult worker could receive occupational radiation exposure of up to 10 rem (0.10 Sv) TEDE over a 12-month period straddling two calendar years. The current 10 CFR 20.1206 also permits an adult worker to receive doses in addition to, and accounted for separately from, the doses received under the limits specified in 10 CFR 20.1201 of five times the annual dose limits during the individual's lifetime, not to accumulate faster than 5 rem (0.05 Sv) TEDE in any one year. As such, an adult worker could receive radiation exposure of up to 10 rem (0.10 Sv) TEDE within a single calendar year period. In setting these standards in the 1991 amendment of 10 CFR part 20 (56 FR 23360; May 21, 1991), the Commission concluded that an infrequent exposure of workers up to twice the occupational dose limit was adequately protective of radiation workers.

The NRC's emergency planning regulations in appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' and planning standards for nuclear power reactors in 10 CFR 50.47, ''Emergency plans,'' require each nuclear power reactor licensee to have an emergency plan that gives the NRC reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The regulation at 10 CFR 50.47(b)(11) requires licensees to establish the means for controlling radiological exposures in an emergency and states that the means for controlling radiological exposures must include exposure guidelines consistent with EPA Emergency Worker and Lifesaving Activity Protection Action Guides (PAG). The EPA exposure guidelines found in the current version of its ''PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents,'' recommend that doses received under emergency conditions should be maintained as low as reasonably achievable and, to the extent practicable, limited to 5 rem (0.05 Sv). The guideline for actions to protect valuable property is 10 rem (0.10 Sv) where a lower dose is not practicable, the guideline for actions to save a life or to protect large populations is 25 rem (0.25 Sv) where a lower dose is not practicable, and exposures greater than 25 rem (0.25 Sv) may be appropriate for lifesaving or protecting large populations if the workers are volunteers who are fully aware of the risks involved.

The events that could result in control room radiation exposures comparable to the 10 CFR part 20 normal occupational exposure limit of 5 rem (0.05 Sv) TEDE would result in the activation of the facility's emergency response plan and the emergency response organization. These emergency actions include establishing higher exposure limits for control room operators if necessary to provide public health and safety, as permitted by paragraph (x) of 10 CFR 50.54, ''Conditions of licenses,'' and paragraph (b) of 10 CFR 20.1001. The emergency coordinator can also authorize issuing potassium-iodide tablets for thyroid protection or use of emergency respiratory protection equipment.

The Commission's framework for emergency planning and response encompasses a combination of regulatory requirements and industry commitments tailored to address a spectrum of potential events, from design-basis scenarios to extremely low-probability severe accident events. This comprehensive approach ensures preparedness to effectively protect public health and safety by enabling robust planning and response capabilities.

Scientific Recommendations for Radiation Protection for Worker and Regulations Under Accident and Emergency Conditions

The NRC reviewed several source materials to understand the current recommendations from national and international organizations responsible for making recommendations for radiation protection standards. The purpose of this review was to determine whether reexamining the scientific and technical basis for the numerical value of the control room design criteria would be warranted. Section XXXVI.E., ''Control Room Requirements in 10 CFR 50.67 and GDC 19,'' of this document describes how the NRC used this review to inform the development of this proposed rule.

ICRP Publication 109, ''Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations,'' issued in 2009, specifies a reference range of 2 to 10 rem (0.02 to 0.10 Sv) acute, or per year, for emergency exposure situations. The reference level represents the level of residual dose or risk above which it is generally judged to be inappropriate to plan to allow exposures to occur. The ICRP considers that a dose rising towards 10 rem (0.10 Sv) will almost always justify protective measures and that protection against all exposures, above or below the reference level, should be optimized.

The IAEA 2024 guidance, ''Portable Digital Assistant for First Responders to a Radiological Emergency: Emergency worker turn-back dose guidance,'' specifies a range of 5 to 100 rem (0.05 to 1 Sv), depending on the severity of the actions needed.

The 2018 NCRP Report No. 180, ''Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States,'' specifies the following: (1) during lifesaving activities or actions to prevent a catastrophic situation, which includes other urgent rescue activities, 50 radiation-absorbed dose (rad) (0.5 gray (Gy)) cumulative whole-body absorbed dose (50 rad) should be implemented at the command level, and (2) for other emergency activities, including extended activities following initial lifesaving, rescue, and damage control response, an effective dose to emergency workers should not exceed 10 rem (0.10 Sv).

Modern Health Physics and Radiation Epidemiology Knowledge

The NRC's comprehensive radiation protection and emergency response framework for protecting individuals during normal and emergency conditions is informed by scientific recommendations by national and international organizations. These recommendations are based on fundamental modern health physics and radiation epidemiology knowledge. The NRC's consideration of these organizations' recommendations has contributed to developing this proposal to amend the control room design criteria value from 5 rem (0.05 Sv) TEDE to 10 rem (0.10 Sv) TEDE with the additional provisions to justify a higher numerical value up to 25 rem (0.25 Sv) TEDE.

The range of proposed control room design criteria values is significantly below the threshold for observable deterministic health effects such as acute radiation syndrome and hematopoietic syndrome, which occurs at a dose around 70 to 100 rad (0.7 to 1 Gy). This range is also far below the mean lethal dose of ionizing radiation without medical treatment, which is estimated to be approximately 300 to 500 rad. This demonstrates that the proposed design criteria range is well within safe limits relative to acute radiation effects that could impair workers from performing their safety function in response to an event. Additionally, the criteria range results in a small radiation risk for cancer mortality, which would be further mitigated by radiation protection and emergency planning actions during an actual event. This ensures a high level of protection is still provided, thereby minimizing long-term health impacts.

In RG 8.29, Revision 1, ''Instruction Concerning Risks from Occupational Radiation Exposure,'' the NRC adopted a risk value, for an occupational dose of 1 rem (0.01 Sv) TEDE, of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates. The radiation risk incurred by a worker depends on the amount of dose received. Under current health physics models, a worker who receives 5 rem (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv).

Thus, in a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation, and using the risk factor of 4 effects per 10,000 rem (100 Sv) of dose, 4 of the 10,000 people might die from delayed cancer because of that 1 rem (0.01 Sv) dose in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. From an individual perspective, a 1 rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rem (0.1 Sv), the estimate would increase to 20.4 percent. A lifetime dose of 100 rem (1.0 Sv) may increase chances of dying from cancer from 20 to 24 percent. This small increase in cancer risk could be inferred over the lifetime, however it is unlikely that an increased incidence of cancer due to irradiation would be discernible. This is because the normal variability in baseline rates of cancer incidence is much larger than the inferred radiation-associated cancer rates. As a point of reference, according to NUREG–0713, Volume 43, ''Occupational Radiation Exposure at Commercial Nuclear Power Reactors and other Facilities,'' published in 2021, the average measurable dose for radiation workers reported to the NRC was 0.16 rem (0.0016 Sv) for 2021.

(v) Fuel Dispersal

(a) 10 CFR 50.46 and Fuel Dispersal

In 1974, the Atomic Energy Commission (AEC) established ECCS acceptance criteria during postulated loss-of-coolant accidents (LOCAs) in 10 CFR 50.46, ''Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors'' (39 FR 1001; January 4, 1974). The core cooling acceptance criteria in 10 CFR 50.46 were based on the available research, operating experience, and fuel operating conditions applicable to that era. Potential impacts of FFRD phenomena were not understood at that time and were not referenced in 10 CFR 50.46 or the accompanying analysis methods described in appendix K to 10 CFR part 50, ''ECCS Evaluation Models.'' The lack of reference to such phenomena in these regulations may be attributed to the fact that, in the early 1970s, fuel discharge burnups were well below the threshold local burnup (*i.e.,* 55 GWd/MTU) at which FFRD phenomena are now recognized to be a risk. Now that increased enrichment and higher fuel discharge burnups are being contemplated, the NRC is examining the original intent of the rulemaking as well as the current state of knowledge and operational experience to date to develop a performance-based regulatory framework that addresses fuel dispersal in a manner that maintains reasonable assurance of adequate protection of public health and safety.

The acceptance criteria in the original 10 CFR 50.46(b) included limits on peak cladding temperature (PCT) and maximum local oxidation (MLO) in 10 CFR 50.46(b)(1) and (b)(2), respectively, as well as the requirement in 10 CFR 50.46(b)(4) that the core should remain amenable to cooling. As stated in the AEC's 1973 opinion announcing its decision on the 10 CFR 50.46 final rule, the limits on PCT and MLO were intended ''to ensure the zircaloy cladding would remain sufficiently intact to retain the UO_2 fuel pellets in their separate fuel rods and therefore remain in an easily coolable array.'' In other words, these criteria were intended to prevent the fuel from leaving the confines of the cladding.

Regarding the coolability criterion, the AEC envisioned two scenarios that were deemed unacceptable: (1) the ballooning of the cladding to the extent that the coolant passages are blocked and (2) allowing the fuel pellets to fall together into a heap that would be difficult to cool. The 1973 AEC opinion stated that the coolability criterion should be superfluous because of the PCT and MLO criteria, but that the AEC maintained it as a basic objective in view of its fundamental and historical importance. In other words, the objective of the core coolability criterion should not be viewed as different from that of the PCT and MLO criteria. While brittle failure is precluded under the PCT and MLO criteria of 10 CFR 50.46, the AEC understood and accepted that ductile failure (*i.e.,* ballooning and burst) would occur, but it would be limited such that it would not block the coolant flow, as stated in the first unacceptable scenario considered in the formulation of the coolability criterion. Fuel dispersal is typically associated with the ductile failure of cladding encapsulating finely fragmented fuel at local burnups in excess of 55 GWd/MTU. Based on the historical record, the AEC expected the fuel would remain confined by the cladding following ductile failure, as fine fuel fragmentation and dispersal was not a known phenomenon at the time and further would not have been operative at the fuel discharge burnups attained in the early 1970s.

After the AEC's approval of 10 CFR 50.46 in 1973, fuel discharge burnups at operating reactors continued to increase. Fuel fragmentation and relocation were first discovered in the early 1980s, when experiments conducted at several test facilities showed that irradiated fuel could fragment into small pieces during a LOCA and may relocate axially, settling into the ballooned regions. In 1984, the NRC decided to consider the implications of the phenomena in the generic issue (GI) program, specifically as GI–92, ''Fuel Crumbling During LOCA,'' as described in NUREG–0933, ''Resolution of Generic Safety Issues,'' issued September 2021. The NRC found that the known conservatisms in appendix K to 10 CFR part 50 would more than offset the heat generation in the balloon region because of the fragmentation and relocation of fuel in calculations performed under appendix K to 10 CFR part 50.

In the early 1990s, the conclusion of GI–92 was that fuel fragmentation and relocation should be placed no higher than the low priority category of the GI program. This meant that there was insufficient justification for starting a major re-review of existing ECCS performance analyses conducted in adherence to appendix K to 10 CFR part

50. However, there were ongoing efforts to develop and license more realistic (and thus less conservative) ECCS performance models. Therefore, the NRC expected that the ECCS evaluation methodologies would appropriately address fuel fragmentation and relocation in their calculations. As a result, the NRC decided that a separate GI was not necessary, and the issue was later dropped from the GI program in 1995.

Until 2006, there was no expectation from any prior research that fragmentation and relocation into the balloon region could result in the loss of fuel particles through the rupture opening. In 2006, several research tests challenged this assumption. Integral LOCA tests conducted at the U.S. Department of Energy's (DOE's) Argonne National Laboratory on rods up to local burnups of 64 GWd/MTU observed a small amount of fuel loss (about the quantity of one fuel pellet). Since the amount of material was small, this discovery was not thought to be of safety significance. In April 2006, a LOCA test was run in the Halden Reactor Project in Norway on a fuel rod segment with a very high local burnup of 91.5 GWd/MTU. Results from this test showed gross loss of fuel material from above the rupture opening. In this very-high-burnup fuel specimen, more than 40 percent of the fuel material was in a nearly powdered form, as described in NUREG–2121, ''Fuel Fragmentation, Relocation, and Dispersal During the Loss-of-Coolant Accident,'' issued March 2012.

In 2008, the NRC's Office of Nuclear Regulatory Research (RES) issued Research Information Letter (RIL)–0801, ''Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46,'' dated May 30, 2008, which discussed research findings in the area of high-burnup fuel performance during postulated LOCAs. The RIL–0801 noted that additional research on fuel dispersal was being conducted but concluded that ''the current NRC burnup limit of 62 GWd/MTU (average for the peak rod) is probably low enough to prevent significant fuel loss during a LOCA.'' The RIL–0801 recommended rulemaking be pursued to revise the criteria in 10 CFR 50.46(b) to account for high burnup phenomena that may cause the current criteria to be non-conservative.

In 2012, the NRC published NUREG–2121 to capture the state of knowledge and history of FFRD as of that time. NUREG–2121 concluded that additional experimental research was needed to quantify the extent and downstream effects of fuel dispersal. Additionally in SECY–15–0148, ''Evaluation of Fuel Fragmentation, Relocation and Dispersal Under Loss-of-Coolant Accident (LOCA) Conditions Relative to the Draft Final Rule on Emergency Core Cooling System Performance During a LOCA (50.46c),'' dated November 30, 2015, the staff concluded that there was ''no imminent safety concern'' for operating reactors with respect to FFRD and that the 10 CFR 50.46c rulemaking should not be delayed to address FFRD. The SECY paper also stated that additional research was ongoing, and that future regulatory action could be initiated, if needed, to address FFRD after more research was conducted.

In December 2021, RES published RIL 2021–13, ''Interpretation of Research on Fuel Fragmentation, Relocation, and Dispersal at High Burnup,'' to inform the NRC's Office of Nuclear Reactor Regulation about RES's interpretation of the FFRD research to date. In RIL 2021–13, the staff defines conservative empirical boundaries for FFRD-related phenomena, such as the amount of fuel that is expected to be dispersed during a LOCA. Additionally, RIL 2021–13 identifies data gaps associated with FFRD-related phenomena. While the models in RIL 2021–13 can be used to estimate the potential mass of fuel that could be dispersed to the coolant, that RIL does not attempt to address the consequences of fuel dispersal into the coolant. To fully characterize such consequences, the NRC needs to better understand the behavior of dispersed fuel particles in the coolant and their impact on core coolability and safety under LOCA conditions that may involve significant core geometry changes due to rod ballooning, significant and varying single- and two-phase core flows, and dynamic LOCA loads. The NRC is involved in several collaborative domestic and international research programs, such as the Studsvik Cladding Integrity Project, which are, in part, addressing some of the data gaps presented in RIL 2021–13. Additionally, the NRC sponsored a phenomena identification and ranking table (PIRT) exercise concerning the consequences of fuel dispersal. The findings of the expert PIRT panel are documented in NUREG/CR–7307, ''Phenomena Identification and Ranking Tables on High Burnup Fuel Fragmentation, Relocation, Dispersal, and Its Consequences for Design-Basis Accidents in Pressurized- and Boiling-Water Reactors,'' and have informed DG–1434, ''Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents,'' which is being issued for comment with this proposed rule. The PIRT will also help inform future research efforts and NRC review of applications that may evaluate FFRD.

In 2022, in SRM–SECY–21–0109, as part of its approval of the staff's plan to begin this increased enrichment rulemaking, the Commission directed that FFRD should be appropriately addressed and analyzed in the rulemaking's regulatory basis. The NRC considered several alternatives in the regulatory basis, along with other options received in the public comments on the regulatory basis, in developing the following path forward to addressing FFRD.

(b) 10 CFR 50.46a Rulemaking

In 2010, the staff sent to the Commission for approval via SECY–10–0161, ''Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a) (RIN 3150–AH29),'' a draft final rule that would have created alternative ECCS requirements in 10 CFR 50.46a. The rule would have divided the current spectrum of LOCA break sizes into two regions. The division between the two regions would have been delineated by the transition break size (TBS). The first region included small breaks, up to and including the TBS. The second region included breaks larger than the TBS, up to and including the double-ended guillotine break (DEGB) of the largest reactor coolant system (RCS) pipe. The likelihood of these larger breaks is much lower than the smaller breaks in the first region, which was used to support a different regulatory treatment for the larger breaks.

In this rulemaking, the NRC proposes to build on the 10 CFR 50.46a rulemaking as a means of analytically resolving FFRD issues. The analytical margins gained from the treatment of large-break LOCAs as beyond-design-basis are expected to eliminate or greatly reduce the calculated quantity of fuel dispersal, as described in section XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' of this document. While the NRC has attempted to update this proposed rule with information available since SECY–10–0161 was issued, the NRC expects stakeholders will provide significant additional information in their comments on this proposed rule that could support the NRC further risk-informing these aspects of the rule.

(c) 10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings

In 2016, the staff sent to the Commission for approval via SECY–16–

0033 a draft final rule to create 10 CFR 50.46c. The draft final rule would have established performance-based regulatory requirements for determining the acceptability of an ECCS for a nuclear power reactor. Similar to existing regulations in 10 CFR 50.46, the draft ECCS performance requirements in 10 CFR 50.46c were largely based upon acceptance criteria for fuel rod cladding performance. The final rule would have expanded the applicability of the 10 CFR 50.46 acceptance criteria from only uranium oxide pellets within cylindrical zircaloy or ZIRLO™ [1] cladding to any LWR fuel, regardless of fuel design or cladding material. The draft final rule also incorporated improved performance-based requirements to address research findings on fuel cladding integrity and degradation mechanisms that were described in RIL–0801.

The Commission returned the 10 CFR 50.46c draft final rule to the staff in SRM–SECY–16–0033, ''Staff Requirements—SECY–16–0033—Draft Final Rule—Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria,'' on April 11, 2024. In this SRM, the Commission stated that the staff should reconsider the topics presented in the 10 CFR 50.46c draft final rule and provided the following directions:

1. The staff should apply an appropriate risk-informed regulatory approach to address the research findings on cladding embrittlement effects under LOCA conditions described in SECY–16–0033.
2. The staff should evaluate Item 1 with other associated technical issues being addressed, such as FFRD and risk-informed treatment of LOCAs, including the 10 CFR 50.46a draft final rule.
3. The staff should evaluate whether specific ECCS criteria such as cladding temperature should be codified or instead addressed in regulatory guidance.

This rulemaking proposes to leverage the previously proposed performance-based approach to ECCS requirements, including the expanded applicability to advanced fuels, and incorporate the embrittlement research findings from the 10 CFR 50.46c draft final rule into the new voluntary 10 CFR 50.46a proposed rule and associated guidance. The following discussion describes the embrittlement research findings that the 10 CFR 50.46c draft final rule planned to address and that this rulemaking proposes to address.

[1] ZIRLO is a registered trademark of Westinghouse Electric Company LLC.

All licensees who adopt the new voluntary 10 CFR 50.46a proposed rule would address the embrittlement research findings through their updated analyses and associated acceptance criteria. The NRC would continue to conduct annual safety assessments for licensees that do not choose to adopt the new requirements to confirm reasonable assurance of adequate protection. After the completion of this rulemaking, the NRC would continue to consider whether any new regulatory requirements are needed for these licensees that do not adopt proposed 10 CFR 50.46a because the research findings show that the current criteria may not always ensure that the fuel cladding remains ductile after the reactor is reflooded, referred to as post-quench ductility (PQD). The NRC expects that its assessment of further actions would consider (1) the resource needs for and results of the ECCS annual safety assessments, (2) the industry's plans for adoption of 10 CFR 50.46a, and (3) whether there is a safety basis for additional requirements beyond the promulgation of this voluntary alternative proposed rule. If the majority of the industry adopts 10 CFR 50.46a, then little to no future regulatory action may be needed to resolve these matters.

1. Overview of Cladding Embrittlement Research Findings

Since 1997, the NRC has undertaken a fuel cladding research program to investigate the behavior of high-exposure fuel cladding under accident conditions. This research program included an extensive LOCA research and testing program at Argonne National Laboratory, as well as jointly funded programs at the Kurchatov Institute (supported by the French Institute for Radiological Protection and Nuclear Safety and the NRC) and the Halden Reactor Project (a jointly funded program under the auspices of the Organization for Economic Cooperative Development—Nuclear Energy Agency, sponsored by national organizations in 18 countries). The effects of both alloy composition and fuel burnup on cladding embrittlement (*e.g.,* loss of ductility) under accident conditions were studied in these research programs. The research programs identified new cladding embrittlement mechanisms that were not previously known and expanded the NRC's knowledge of previously identified mechanisms.

2. Major Research Findings Cladding Embrittlement

These research findings have been summarized in RIL–0801, and the detailed experimental results from the program at Argonne National Laboratory are contained in NUREG/CR–6967, ''Cladding Embrittlement during Postulated Loss-of-Coolant Accidents,'' dated July 31, 2008. Since the publication of NUREG/CR–6967 and RIL–0801, additional testing was conducted related to the embrittlement phenomenon, which has been documented in supplemental reports. Where the additional testing relates to conclusions and recommendations in RIL–0801, RIL–0801 has been supplemented to reference the additional reports and incorporate findings (''Update to Research Information on Cladding Embrittlement Criteria in 10 CFR 50.46,'' dated December 29, 2011).

i. Hydrogen-Enhanced Beta-Layer Embrittlement

In current 10 CFR 50.46, the preservation of cladding ductility, via compliance with regulatory criteria on PCT (10 CFR 50.46(b)(1)) and local cladding oxidation (10 CFR 50.46(b)(2)), provides a level of assurance that fuel cladding will not experience gross failure and that the fuel rods will remain within their coolable lattice arrays. The 1997–2016 LOCA research program, as summarized in NUREG/CR–7219, ''Cladding Behavior During Postulated Loss-of-Coolant Accidents,'' identified new cladding embrittlement mechanisms that demonstrated that the current combination of PCT (2200 degrees Fahrenheit (°F) (1204 degrees Celsius (°C)) and local cladding oxidation (17 percent equivalent cladding reacted (ECR)) criteria may not always ensure PQD. As explained in section 1.5 of NUREG/CR–7219, oxygen diffusion into the base metal under LOCA conditions promotes a reduction in the thickness (referred to as beta-layer thinning) and ductility (referred to as beta-layer embrittlement) of the metallurgical structure within the cladding that provides its macroscopic mechanical behavior. The presence of hydrogen within the cladding accelerates this embrittlement process. Hydrogen is produced from the corrosion of zirconium in water, some of which is absorbed by the cladding, which is frequently referred to as ''hydrogen pickup.''

The NRC's cladding embrittlement program did not investigate cladding degradation mechanisms or develop the technical basis for performance-based requirements beyond the existing 2200 °F (1204 °C) PCT criterion. Examples of degradation mechanisms beyond cladding embrittlement (via oxygen diffusion) include excessive exothermic metal-water reaction, alloy-specific eutectics, and loss of fuel rod geometry due to plastic deformation. As a result, the existing 2200 °F (1204 °C) limit remains an upper limit on PCT for zirconium-based alloys. However, as reflected in this embrittlement criterion in DG–1263, ''Establishing Analytical Limits for Zirconium-Based Alloy Cladding,'' and based on the results of the fuel cladding research program, a lower PCT may be required to preserve ductility. Although the 2200 °F (1204 °C) limit in 10 CFR 50.46 remains unchanged in this rulemaking, the acceptance criteria in proposed 10 CFR 50.46a would establish a requirement to address cladding degradation phenomena, which would include cladding embrittlement. The 2200 °F (1204 °C) temperature is proposed as an acceptable limit in DG–1263 rather than codified in 10 CFR 50.46a.

ii. Oxygen Ingress From Cladding Inside Diameter

As explained in section 1.5.6 of NUREG/CR–7219, oxygen sources may be present on the inner surface of irradiated cladding due to gas-phase uranium trioxide transport prior to gap closure, fuel-cladding-bond formation (uranium dioxide in solid solution with zirconium dioxide), and the fuel bonded to this layer. Under LOCA conditions, this available oxygen may diffuse into the base metal of the cladding, which could cause the cladding to become more brittle.

iii. Breakaway Oxidation

As explained in section 1.5.5 of NUREG/CR–7219, zirconium dioxide can exist in several crystallographic forms, or allotropes. During normal operation, the zirconium dioxide layer that develops has a monoclinic crystallographic structure, which is neither fully dense nor fully protective. During LOCA conditions, the monoclinic oxide will transform to a tetragonal structure, and the oxide that newly forms under LOCA conditions is also tetragonal. The tetragonal oxide is dense, adherent, and protective against hydrogen pickup. However, there are conditions, both mechanical (*e.g.,* local regions of tensile stress) and chemical (*e.g.,* impurities at the metal surface), that promote a transformation of the zirconium dioxide from the tetragonal back to the monoclinic phase. The tetragonal-to-monoclinic transformation is an instability that initiates at local regions of the metal-oxide interface and grows rapidly throughout the oxide layer. Because this transformation results in an increase in oxidation rate, it is referred to as breakaway oxidation. Along with this increase in oxidation rate resulting from cracks in the monoclinic oxide, significant hydrogen pickup also occurs. Hydrogen that enters in this manner during a LOCA transient promotes rapid embrittlement of the cladding.

While all zirconium alloys will eventually experience breakaway oxidation when exposed to long enough durations of high-temperature steam oxidation, the fuel cladding research program demonstrated that alloying composition and manufacturing process (*e.g.,* surface roughness) influence the timing of this phenomenon.

iv. Applicability of Ductility-Based Analytical Limits to Burst Region

During a postulated LOCA, a portion of the fuel rod population may be predicted to experience fuel rod ballooning and cladding rupture as a result of rapid depressurization of the RCS in combination with elevated cladding temperature. The number of burst rods depends on several variables including initial conditions (*e.g.,* fuel rod design, rod internal pressure, rod power) and accident conditions (*e.g.,* LOCA break size, cladding temperature). A burst section of the fuel rod may experience degradation mechanisms beyond oxygen diffusion embrittlement encountered in the remaining portions of the fuel rod, including significant amounts of hydrogen uptake from steam entering the fuel rod through the rupture.

To investigate the mechanical behavior of ruptured fuel rods, the NRC conducted testing, designed to result in the ballooning and burst of as-fabricated and hydrogen-charged cladding specimens and high-burnup fuel rod segments exposed to high-temperature steam oxidation followed by rapid cooling by liquid water, or quench. The research results and conclusions are documented in the NUREG–2119, ''Mechanical Behavior of Ballooned and Ruptured Cladding.'' This testing confirms that continued exposure to a high-temperature steam environment weakens the already flawed region of the fuel rod surrounding the cladding rupture. Hence, limitations on PCT and integral time-at-temperature are necessary to preserve an acceptable amount of mechanical strength and fracture toughness to maintain a coolable fuel geometry. Integral time-at-temperature is related to the time spent at the elevated temperatures seen during the LOCA and typically expressed in terms of the ECR. In addition, the research demonstrated that the degradation in strength and fracture toughness with prolonged exposure to steam oxidation was increased with pre-existing cladding hydrogen content.

These research findings have been summarized in RIL–0801, and the detailed experimental results from the program at Argonne National Laboratory are contained in NUREG/CR–6967, ''Cladding Embrittlement during Postulated Loss-of-Coolant Accidents,'' dated July 31, 2008. Since the publication of NUREG/CR–6967 and RIL–0801, additional testing was conducted related to the embrittlement phenomenon, which has been documented in supplemental reports. Where the additional testing relates to conclusions and recommendations in RIL–0801, RIL–0801 has been supplemented to reference the additional reports and incorporate findings (''Update to Research Information on Cladding Embrittlement Criteria in 10 CFR 50.46,'' dated December 29, 2011).

These research findings presented the NRC with two options for revising the fuel performance requirements: (1) establish a separate performance requirement within the burst region (*i.e.,* analytical limits that preserve sufficient fracture toughness to ensure burst region survival), or (2) apply the hydrogen-based embrittlement analytical limits to the entire fuel rod.

In the absence of a credible analysis of loads, cladding stresses, and cladding strains for a core degraded by LOCA conditions, there are no absolute metrics to determine how much ductility or strength would be needed to provide assurance that fuel rod cladding would maintain its geometry during and following post-LOCA quench. It is also not clear what impact breakage of some fuel rods into two pieces, owing to potential loads following a hypothetical LOCA, would have on core coolability. Fragmentation of fuel rod cladding would be more detrimental to core coolability than severance of rods into two pieces. Even minimal ductility ensures that cladding will have high strength and toughness and, therefore, high resistance to fracturing. Brittle cladding, on the other hand, might fail at low strength and shatter. Therefore, the intent to maintain ductility is beneficial even with limited knowledge of LOCA loads. The research documented in NUREG–2119 showed that if wall thinning and double-sided oxidation are accounted for, then hydrogen-based embrittlement limits, such as the limit provided in Figure 2 of DG–1263, are sufficient to ensure reasonable behavior of the ballooned and ruptured region.

Therefore, the NRC elected to propose a revision to the fuel performance requirements by applying a single performance-based criterion to the entire fuel rod. This decision recognizes that portions of the cladding within the burst region may not maintain ductility. This position is reflected in DG–1263 and supported by the technical basis documented in NUREG–2119.

D. Regulatory Basis

The NRC published the regulatory basis to support a rulemaking for the ''Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors'' in the **Federal Register** on September 8, 2023 (88 FR 61986). In the regulatory basis, the NRC presented draft recommendations that focused on those requirements needed for LWR high-assay, low-enriched uranium fuel, specifically with approved conventional or ATF designs. The NRC requested public comment on these recommendations and asked specific questions associated with the identified regulatory topics. The NRC concluded that there was sufficient regulatory basis to proceed with rulemaking to address the regulatory issues associated with the use of fuel enriched to greater than 5.0 weight percent U–235. The NRC held a public meeting on October 25, 2023, to discuss the regulatory basis and issued a summary of the meeting on November 21, 2023.

The public comment period for the regulatory basis closed on January 22, 2024. The NRC received 15 public comment submissions on the regulatory basis, which are available for review at *www.regulations.gov* under Docket ID NRC–2020–0034. Table 1 of this document provides ADAMS references for these public comment submissions. Section XXXVI.F.(xiv), ''Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis,'' of this document includes the NRC's summaries of, and responses to, the comments that the NRC used to inform the development of this proposed rule and the draft regulatory analysis.

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Table 1—ADAMS References for Public Comment Submissions on the Regulatory Basis.

Commenter	Commenter Type	Accession Number
Michael Ravnitzky	Individual	ML23312A238
Union of Concerned Scientists	Advocacy organization	ML23331A263
PWR Owners Group	Nuclear industry trade association	ML24017A175
Urenco USA	Nuclear industry company	ML24022A127
World Nuclear Transport Institute	Nuclear industry trade association	ML24022A128
John Parillo	Individual	ML24022A241
Grant Wade	Individual	ML24022A242
BWR Owners' Group	Nuclear industry trade association	ML24023A601
Anonymous 1	Anonymous	ML24023A602
Anonymous 2	Anonymous	ML24023A603
Nuclear Energy Institute	Nuclear industry trade association	ML24023A604
Westinghouse Electric Company	Nuclear industry company	ML24023A655
Connie Kline	Individual	ML24024A051
Framatome	Nuclear industry company	ML24024A071
Kalene Walker	Individual	ML24025A012

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XXXVI. Discussion—Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

This proposed rule would amend the current regulations related to the use of conventional and accident tolerant LWR fuel designs. From interactions with stakeholders, the NRC is aware that licensees and applicants plan to request higher fuel burnup limits (*i.e.,* above 62 GWd/MTU rod average) along with the deployment of ATF concepts. To achieve higher burnup limits, licensees and applicants would need to request increases in fuel enrichment above the current standard of 5.0 weight percent U–235.

One of the NRC's goals in this rulemaking is to establish effective and efficient licensing of applications using fuels enriched to greater than 5.0 weight percent U–235, including reducing the need for requests for exemptions from existing regulations, while continuing to provide reasonable assurance of adequate protection of public health and safety.

The NRC proposes revising requirements in six technical areas.

A. Criticality Accident Requirements in 10 CFR 50.68

The NRC proposes to amend 10 CFR 50.68(b)(7) to allow licensees or applicants that comply or propose to comply with that section's criticality safety requirements to enrich their fuel beyond the current limit of 5.0 weight percent U–235. Each licensee or applicant would have the option between the existing 5.0 weight percent U–235 enrichment limit or the value specified in their OL. The enrichment limit is most often specified as a technical specification design feature as defined in 10 CFR 50.36(c)(4) and is currently part of generic standard technical specifications for various reactor technologies, as described in section XXXV.C.(i), ''10 CFR 70.24 and 10 CFR 50.68 Criticality Accident Requirements,'' of this document.

The proposed change would not affect safety. Licensees and applicants electing higher enrichments would be required to ensure the same minimum margin to subcriticality that is required for licensees implementing 10 CFR 50.68 with fuel enriched up to 5.0 weight percent U–235. Maintaining these margins of safety would be accomplished by applying the same keff safety limits for higher enriched fuels as for fuel enriched up to 5.0 weight percent U–235. Licensees or applicants that would seek to implement the requirements of 10 CFR 50.68 while using fuel enriched above 5.0 weight percent U–235 would need to submit for NRC review and approval a fuel transition license amendment request. These requests would need to include calculations that show that the new and spent fuel storage applications demonstrate compliance with the keff safety limits specified in 10 CFR 50.68.

The proposed revision also would meet one of the purposes of this rulemaking: allow a licensee the option to implement fuel enriched to greater than 5.0 weight percent U–235 without requiring the licensee to seek specific exemptions from 10 CFR 50.68 requirements.

This change would not result in any significant radiological consequences that could impact plant workers or members of the public. While increased enrichment would add more radioactive material to the spent fuel pool, this increase would not change the anticipated dose rates for occupational dose to workers in and around the fuel storage areas or for members of the public beyond the site boundary because the material in the pool is completely shielded by water.

The keff safety limits specified in 10 CFR 50.68(b)(2), (3), and (4) would be maintained at their current levels with the same required probability and confidence levels. The feasibility study contracted by the NRC, ORNL/TM–2024/3350, ''Scoping Studies on the Impacts of Increased Enrichment on Nuclear Criticality Safety,'' May 2024, indicates that existing fuel technologies, like integral fuel burnable adsorber coatings and gadolinium burnable poisons, should be able to maintain compliance with 10 CFR 50.68 requirements for the entire range of low enriched uranium (*i.e.,* up to 19.75 weight percent U–235). However, if the increased enrichment were to adversely impact the subcriticality requirements, then additional modifications to the fuel storage facilities would be required to restore compliance.

The NRC received several comments on the regulatory basis that suggested that the NRC revise RG 1.240, ''Fresh and Spent Fuel Pool Criticality Analyses,'' in coordination with any changes to 10 CFR 50.68. In March 2021, the NRC issued RG 1.240, which endorses NEI 12–16, Revision 4, ''Guidance for Performing Criticality Analyses of Fuel Storage at Light-Water Reactor Power Plants,'' dated September 2019. The NRC reviewed this guidance during the development of the regulatory basis and determined that neither RG 1.240 nor NEI 12–16, Revision 4 is specifically dependent on enrichment levels, whether at the current levels or those considered in this proposed rule. During this review, the NRC also noted that RG 1.240, section C.1.o specifies that the document's recommendations are based on existing fuel applications currently in widespread industry use, and that new and novel configurations and concepts implemented in the future may require additional justification for continued use of the assumptions and recommendations. However, the NRC did not identify any cases where the regulatory guidance would not be applicable to the enrichment levels being considered in this proposed rule. Further, licensees may provide any necessary justification as part of license amendment requests. Therefore, the NRC concluded that the guidance does not need to be immediately updated as a part of this rulemaking effort. The NRC observes that future revisions of RG 1.240 desired by industry stakeholders should be pursued separately under the standard regulatory guide maintenance and revision process.

B. Uranium Fuel Cycle Environmental Data—Table S–3 in 10 CFR 51.51

The NRC proposes to provide a regulatory justification in 10 CFR 51.51(b) for the use of table S–3 for fuel enrichment up to 20.0 weight percent U–235. This rulemaking action is predicated on the information provided by current LWR licensees to use enriched nuclear fuel of up to 10.0 weight percent U–235 and by new reactor developers to use high-assay low enriched uranium with enrichment levels greater than 10.0 weight percent U–235 and less than 20.0 weight percent U–235. The regulatory justification would be included in a proposed amendment of 10 CFR 51.51(b), table S–3, note 1. Specifically, note 1 would be amended to add a discussion of NUREG–2249, ''Generic Environmental Impact Statement for Licensing of New Nuclear Reactors—Final Report,'' for the environmental effects of up to 20.0 weight percent U–235 on the uranium fuel cycle as still bounded by table S–3, and text explaining the rationale for the addition of this document. NUREG–2249 discusses the High-Assay Low-Enriched Uranium (HALEU) Availability Program under the DOE with the direction to secure a domestic supply of HALEU fuel following the Energy Act of 2020. As outlined in NUREG–2249 section 3.14.1.3, DOE has identified and contracted with partners for enrichment services for the production of HALEU as UF_6. Additionally, DOE has identified and contracted with partners for deconversion of HALEU stored as UF_6 to other chemical forms (*i.e.,* metal or oxide) for fuel fabrication purposes. The DOE HALEU Availability program is ongoing and has produced the first quantities of HALEU with further expansion of production capacities expected over the next several years. NUREG–2249 concludes that for the enrichment of uranium, table S–3 would bound the environmental impacts from a centrifuge enrichment facility to produce HALEU and the impact would be SMALL.

Note 1 would also be amended to add a reference to NUREG–2266, ''Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels,'' for the environmental effects of up to 80,000 MWd/MTU maximum assembly averaged burnup as still bounded by table S–3, and text explaining the rationale for the addition of this document. This is because the analysis in WASH–1248 was based on 12-month refueling cycles and lower enrichment and burnup levels than are used for the current fleet of LWRs. The higher burnup levels achieved since issuance of WASH–1248 result in greater utilization of the uranium fuel (*i.e.,* greater efficiency in extracting energy from the fuel). This also has resulted in extended time between refueling operations and the removal of fewer fuel assemblies on a per reactor-year basis for many of the operating nuclear power plants. Deployment and use of nuclear fuels with increased enrichment and higher burnup levels would result in further increases in fuel efficiency in extracting energy, resulting in further reductions in the number of spent nuclear fuel assemblies removed during refueling operations and further extending the time between refueling operations. Thus, the use of nuclear fuels with increased enrichment and higher burnup levels would reduce the annual nuclear fuel needs to support refueling to below the figures that were used in the analysis supporting Table S–3.

C. Environmental Effects of Transportation of Fuel and Waste—Table S–4 in 10 CFR 51.52

The NRC proposes to permit the use of table S–4 of 10 CFR 51.52 for fresh nuclear fuel shipments with increased enrichment up to 8.0 weight percent U–235 by applying the supporting transportation analysis from NUREG–2266. The maximum enrichment level in the supporting core analysis relied upon in NUREG–2266 went as high as 8.0 weight percent U–235. This proposed amendment would include a change to the enrichment and burnup conditions under 10 CFR 51.52(a), adding a new note 2 to table S–4 along with moving the current note 2 to note 3, and adding a new note 4 to table S–4 to replace the current note 3. The transportation analyses in NUREG–2266 would be referenced in table S–4, note 2, with text explaining the rationale for the addition of this document for addressing this enrichment level as well as a level of burnup of up to 80,000 MWd/MTU for UO_2 fuel. Any licensing action with enrichments above 8.0 weight percent U–235 would have to be addressed on a case-by-case basis, in accordance with 10 CFR 51.52(b), by providing a full description and detailed analysis of the environmental effects of the transportation of fuel and waste. The methodology in NUREG–2266, section 3, ''Transportation,'' could be applied for such a detailed analysis. Note 2 would also include the environmental effects of burnup levels of up to 133,000 MWd/MTU for TRISO fuel as still bounded by table S–4.

This rulemaking also proposes revisions and updates to 10 CFR 51.52(a), (b), and (c), which provide for the evaluation of the environmental impacts of transportation of fuel and waste to and from the reactor for LWRs. Reactors other than light-water-cooled nuclear power reactors (*i.e.,* non-LWRs) will utilize the same uranium fuel cycle as LWRs with the transportation of material between uranium fuel cycle stages plus transportation to and from the nuclear power plant. The transportation of fuel to and waste from non-LWRs, like transportation of fuel and waste for LWRs, is necessary to support the operation of the plant. Therefore, the environmental impacts of transportation, regardless of whether for an LWR or non-LWR, must be assessed by the NRC. Similarly, the NRC's regulations in 10 CFR 51.50(b)(3) and (c) already provide for the evaluation of the environmental impacts of the uranium fuel cycle for non-LWRs. To ensure there is regulatory clarity for the transportation of non-LWR fuel and waste in a similar manner as there is for the uranium fuel cycle for non-LWRs, and for the transportation of fuel and waste for LWRs and non-LWRs, the words ''other than light-water-cooled nuclear power reactors'' from 10 CFR 51.50(b)(3) and (c), would be added to the introductory paragraph of 10 CFR 51.52 and 10 CFR 51.52(b).

The NRC also proposes to update the information in paragraph (c), table S–4, to the current conditions for the transportation of radioactive material and the impacts important to such transportation. The transportation weight values would be adjusted for trucks to the current U.S. Department of Transportation regulations of 80,000 lb per truck (23 CFR part 658, ''Truck Size and Weight, Route Designations—Length, Width and Weight Limitations'') and for rail cars to 240 tons per cask per rail car based on DOE information on the developed Atlas spent fuel rail car (DOE Article, ''New Railcar Designed to Transport Spent Nuclear Fuel Cleared for Operation,'' June 4, 2024). The NRC also would remove the cumulative dose values from table S–4 because this information is redundant to the exposed individual doses also being provided in table S–4 and is a very small fraction of the average natural background annual radiation exposure of 310 millirem (0.0031 Sv) per person. For example, the 1,469,000 persons along the route for the updated table S–4 would receive on an annual basis approximately 1469 person-rem from natural radiation sources. Thus, the 3 or 4 person-rem in the current table S–4 would only add the insignificant amount of approximately 0.3 percent of additional cumulative radiation exposure from the transportation of fuel and waste for the 1,469,000 persons along the route for all annual shipments.

The $475 property damage per reactor year would be removed from table S–4 because this value dates back to 1972 in appendix C of WASH–1238, the risk of a transportation accident is very small as shown in NUREG–2266, and there has not been a radiological transportation accident in the United States that would have resulted in property damage greater than the amount of damages from a commercial hazardous material transportation accident. If necessary, to determine the property damage risk from transportation accidents, the same methodology in appendix C of WASH–1238 can be applied on a case-by-case basis by assessing the annual shipment miles multiplied by the probability of an accident per mile and multiplied by the average worth of property damage per accident with property damage in that year.

D. Fissile Material Packaging Requirements in 10 CFR 71.55

The NRC proposes to increase the allowable enrichment range in its fissile packaging requirements through a graded approach and include an additional design requirement for enrichment levels from 5.0 to 10.0 weight percent U–235 to enable the use of the exception in 10 CFR 71.55(g) and remove the requirement to consider water in-leakage. The existing 5.0 weight percent U–235 enrichment limitation is based on standard industry and worldwide practice rather than a calculated effect on criticality of moderator in-leakage for UF_6 enriched to this level. Because the basis for approval of the exception relies on the performance requirement for the cylinder during the specified tests in 10 CFR 71.73, ''Hypothetical accident conditions,'' the NRC has concluded that the addition of a design feature (*e.g.,* valve protection device) of the individual cylinders containing UF_6 with enrichments greater than 5.0 weight percent U–235 would be consistent with the current performance-based requirements contained in 10 CFR 71.55(g) as well as risk insights gained from operational experience. This design enhancement requirement would provide additional defense-in-depth against water in-leakage that considers the relative consequences of an inadvertent criticality as a function of increasing enrichment level.

The NRC considered including in the proposed rule enrichments between 10.0 weight percent U–235 up to but less than 20.0 weight percent U–235. Although the NRC could consider additional prescriptive and non-technology inclusive defense-in-depth design requirements to mitigate the increasing risk of a criticality event as a function of this range of enrichment levels, the NRC could not formulate a technical or regulatory justification for providing a redundant, prescriptive, and non-technology inclusive exception from 10 CFR 71.55(b), which was already functionally present in 10 CFR 71.55(c) for all fissile material transportation packages. The provisions in 10 CFR 71.55(c) could be used to achieve the same desired regulatory outcome, including enrichments for UF_6 packages up to but less than 20.0 weight percent U–235, while maintaining the principles of good regulation of efficiency, clarity, and reliability.

This proposed amendment to 10 CFR 71.55(g) differs from the regulatory basis recommendation to not pursue a change in the regulations. Part of the rationale for that recommendation was based on the staff's assumption that the rule change would be cost-neutral based on only rulemaking and licensing costs. However, that analysis did not consider indirect shipping costs to the industry, an exclusion that the nuclear industry, in comments on the regulatory basis, described as a departure from the principles of good regulation. The NRC received public comments on the regulatory basis that demonstrated that there was sufficient net positive effect for fuel enrichment facilities and fuel fabricators to consider a rulemaking approach that would be cost-beneficial and maintain adequate protection of the public health and safety.

During the development of the regulatory basis for this proposed rule, the nuclear industry and the NRC identified that a change to 10 CFR 71.55(g) could create a misalignment with U.S. Department of Transportation and IAEA standards. The American National Standards Institute (ANSI) was in the process of revising its N14.1 standard, ''Nuclear Materials–Uranium Hexafluoride–Packagings for Transport'' (ANSI N14.1), when the regulatory basis was developed. The standard ANSI N14.1 was subsequently finalized, and its incorporation into U.S. Department of Transportation regulations will likely remove any potential misalignment that was identified in the regulatory basis. Specifically, ANSI N14.1 maintains a reference to a 5.0 weight percent U–235 limit but now allows for additional flexibility to the regulatory authority to make the final safety determination independent of an enrichment limit. In addition, future routine harmonization activities for transportation regulations with the IAEA will also likely remove any misalignment.

E. Control Room Requirements in 10 CFR 50.67 and GDC 19

This proposed rule would increase the numerical value of the control room design criteria from 5 rem to 10 rem (0.05 to 0.10 Sv); the value may range up to 25 rem (0.25 Sv) TEDE with consideration of the plant-specific risk profile or risk information. Increasing this value would support increased fuel enrichments and the expected associated increases in power levels and fuel burnup by preserving operational flexibility by providing additional safety margin and avoiding occupational exposures. In addition, the NRC would make minor editorial changes to 10 CFR 50.67 to remove the term ''total effective dose equivalent'' after the abbreviation ''TEDE'' is provided for that term.

Comments on the regulatory basis document indicated potential misunderstanding and concern about potential outcomes resulting from the proposal to amend the control room design criteria. Although the control room design criteria are distinct from operational dose limits, the NRC recognizes the two concepts share some similarities. Specifically, both the operational occupational exposure limit in 10 CFR part 20 and the control room design criteria are numerically equivalent and use the same unit of ''rem TEDE.'' As part of this rulemaking effort, the NRC attempts to clearly explain that the proposed changes would only be to the control room design criterion and would not change normal operational and emergency exposure limits of 10 CFR part 20.

The NRC recognizes the challenges that licensees face to retain margin within their licensing bases for the purposes of operational flexibility and the small amount of margin to the control room design criteria itself. The key driver behind the proposal to amend the control room design criteria is to facilitate increased regulatory efficiency and consistency while continuing to provide adequate protection of public health and safety. An unjustifiably low design criteria could unnecessarily burden licensees for seeking increased enrichments by requiring extensive analyses to preserve margin for operational flexibility purposes. As discussed in section XXXV.C.(iv), ''Appendix A to 10 CFR part 50 (General Design Criterion 19) and 10 CFR 50.67(b)(2)(iii),'' of this document, these analyses do not necessarily result in safety benefits and can increase actual operational exposure to workers due to increased maintenance activities.

The proposed numerical value of the control room design criteria in 10 CFR 50.67 and GDC 19 would increase from 5 to 10 rem (0.05 to 0.10 Sv) with a consideration of the plant-specific risk profile or risk information. Nuclear power reactor licensees would benefit from a higher, and safe, performance level between 5 and 10 rem (0.05 and 0.10 Sv) TEDE when implementing advanced nuclear fuel technologies and operational flexibility. If additional operational flexibilities are needed beyond 10 rem (0.10 Sv) TEDE, facility-specific risk profile or risk information can be leveraged to justify a higher numerical value up to 25 rem (0.25 Sv) TEDE.

Under the current regulations in 10 CFR 20.1201 and 20.1206, an adult worker can receive radiation exposure of up to 10 rem (0.10 Sv) TEDE within a single calendar year or over a 12-month period straddling two calendar years under normal operations. The control room design criterion of 5 rem (0.05 Sv) TEDE, which is intended to assess the acceptability of a given control room design for a potential reactor accident of exceedingly low probability, is at least a factor of two lower than what is found to be acceptable under normal operations. Thus, the proposed rule increase in the control room design criterion to 10 rem (0.10 Sv) TEDE would be consistent with the Commission's current regulations for normal operations.

The proposed rule would enable a higher control room design criteria, ranging from 10 to 25 rem (0.10 to 0.25 Sv) TEDE, for licensees whose facility-specific risk profiles warrant them. This range is consistent with recommendations from national and international organizations responsible for radiation protection standards. These recommendations are based on fundamental modern health physics and radiation epidemiology knowledge. These organizations generally recommend emergency exposure doses up to 25 rem (0.25 Sv) TEDE or 50 rad (0.5 gray) whole body. Thus, the proposed control room design criterion of 10 rem (0.10 Sv) TEDE intended to assess the acceptability of a given control room design for a potential reactor accident of exceedingly low probability is generally bounded by recommended values to protect against radiation exposure during an accident. As described in section XXXV.C., ''Background and History of Affected

Regulations,'' of this document, updated scientific recommendations for radiation protection for workers under accident and emergency conditions help form the technical basis for the proposal to increase the control room design value from 5 rem (0.05 Sv) TEDE originally based on the occupational exposure limit in 10 CFR part 20.

The upper range of the proposed numerical values would be consistent with the Commission's use of the 25 rem (0.25 Sv) TEDE limit primarily in regulations for power reactor siting to protect the public during emergencies, as specified in 10 CFR 100.11, ''Determination of exclusion area, low population zone, and population center distance''; 10 CFR 50.34, ''Contents of applications; technical information''; 10 CFR 50.67; and 10 CFR part 52 for the exclusion area boundary and low population zone. As discussed in the preamble for the final rule updating the NRC's siting criteria (61 FR 65157; December 11, 1996), the Commission's use of 25 rem (0.25 Sv) TEDE does not imply that the Commission considers it to be an acceptable limit for an emergency dose to the public under accident conditions, but only that it represents a reference value to be used for evaluating plant features and site characteristics intended to mitigate the radiological consequences of accidents in order to provide assurance of low risk to the public under postulated accidents. The Commission, based upon extensive experience in applying this criterion and in recognition of the conservatism of the assumptions in its application (*i.e.,* a large fission product release within containment associated with major core damage; maximum allowable containment leak rate; a postulated single failure of any of the fission product cleanup systems, such as the containment sprays; adverse site meteorological dispersion characteristics; an individual presumed to be located at the boundary of the exclusion area at the centerline of the plume for two hours without protective actions), determined that the 25 rem (0.25 Sv) TEDE criterion clearly resulted in an adequate level of protection. As an illustration of the conservatism of this assessment, the Commission noted that the maximum whole-body dose received by an actual individual during the accident at Three Mile Island Nuclear Station in March 1979, which involved major core damage, was estimated to be about 0.1 rem (0.001 Sv).

A review of modern health physics and radiation epidemiology knowledge provides further technical background for proposing to amend the control room design criteria to a higher, and safe, performance level. An important distinction from this review (see section XXXV.C., ''Background and History of Affected Regulations,'' of this document) highlights that the control room design criterion radiation unit of ''rem TEDE'' does not technically correspond with the expected measured deterministic health effects from a reactor accident that would prevent operators from performing their safety function of protecting the public health and safety. These deterministic health effects are best expressed in the radiation unit of ''rad.'' The 10 CFR part 20 annual occupational exposure limit of 5 rem (0.05 Sv) TEDE, which is applicable under accident and emergency conditions, is set sufficiently low that no deterministic threshold dose would be reached.

To clarify the purpose of the control room design criteria contained in GDC 19 and repeated in 10 CFR 50.67, and to distinguish the control room design criteria from the radiation protection and EP frameworks, the NRC is proposing several editorial changes to both provisions. The phrase ''Adequate radiation protection'' in 10 CFR 50.67(b)(2)(iii) and GDC 19 would be replaced with ''The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety.'' As explained in the introduction to appendix A to 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' SSCs important to safety are those SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. In the case of control room design, the original role of GDC 19 was to ensure that adequate SSCs were provided to permit occupancy of the control room during an accident. The adequacy of the control room SSCs was to be determined by the ability of workers to occupy the control room for the duration of an accident without exceeding the radiological design criteria specified in GDC 19. However, over time the phrase ''adequate radiation protection'' in GDC 19 has been conflated with the NRC's statutory standard of adequate protection. Adequate protection is achieved through a licensee's compliance with the NRC's comprehensive regulatory framework, of which the GDC is one part, and not just a particular design criterion. To increase consistency between these rules, the phrase ''Adequate radiation protection'' in 10 CFR 50.67(b)(2)(iii) and GDC 19 would be replaced with ''The necessary design, fabrication, construction, testing, and performance'' to be consistent with appendix A to 10 CFR part 50. Appendix A to 10 CFR part 50 requires that the principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety.

To further clarify the purpose of 10 CFR 50.67 and GDC 19 as they relate to the radiation protection and emergency response frameworks, the phrase ''personnel receiving'' in 10 CFR 50.67 and GDC 19 would be replaced with ''calculated'' and the phrase ''access to and'' would be deleted because the traditional DBA radiological consequence analyses performed to demonstrate compliance with the criteria do not assess actual ''personnel receiving'' radiation exposures or plant personal traveling from the site boundary to the control room. The use of a dose-based control room design criterion does not imply that it would be an acceptable exposure during emergency conditions, or that the radiation protection standards and emergency response standards of 10 CFR part 20 and part 50 might not apply. Rather, these analyses assess the acceptability of design provisions for protecting control room operators under postulated DBA conditions. The DBA conditions assumed in these analyses, although credible, generally do not represent actual accident sequences. These DBA conditions are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.

However, rare events (*e.g.,* events involving multiple failures) can exceed the design basis of the facility originally envisioned by the designers. During such events, the Commission's regulations for radiation protection and emergency response programs require licensees to take measures to minimize actual radiation exposures. The on-shift emergency coordinator has the authority and responsibility to immediately and unilaterally initiate any emergency actions. These emergency actions include establishing higher exposure limits if necessary to provide public health and safety. Furthermore, arrangements are made not only with respect to the detection and assessment of dose or intake of ionizing radiation, but also with respect to the mitigating interventions that may have to be applied to further protect workers. The traditional DBA radiological consequence analyses do not necessarily credit these mitigative interventions as they do not directly assess the performance of the control room habitability envelop design itself. As a result, actual doses received during an event are expected to be significantly lower than the computed results in realistic accident scenarios.

The graded, risk-informed, and performance-based framework developed for DG–1425 (proposed revision 2 of RG 1.183), ''Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors,'' would enable a performance-based evaluation using traditional deterministic radiological consequence analysis methods within defined risk-informed boundaries as described in ''Method for Graded Risk-Informed Performance-Based Control Room Design Criteria Framework,'' dated September 2024. These boundaries would be defined by acceptable radiation exposure guidelines for radiation workers during accident and emergency conditions and acceptable contemporary nuclear facility risk profiles using modern PRA methods. Such a framework would provide flexibility when determining how to meet an established acceptance criterion in a way that encourages and rewards safety of the facility consistent with the Commission's policy in SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk-Informed and Performance-Based Regulation,'' dated March 1, 1999. In practice, the method would produce a framework that uses, in part, the facility's safe design and operations to justify a higher control room design criterion with a lower plant-specific risk metric.

The DG–1425 framework leverages a licensee's existing PRA model. Acceptability of the PRA model used to demonstrate that the specified criterion is commensurate with the risk of the plant is determined for the following aspects: scope, level of detail, conformance with PRA technical elements (*i.e.,* technical robustness), and plant representation and PRA configuration control. The PRA model would be consistent with the philosophy in RG1.174 and the technical adequacy expectations for the model in RG 1.200. For instance, the use of overall core damage frequency (CDF) results from an NRC-approved license amendment request that incorporates the risk-informed completion time program into the facility's technical specifications (*i.e.,* Technical Specifications Task Force Traveler 505, ''Provide Risk-Informed Extended Completion Times—RITSTF Initiative 4b'') would be acceptable. The baseline PRA model would estimate the overall CDF for all significant sources of risk both internal and external to the plant (*e.g.,* internal, flood, fires, seismic, high winds, and others).

The CDF risk metric would be the most appropriate for the purposes of a graded, risk-informed, and performance-based control room design criteria framework. This is because CDF accounts for a broad range of accident scenarios and can generally encompass the risk relevant to the sequences considered for control room habitability when deriving the maximum hypothetical accident source term. There is also consistency between the CDF risk metric, which does not consider radiation protection protective actions, and the traditional DBA radiological consequence analysis performed to demonstrate compliance. Additionally, control room habitability design primarily concerns the ability of personnel to maintain reactor safety during and after accidents, which aligns closely with the overarching goals of preventing core damage and mitigating radiological releases, which are captured by the CDF risk metric.

In the regulatory basis for this proposed rule, the NRC sought comments on the alternatives proposed in that document's appendix A, ''Control Room Requirements.'' Additionally, the NRC asked two questions. The first question sought input as to whether the numerical selection of the control room design criteria would be better aligned with regulations designed to limit occupational exposures during emergency conditions or regulations designed to limit annual occupational radiation exposures during normal operations. The second question sought input as to whether a graded, risk-informed method to demonstrate compliance with a range of acceptable control room design criterion values instead of a single selected value, such as the current 5 rem (0.05 Sv) TEDE, provides the necessary flexibilities for current and future nuclear technologies.

Overall, public comments were supportive of the staff's recommendation to amend the control room design criteria. The comments in support of alternative 2 generally suggested a value of 25 rem (0.25 Sv) TEDE be applied in amended regulations. Commenters stated that using a value of 25 rem (0.25 Sv) TEDE would be more consistent with the various U.S. and international organizations' recommendations for emergency dose limitations up to 25 rem (0.25 Sv) TEDE. Nearly all comments included suggestions to develop a graded, risk-informed approach to the control room design criteria. Several comments relied on PRA technology and methods and contemporary understandings of facility risk to justify a higher numerical value for low-probability, high-consequence events.

Based, in part, on the comments received, the NRC is proposing to increase the numerical value of the control room design criteria from 5 to 10 rem (0.05 to 0.10 Sv) TEDE but range up to 25 rem (0.25 Sv) TEDE with a consideration of the plant-specific risk profile or risk information. In response to stakeholder interest, the NRC developed a graded, risk-informed, and performance-based control room design criteria framework for the supporting regulatory guidance.

F. Fuel Dispersal

(i) Overview

Based on the Commission's direction in SRM–SECY–21–0109, the public comments on the regulatory basis (see section XXXVI.F.(xiv), ''Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis,'' of this document) for details on the public comments received on the fuel dispersal portions of the regulatory basis), the anticipated impacts on this rulemaking's schedule from each of the alternatives described in the regulatory basis, the technical maturity of those alternatives, and the anticipated impact on safety of each of the alternatives, the NRC proposes to address fuel dispersal in this rulemaking. Specifically, the proposed rule would designate LOCAs above the TBS as beyond-design-basis, allowing for best-estimate analysis for such LOCAs, while instituting performance-based cladding embrittlement criteria, and clarifying and updating the NRC's definition of coolability for the LOCA event to encompass both fuel in the reactor core and any fuel dispersed into the RCS or containment.

The proposed flexibility in ECCS analyses for LOCAs above the TBS might enable entities using the proposed rule to demonstrate that no fuel dispersal occurs for LOCAs above the proposed TBS. These entities would be able to use the best-estimate (*i.e.,* based on conditions consistent with expected, nominal operating conditions without biases or uncertainties) modeling under proposed 10 CFR 50.46a(e)(3) for this category of LOCAs until more data or analyses are developed to address fuel dispersal in another way, such as a demonstration that the fuel remains coolable if there is fuel dispersal and the other downstream consequences of dispersal do not have any significant deleterious impacts. The proposed rule would redesignate existing 10 CFR 50.46a (which contains acceptance criteria for RCS venting systems) as 10 CFR 50.46b and establish an alternative set of risk-informed requirements in a new proposed 10 CFR 50.46a with which entities could choose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using these alternative ECCS requirements would provide some entities with opportunities to change various aspects of their facility design and operation, although potential impacts of the changes pertaining to plant physical security or cybersecurity would be evaluated during license amendment reviews.

As used in proposed 10 CFR 50.46a and this discussion of proposed 10 CFR 50.46a, ''entities'' would include applicants for and holders of CPs, OLs, COLs, standard design approvals, and MLs, and applicants for standard design certification rules (including such applicants after NRC issuance of a final standard design certification rule).

The proposed rule would divide the current spectrum of LOCA break sizes into two regions. The division between the two regions would be delineated by the TBS. The first region would include small size breaks, up to and including the TBS. The second region would include breaks larger than the TBS, up to and including the DEGB of the largest RCS pipe. While both sets of breaks are unlikely to occur, the larger breaks are considered to have a much lower likelihood of occurring than the smaller breaks in the first region. Under the proposed rule, the ECCS design requirements for breaks smaller than the TBS would remain the same as the requirements for all breaks under the current 10 CFR 50.46 ECCS rule. By contrast, under the proposed rule, the ECCS design requirements for the pipe breaks larger than the TBS could be analyzed using less conservative assumptions based on their lower likelihood of occurrence. Although LOCAs for break sizes larger than the TBS would be classified as ''beyond-design-basis accidents'' for entities that implement the proposed 10 CFR 50.46a, these break sizes in license applications would still be subject to regulatory evaluation. The proposed rule would require that entities maintain the ability to mitigate all LOCAs, up to and including the DEGB of the largest RCS pipe. Mitigation analyses for LOCAs larger than the TBS would not need to assume the loss of offsite power or the occurrence of a coincident single failure event. Entities also would be allowed to credit the use of non-safety-grade systems.

Entities who perform LOCA analyses using the proposed risk-informed alternative requirements could find that their plant design or operation is no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations would allow some entities to propose a wide scope of design or operational changes until another parameter in required accident analyses becomes limiting. Potential design changes could include fuel burnup increases and other management improvements; power uprates; and changes to the required number of accumulators, diesel start times, sequencing of equipment, valve stroke times, and containment spray system setpoints. Some of these design and operational changes could increase plant safety because an entity could modify its systems to better mitigate the more likely, but still very rare, smaller LOCAs. Other changes, such as increasing power, could increase the overall risk of inadvertent release of radioactive material, which may be acceptable if the overall plant risk increase is demonstrated to be acceptably small.

The risk-informed proposed 10 CFR 50.46a would include risk acceptance criteria for evaluating future design changes to ensure that any risk increases would be acceptably small. These acceptance criteria would be consistent with the guidelines for risk-informed license amendments in RG 1.174, ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,'' and ensure both the acceptability of the changes from a risk perspective and the retention of sufficient defense-in-depth, safety margins, and performance monitoring. The requirements for the risk-informed evaluation process are discussed in detail in section XXXVI.F.(vi), ''Risk-Informed Changes to the Facility, Technical Specifications, or Procedures,'' of this document.

In addition to changes to current 10 CFR 50.46a, which would be redesignated as 10 CFR 50.46b, and establishing a new proposed 10 CFR 50.46a, the NRC would make conforming changes to existing 10 CFR 50.46, and 50.69; GDC 17, 35, 38, 41, 44, and 50 in appendix A to 10 CFR part 50; appendix K to 10 CFR part 50; 10 CFR 52.54; and appendix G to 10 CFR part 52.

(ii) Original Determination of the Transition Break Size

To help determine the TBS in support of the prior 10 CFR 50.46a rulemaking (see section XXXV.C.(v)(b), ''10 CFR 50.46a Rulemaking,'' of this document), the NRC developed pipe break frequencies as a function of break size using an expert elicitation process for degradation-related pipe breaks in typical BWR and PWR RCSs (NUREG–1829, ''Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process,'' March 2008). The elicitation process is used for quantifying phenomenological knowledge when data or modeling approaches are insufficient. The NUREG–1829 elicitation focused solely on determining event frequencies that initiate from failures of the unisolable reactor coolant pressure boundary (RCPB), or primary system side, related to material degradation. This effort did not consider the AP1000 and other similar passive-safety reactor designs.

A baseline TBS was established from the expert elicitation results for each reactor type (*i.e.,* PWR and BWR) that corresponded to a break frequency of once per 100,000 reactor years (1×10^{-5}, or 10^{-5} per reactor year). The NRC then considered uncertainty in the elicitation process, other potential mechanisms that could cause passive component failure that were not explicitly considered in the expert elicitation process, and the higher susceptibility to rupture/failure of specific locations in the RCS by adjusting the TBS upward to account for these factors. Other mechanisms that contribute to the overall LOCA frequency include LOCAs resulting from failures of non-passive components and LOCAs resulting from low probability direct and indirect events (*e.g.,* earthquakes of magnitude larger than the safe shutdown earthquake and dropped heavy loads). These LOCAs have a strong dependency on plant-specific factors.

LOCAs caused by failure of non-passive components, such as stuck-open valves and blown out seals or gaskets, have a greater frequency of occurrence than LOCAs resulting from the failure of passive components. LOCAs resulting from the failure of non-passive components would be small-break LOCAs, when considering the size of the opening that could result should components fail open or blow out (*e.g.,* safety valves, pump seals). LOCAs resulting from stuck-open valves are limited by the size of the auxiliary pipe. In some PWRs, there are large loop isolation valves in the reactor pressure vessel outlet and inlet piping. However, a complete failure of the valve stem packing is not expected to result in a high rate of coolant loss due to the size of the resulting penetration in the system, because the valves are sealed in such a way that limits leaks when they are open (*i.e.,* they are back-seated in the open configuration). Based on these considerations, non-passive LOCAs are relatively small in size and are bounded by the selected TBS.

LOCAs could also be caused by dropping heavy loads that could cause a breach of the RCS piping or damage safety-related equipment. The majority of heavy loads are lifted during refueling when the reactor is shut down and the primary system is depressurized, further reducing the risk of a LOCA and a loss of core cooling. During power operation, personnel entry into the containment is typically infrequent and of short duration and the largest cranes are generally not accessible. There are also operational limitations designed to limit risk due to heavy load drops. Consequently, loads moved at power are substantially fewer than during refueling. In addition, the RCS is inherently protected by surrounding concrete walls, floors, missile shields, and biological shielding. For these reasons, the NRC did not consider the contribution of heavy load drops to overall LOCA frequency to be significant or affect the TBS.

Seismically induced LOCA break frequencies can vary greatly from plant to plant because of factors such as site seismicity, seismic design considerations, and plant-specific layout and spatial configurations. Seismic break frequencies are also affected by the amount of pipe degradation occurring prior to postulated seismic events. Seismic PRA insights were accumulated from the NRC Seismic Safety Margins Research Program and the Individual Plant Examination of External Events submittals available in the late 1990s. Based on these studies, piping and other passive RCPB components generally exhibit high seismic capacities and, therefore, are not significant risk contributors. However, these studies did not explicitly consider the effect of degraded component performance on the risk contributions. Therefore, the NRC conducted a study in the early 2000s to evaluate the seismic performance of undegraded and degraded passive system components (NUREG–1903, ''Seismic Considerations for the Transition Break Size,'' February 2008). This effort examined operating experience, seismic PRA insights, and models to evaluate the failure likelihood of undegraded and degraded piping. The operating experience review considered passive component failures that have occurred as a result of strong motion earthquakes in nuclear and fossil power plants as well as other industrial facilities. No catastrophic failures of large pipes resulting from earthquakes between 0.2g and 0.5g (where g is the gravitational acceleration or approximately 9.81 meters/second^2) peak ground acceleration have occurred in power plants. However, piping degradation could increase the LOCA frequency associated with seismically induced piping failures. The NUREG–1903 report evaluated seismic loadings on degraded piping and concluded that a large, pre-existing crack on the order of 30 percent through-wall and 145 degrees around the piping circumference would have to be present during a large, rare earthquake (*i.e.,* corresponding to the mean annual frequency of exceedance equivalent to 10^{-5} or 10^{-6} per year) in order for pipe failure to occur. The NRC concluded that the likelihood of flaws large enough to fail during such a seismic event was sufficiently low that the TBS need not be modified to address seismically induced direct piping failures.

Indirect RCPB failures are primary system ruptures that are a consequence of failures in primary and non-primary system components or structural support failures (such as reactor coolant pump supports and steam generator supports). Structural support failures could then cause displacements in components, causing stress on the piping and potential failure. The NRC performed studies on two plants to estimate the conditional pipe failure probability due to structural support failure given a large, rare earthquake (*i.e.,* 10^{-5} to 10^{-6} per year). These studies used seismic hazard curves from NUREG–1488, ''Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains,'' April 1994. The results of these studies, as described in NUREG–1903, showed that indirectly induced piping failure attributable to major component support failure has a mean failure probability on the order of 10^{-6} per year, which was less than the TBS criterion. However, the NRC noted in NUREG–1903 that indirect failure analyses are highly plant-specific. Therefore, it is possible that example plants assessed in the NRC analyses were not necessarily limiting for all plants.

The NRC considered the importance of indirect failures on the selection of the TBS. For the cases considered in NUREG–1903, the likelihood of indirectly induced piping failures resulting from major component support failures was less than 10^{-5} per reactor year, the frequency criterion used to select the TBS. Also, the median seismic capacities for both the primary piping system and primary system components are typically higher than other safety-related components within the nuclear power plant. Because of these relative capacities, the NRC expected that a seismic event of sufficient magnitude to cause consequential failure within the primary system would also induce failure of components in multiple trains of mitigation systems, or even induce multiple RCS pipe breaks. Consequently, the risk contribution from seismically induced indirect failures was expected to depend more heavily on the relative fragilities of plant components and systems than the size of the TBS. Therefore, the NRC determined that adjustment to the TBS for seismically induced indirect LOCAs was not warranted.

The final consideration in selecting the TBS was actual piping system design (*e.g.,* piping sizes) and operating experience. For example, due to system configuration and operating environment, certain piping was considered to be more susceptible to degradation and failure than other piping in the same size range.

For PWRs, the NRC determined that 6- to 10-inch inside diameter (*i.e.,* inside dimension) was an appropriate range of pipe break sizes associated with the 95th percentile LOCA frequency estimates of 1×10^{-5}/yr from NUREG–1829. This range is only slightly smaller than the PWR surge lines, which are attached to the RCS main loop piping (*i.e.,* hot leg, cold leg, and crossover leg) and are typically 12- to 14-inch diameter Schedule 160 piping with inside diameters of 10.1 to 11.2 inches. The RCS main loop piping is in the range of 30 inches in diameter and has substantially thicker walls than the surge lines. The expert elicitation panel concluded that this main loop piping is much less likely to break than other RCS piping. The shutdown cooling lines and safety injection lines may also be 12- to 14-inch diameter Schedule 160 piping and are likewise connected to the RCS. In some cases (*e.g.,* Babcock and Wilcox plants), the core flood lines may be bigger than the surge and residual heat removal lines that are attached to the main loop piping. The difference in diameter and thickness of the reactor coolant piping and the piping connected to it forms a reasonable line of demarcation to define the TBS. Therefore, in SECY–10–0161, to capture the surge, shutdown cooling, core flood, and safety injection lines in the range of piping considered to be equal to or less than the TBS, for PWRs, the NRC staff specified the TBS as the largest cross-sectional flow area of the RCPB piping excluding the main loop piping.

For BWRs, the NRC determined that 13- to 20-inch inside diameter was an appropriate range of pipe break sizes associated with the 95th percentile LOCA frequency estimates of 1×10^{-5}/yr from NUREG–1829. The information gathered from the elicitation for BWRs also showed that the estimated frequency of pipe breaks dropped markedly for break sizes beyond the range of approximately 18 to 20 inches. After evaluating BWR designs, the NRC determined that typical residual heat removal piping connected to the recirculation loop piping and feedwater piping is about 18 to 24 inches in diameter. These pipe sizes are consistent with break sizes beyond which the pipe break frequency was expected to decrease markedly below 10^{-5} per year. The NRC staff recognized that the sizes of attached pipes vary somewhat among plants. Thus, for BWRs, in SECY–10–0161, the staff specified the TBS as the larger cross-sectional flow area of either the feedwater or the residual heat removal piping inside primary containment.

Because the effects of TBS breaks on core cooling vary with the break location, the NRC evaluated whether the frequency of TBS breaks varies with location and whether TBS breaks could, therefore, vary in size with location. In PWRs, the pressurizer surge line is only connected to one hot leg and the pipes attached to the cold legs are generally smaller than the surge line. The cold legs (including the intermediate legs) also operate at slightly cooler temperatures such that thermally activated degradation mechanisms would be expected to progress more slowly in the cold leg than in the hot leg. The frequency of occurrence of a break of a given size is composed of both the frequency of a completely severed pipe of that size (*i.e.,* a complete circumferential break) plus the frequency of a partial break of that size in an equal or larger size pipe (*i.e.,* a partial circumferential or longitudinal break). Therefore, the NRC considered an option where the TBS for the hot and cold legs would be distinctly different by considering the frequency contributions of these two break components: (1) complete breaks of the pipes attached to the hot or cold legs at the limiting locations within each attached pipe, and (2) partial breaks of a constant size, as appropriate for either the hot or cold leg, at the limiting locations within the hot or cold legs. However, the elicitation was not envisioned to develop LOCA frequencies specific to piping systems. As a result, there was insufficient detail from the elicitation to draw conclusions about either the difference between hot and cold leg failure frequencies or the frequency of occurrence of smaller LOCAs within a large diameter pipe. Therefore, the NRC concluded that the TBS associated with partial breaks in the hot and cold legs should remain equivalent in size to the internal cross-sectional area of the largest piping system other than the main loop. Similarly, the elicitation results do not contain sufficient detail to quantify break frequency differences among the BWR recirculation, residual heat removal, and feedwater system piping. Thus, a smaller partial break TBS criterion also could not be established for BWR recirculation piping. Notably, mitigating the effects of such partial breaks up to and including a TBS break remains within the design basis for all RCPB piping with an inner diameter equivalent to or larger than the TBS.

During this time, the NRC also evaluated whether TBS breaks should be analyzed as single-ended or double-ended breaks. A postulated double-ended break assumes that the pipe rupture causes a complete separation and displacement of both ends of the pipe at the break such that coolant loss occurs from both sides of the displaced piping. A single-ended break results in an orifice through which the coolant would flow. To address this issue, the NRC reviewed the expert elicitation process and the guidance given to the experts in developing their frequency estimates. The NRC concluded that the expert elicitation LOCA frequency estimates correspond to a break area having an equivalent circular diameter at each break size. This correspondence is representative of a single-ended break. Additionally, the experts based their estimates on knowledge of postulated failure mechanisms in pressure boundary components and not on the flow rates emanating from the breaks. The flow rates are governed by the break location and system configuration, which determines whether reactor coolant will be discharged from both ends of the break.

The current design-basis analysis for LWRs requires analysis of a DEGB of the largest pipe in the RCS. Under the proposed rule, all breaks up to and including the TBS would be analyzed under existing requirements. A possible reason for specifying the TBS for PWRs as double-ended could be that a complete break of the pressurizer surge line would result in reactor coolant exiting both ends of the break. Although this occurs initially during a LOCA, core cooling requirements are dominated by the flow rate of coolant exiting from the hot leg side of the break, with much less contribution from the flow rate of coolant exiting from the pressurizer side. Therefore, specifying the TBS break as an area equivalent to a double-ended break of the surge line would be overly conservative. For BWRs, the effect of a double-ended break area is also considered to be overly conservative. The selected TBS for BWRs would be based on the larger of the residual heat removal or main feedwater lines. A single-ended break in these lines would bound double-ended breaks of the smaller lines in the reactor recirculation and feedwater system. Therefore, the NRC is proposing that the TBS be based on a single-ended break, which reasonably characterizes the expert elicitation results and represents the flow rates associated with postulated pipe breaks within the RCS. The NRC's proposed TBS definition is in proposed 10 CFR 50.46a(a)(9). As an option and to allow maximum flexibility, the proposed 10 CFR 50.46a(a)(9) definition would allow an entity to develop and justify an alternate TBS.

(iii) Determining the Ongoing Validity of the Transition Break Size

Because the work in the development of the TBS was conducted almost 20 years ago as part of the development of the earlier rulemaking to create alternative ECCS requirements in 10 CFR 50.46a, the NRC assessed if the TBS developed in the early 2000s is still valid today. This research identified possible scenarios not considered, or underestimated, in NUREG–1829 or NUREG–1903 that could result in primary pressure boundary breaches that are larger than the TBS in either PWR or BWR plants. These breaches could be directly due to operational transients (*e.g.,* anticipated transient without scram, water hammer, pressurized thermal shock) or indirectly due to other failures within the plant (*e.g.,* crane drop, secondary side failures). Age-related degradation of the RCPB components may be a contributing, or required, causal factor. Additionally, the breach could stem from failure of a single RCPB component or multiple common-cause RCPB component failures (*e.g.,* anticipated transient without scram event leading to the rupture of multiple degraded safety injection system lines on separate PWR loops). Improper maintenance and human factors may also be a causal factor (*e.g.,* not properly torquing pressurizer manway bolts following inspection). The likelihood of such breaches was also considered up to the end of the subsequent license renewal period (*i.e.,* 80 years) or the maximum extent of the licensing period for plants that could adopt this proposed rule.

In its effort to determine the ongoing validity of the TBS, the NRC only considered reactors authorized to operate under 10 CFR part 50 on December 31, 2015 (*i.e.,* the NRC did not consider the AP1000 design or any other new LWR reactor design) because the NUREG–1829 study did not consider plant designs that were authorized to operate after December 31, 2015 or authorized to operate under 10 CFR part 52. LWRs licensed after that date may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and thus the TBS. A detailed description of the technical justification for the continued applicability of the NUREG–1829 results is found in the ''White Paper on Continued Applicability of NUREG–1829,'' dated November 13, 2024, while the technical justification for the continued applicability of NUREG–1903 is found in the ''White Paper on Continued Applicability of NUREG–1903,'' dated November 18, 2024.

To confirm the TBS's current validity, the NRC conducted a series of probabilistic fracture mechanics analyses using the xLPR code Version 2.3 to confirm the base cases analyzed in NUREG–1829. For these analyses, four of the original base case pipe systems were chosen for this validation: 12-inch recirculation line, 28-inch recirculation line, 30-inch hot leg, and a 10-inch surge line. The base case conditions, assumptions, and inputs from NUREG–1829 were generally adopted in these analyses. However, inputs were supplemented from Technical Letter Report TLR–RES/DE/REB–2021–09, ''Probabilistic Leak-Before-Break Evaluation of Westinghouse Four-Loop Pressurized-Water Reactor Primary Coolant Loop Piping using the Extremely Low Probability of Rupture Code,'' dated August 13, 2021, and Technical Letter Report TLR–RES/DE/REB–2021–14, ''Probabilistic Leak-Before-Break Evaluations of Pressurized-Water Reactor Piping Systems using the Extremely Low Probability of Rupture Code,'' dated September 28, 2021, for the PWR cases; and from NUREG–0313, ''Technical Report on Material Selection and Processing Guidelines for BWR Coolant Pressure Boundary Piping,'' dated January 1988, NUREG/CR–6674, ''Fatigue Analysis of Components for 60-Year Plant Life,'' dated June 2000, and NUREG/CR–4792, ''Probability of Failure in BWR Reactor Coolant Piping, Volume 1: Summary Report,'' dated December 1988, for the BWR cases as needed. Analyses were run to 80 years, and several sensitivity cases were conducted to investigate the impacts of mitigation and inspection on the probability of failure. The annual frequency of small-break, medium-break, and large-break LOCAs were calculated at 25, 40, 60, and 80 calendar years as well as the cumulative probability of a crack, leakage, and rupture at 80 years. A summary of the analyses and results can be found in section 5.3 of the ''White Paper on Continued Applicability of NUREG–1829.'' The analyses conducted show that annual frequencies calculated for the base case problems in the current effort were either bounded by, or representative of, those determined in NUREG–1829.

In addition to the probabilistic fracture mechanics analyses, the NRC conducted both an internal and external elicitation similar to the full elicitation conducted in the original development of NUREG–1829. The purpose of this elicitation was two-fold. The first objective was to determine scenarios that could result in primary pressure boundary breaches that are larger than the TBS in either PWR or BWR plants. The second objective was to determine the representativeness of NUREG–1829 to the current day. The internal elicitation included subject matter experts within the NRC with expertise in structural integrity analysis, materials performance, aged-related degradation, risk assessment, and thermal-hydraulic analysis. The external elicitation queried two of the original NUREG–1829 elicitation effort participants. The external elicitation confirmed that the current-day frequency of LOCAs, and specifically the frequency of LOCAs having a break size greater than the TBS, is conservatively represented by the NUREG–1829 estimates. Neither the internal nor external elicitations identified any generic issues or scenarios that either were not considered in the TBS development or have significantly changed since the TBS development that could undermine its technical basis.

However, both the internal and external elicitations did identify topics that should be addressed within the proposed rulemaking and associated guidance. Some of these topics included PRA requirements; impacts of plant changes; stress corrosion cracking in main loop and recirculation piping; indirect piping failures; direct and indirect seismic failure evaluations; maintaining mitigative capabilities; NUREG–1829 uncertainties; and attributes that could increase plant-specific LOCA frequencies. Many of these topics were already being addressed within this rulemaking effort, and the elicitations served to refine the proposed treatment of these topics, as well as identify some novel issues that were not initially considered. A more detailed summary of these elicitations is in the ''White Paper on Continued Applicability of NUREG–1829.''

The NRC reviewed operational experience since the original NUREG–1829 effort to use as a basis for determining both piping and non-piping failure frequencies. There have been only a few small (*i.e.,* smaller than 2-inch diameter piping) passive-system primary pressure boundary ruptures, and the operational experience indicates that degradation mechanisms such as cracking, wall thinning, or through-wall leakage are a precursor to a rupture. The precursor event frequency can be directly calculated from operational experience, while modeling is required to estimate the likelihood that these precursor events could lead to LOCAs of various sizes and, hence, estimate LOCA frequencies. The NUREG–1829 LOCA frequency estimates were based, in part, on operating experience accumulated up to approximately 2004. The NRC's more recent effort considered operating experience trends from 1970 to 2004, and then 2005 to the present day. This binning was used to compare precursor event frequencies and ultimately LOCA frequencies within the two time periods to assess trending since the completion of NUREG–1829.

Quantitative LOCA frequency estimates were calculated for each time period for PWR and BWR systems and for break sizes greater than and less than the TBS in this proposed rule. Initially, estimates were developed for each degradation mechanism that is applicable for a particular piping or non-piping primary pressure boundary system or component. The attribute-specific frequencies were then multiplied by the number of attributes (*e.g.,* number of welds) for each component and then the contributions from each applicable degradation mechanism were combined to develop component-specific piping and non-piping frequencies. The component-specific frequencies were then further combined to determine global piping and non-piping LOCA frequency estimates. Finally, the piping and non-piping contributions are summed so that, ultimately, LOCA frequency estimates are determined as a function of rupture size. Uncertainties were initially addressed when determining degradation mechanism-specific estimates and appropriately combined so that the final estimates are expressed as distributions with associated mean values and 5th and 95th percentile LOCA frequency estimates. The findings predict that both the BWR and PWR large LOCA frequency estimates (*i.e.,* the largest NUREG–1829 LOCA size categories starting just below the TBS up to the highest category, which includes a DEGB of the largest pipe in the plant), based on operating experience from 2005 to the present day, are less than estimates based on operating experience from 1970–2004. Therefore, this work supports the expectation that the NUREG–1829 LOCA frequency estimates used to establish the TBS conservatively represent the current-day estimates, and that the TBS established for proposed 10 CFR 50.46a is appropriate. Additional details of this activity can be found in section 5.2 of the ''White Paper on Continued Applicability of NUREG–1829.''

In the ''White Paper on Continued Applicability of NUREG–1829,'' the NRC performed a qualitative analysis of the elicitation results, the operational experience, ongoing American Society of Mechanical Engineers (ASME) code activities, and recent research findings to determine if any of these findings impact the proposed TBS or may cause a break larger than the TBS. The NRC analyzed topics such as thermal embrittlement of cast austenitic stainless steel and stainless-steel welds; stress corrosion cracking in secondary PWR stainless lines; the effects of carbon macrosegregation, small surface breaking flaws, and quasi-laminar defects on reactor pressure vessel integrity; radiation embrittlement; and changes to passive-system inspection frequencies. The NRC evaluated each item's impact on both the direct and indirect failures and determined that these mechanisms would not impact the proposed TBS.

The NUREG–1903 report and the original analyses by the NRC considered the effects of direct (flawed and unflawed) and indirect piping failures on the selection of the TBS. For the direct unflawed piping failure, the NRC originally used the screening approach where the probability of exceedance of stresses corresponding to a 1 percent probability of failure was obtained for the 26 PWRs for the most highly stressed hot leg, cold leg, or crossover (suction) legs. The NRC concluded that failure probabilities of unflawed piping are significantly low compared to the frequency of 10^{-5} per year used as a basis to establish the TBS. For this original assessment, the NRC used the mean Lawrence Livermore National Laboratory seismic hazard curves corresponding to each selected site. Since then, all currently operating U.S. nuclear power reactor licensees have re-evaluated and submitted their Seismic Hazard and Screening Reports (SHSRs) in response to the March 12, 2012, letter issued by the NRC under 10 CFR 50.54(f), ''Request for Information Pursuant to Title 10 of the *Code of Federal Regulations* 50.54(f) Regarding Recommendations 2.1, 2.3, and 9.3, of the Near-Term Task Force Review of Insights from the Fukushima Dai-Ichi Accident,'' following the 2011 accident at the Fukushima Dai-Ichi nuclear power plant. As such, the original assessment results have been updated by using the more up-to-date site hazard information.

In addition, to better determine whether seismic loading conditions significantly increases the probability of a break above the TBS in the current NRC assessment, an unconditional mean piping failure probability value has been obtained by convolving a site-specific mean hazard curve with a representative mean large LOCA piping fragility function obtained from the Electric Power Research Institute (EPRI) Report (3002000709), ''Seismic Probabilistic Risk Assessment Implementation Guide.'' The results of this analysis show that failure probabilities of unflawed piping for a limited number of plants considered are well below the TBS frequency criterion. In addition, the study results show that the probabilities of exceedance corresponding to 1 percent probability of failure are all below the TBS threshold, even using the most conservative design stress intensity value and the most conservative failure criterion. Therefore, there is a clear indication that unflawed piping generally has a very low probability of failure attributable to seismic loads, which is consistent with the original NRC assessment conclusion in NUREG–1903 and the excellent performance experience of piping systems observed during past strong damaging earthquakes (''Summary and Evaluation of Historical Strong-Motion Earthquake Seismic Response and Damage to Above-Ground Industrial Piping,'' April 1985).

The NUREG–1903 report also showed that, for the direct flawed piping failure, the probabilities of pipe breaks larger than the TBS are likely to be less than 10^{-5} per year as the critical flaws associated with the stresses corresponding to the 10^{-5} and 10^{-6} probability of exceedance seismic events are generally large. However, considering the limited applicability of the results and the effects of the recent seismic hazard updates on the TBS, this conclusion needs to be verified by an entity on a case-by-case basis under proposed 10 CFR 50.46a(c)(1)(i).

For the two indirect piping failure cases considered in the original NUREG–1903 analysis, the likelihood of indirectly induced piping failures resulting from major component support failures is less than 10^{-5} per year, which was the frequency criterion used to select the TBS. Based on this frequency criterion, the NUREG–1903 report concluded that indirectly induced piping failure is unlikely to govern the combined failure of piping. However, the NRC noted that this conclusion is not necessarily bounding and may not be applicable to all sites because the assessment used generic seismic hazard curves and representative major support fragilities in lieu of plant-specific hazard curves and fragilities. This is further complicated by the recent seismic hazard updates documented in the aforementioned SHSRs. The assessment results documented in NUREG/KM–0017, ''Seismic Hazard Evaluations for U.S. Nuclear Power Plants: Near-Term Task Force Recommendation 2.1 Results,'' dated December 16, 2021, show that some sites have experienced noticeable changes in both seismic exceedance frequencies and Ground Motion Response Spectrum shapes relative to those of the prior assessments. Taken together, these changes affect seismic demand estimates used as an input to fragility analysis of key component supports as well as the resulting unconditional failure probability of indirectly induced piping failure. More details on this effort can be found in the ''White Paper on Continued Applicability of NUREG–1903.'' Because the risk associated with indirect piping failures is plant-specific, the NRC would require in proposed 10 CFR 50.46a(c)(1)(i) that each entity perform an assessment of indirect piping failures using the most up-to-date seismic hazard information. This assessment would be part of the comprehensive risk assessment required to implement 10 CFR 50.46a and graded approaches would be possible depending on the significance of the associated risk. More detailed guidance on this topic would be provided in DG–

1426, ''An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors,'' and DG–1428, ''Plant-Specific Applicability of the Transition Break Size.''

Periodic inservice inspections are a key performance monitoring strategy for verifying that analyses that predict component failure remain accurate through the time the component is analyzed, and they provide a method to identify novel degradation that may impact the analysis and the structural integrity of the component. Reactor coolant boundary piping in PWRs and BWRs is both ASME Class 1 piping and risk significant and is typically inspected by a prescribed inservice inspection program, a risk-informed inspection program, or an augmented inspection program under 10 CFR 50.55a, ''Codes and standards.'' For instance, in PWRs, the dissimilar metal welds that join the hot leg to the reactor pressure vessel nozzle are inspected through ASME Code Case N–770, ''Alternative Examination Requirements and Acceptance Standards for Class 1 PWR Piping and Vessel Nozzle Butt Welds Fabricated With UNS N06082 or UNS W86182 Weld Filler Material With or Without Application of Listed Mitigation Activities,'' as incorporated by reference in 10 CFR 50.55a, which requires different inspection frequencies depending on the type of mitigation employed. Also, the stainless-steel welds in the same piping system are typically covered under Category R.1.20 in ASME Code Case N–716–2, ''Alternative Classification and Examination Requirements,'' as incorporated by reference in 10 CFR 50.55a through RG 1.147, Revision 20, ''Inservice Inspection Code Case Acceptability, ASME section XI, Division 1.'' However, the wording of the code case does not require a minimum number of these welds to be inspected in the overall program (see section 4(b)(2) of Code Case N–716–2). In addition, there is a concerted effort within the ASME code community to use risk arguments to reduce inspections in piping (thereby increasing time between inspections) and other components, such as steam generator shell welds, which may extend to Class 1 piping for cases with no active degradation. This industry, EPRI, and ASME effort is addressed in the 2023 white paper entitled, ''Draft White Paper: Statistical Approach to Optimizing a Performance Monitoring Program.''

The analyses conducted within NUREG–1829 rely on the continuing inservice inspection of the piping considered in predicting LOCA frequencies. The inspections assumed were historical prescribed ASME inspection procedures and frequencies (*e.g.,* once in a 10-year interval). The impact of increasing the time between inspections on the predicted LOCA frequencies estimated in the elicitation is unknown, therefore performance monitoring is needed to confirm the continued adequacy of the analyses used to calculate the LOCA frequencies and identify novel degradation that may challenge the component integrity. To provide appropriate performance monitoring, proposed 10 CFR 50.46a(b)(3) would require that a sampling inspection program be conducted on the welds in piping systems whose diameter is greater than the TBS. Under the proposed rule, credit may be given for those welds inspected as part of an established inspection program (*e.g.,* these welds could be included in the sample inspected in the risk-informed piping inspection programs in lieu of other welds in the same risk-informed category). The dissimilar metal welds in PWRs, which are susceptible to primary water stress corrosion cracking, are inspected periodically per Code Case N–770, while the similar circumferential welds are part of a risk-informed program. Due to the number of similar metal, circumferential, Class 1 welds in a PWR reactor coolant loop, or those circumferential welds in a BWR that are classified as Category A welds (*i.e.,* welds of resistant material as defined in Generic Letter 88–01), it is possible that welds from the systems whose diameter is greater than the TBS might not be included in the sample inspected as part of the risk-informed inspection program. In addition, future ASME code changes might decrease the number of these circumferential welds inspected. Therefore, the proposed rule would require licensees to inspect an NRC-approved risk-informed sample of these similar metal circumferential welds in a PWR or the Category A circumferential welds in a BWR in accordance with 10 CFR 50.55a with the highest failure potential before implementation of proposed 10 CFR 50.46a and every subsequent in-service inspection interval. This proposed requirement, coupled with the ongoing inspection programs, would provide for the appropriate amount of performance monitoring data over the course of the plant's licensed life. Additional technical background supporting this proposed requirement can be found in the ''White Paper on Continued Applicability of NUREG–1829.''

The NRC also considered the possibility that currently licensed AP1000 facilities; other currently certified designs listed in appendices A through G of 10 CFR part 52 (*i.e.,* the AP600, ESBWR, APR1400, System 80+, U.S. Advanced Boiling Water Reactor, and NuScale designs); and other future LWR plants could apply the proposed TBS. The original elicitation effort did not consider these newer reactor designs when developing the LOCA frequencies. The current validation effort also did not consider the effects of design differences between these newer plants and other currently operating PWRs on the TBS. These newer plants may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and, thus, the TBS. Therefore, the NRC decided that the proposed TBS would not be applicable to newer plant designs, and these reactors should collectively be treated as ''new reactors'' as described in section XXXVI.F.(xii), ''Applicability to New Reactor Designs,'' of this document.

(iv) Evaluation of the Plant-Specific Applicability of the Transition Break Size

Because both the NUREG–1829 and NUREG–1903 studies developed representative and not bounding estimates, and the recent validation efforts in the ''White Paper on Continued Applicability of NUREG–1829'' and ''White Paper on Continued Applicability of NUREG–1903'' only confirmed the continued applicability of these representative estimates, unique plant attributes may result in plant-specific LOCA frequencies that are greater than reported in either NUREG–1829 or NUREG–1903. Consequently, proposed 10 CFR 50.46a(c)(1)(i) would require entities applying to implement proposed 10 CFR 50.46a for plants authorized to operate under 10 CFR part 50 on December 31, 2015, to conduct an evaluation to demonstrate the applicability of the TBS as defined in 10 CFR 50.46a(a)(9) to their individual plants. In addition, proposed 10 CFR 50.46a(a)(9) and 10 CFR 50.46a(c)(1)(i) also would allow for an alternate TBS to be proposed and justified. Similarly, proposed 10 CFR 50.46a(c)(2) would require that entities applying to implement proposed 10 CFR 50.46a for all other LWRs submit an analysis demonstrating that the proposed reactor design is similar to the designs of reactors authorized to operate under 10 CFR part 50 on December 31, 2015. This analysis should demonstrate that the NUREG–1829 and NUREG–1903 results, which supported the development of the proposed TBS definition as described in section XXXVI.F.(iii), ''Determining the Ongoing Validity of the Transition Break Size,'' of this document, are generally applicable to these plant designs. Applicants for all other plants would also need to propose and justify an appropriate TBS.

Additionally, proposed 10 CFR 50.46a(c)(1)(i) for reactors authorized to operate under 10 CFR part 50 on December 31, 2015, and proposed 10 CFR 50.46a(c)(2) for all other LWRs would require demonstration that the TBS as defined in proposed 10 CFR 50.46a(a)(9) remain applicable after initial plant changes such that the TBS remains valid. Proposed 10 CFR 50.46a(d)(4) would require demonstration that subsequent plant changes enacted under this proposed rule also do not invalidate the TBS. Most anticipated plant changes should not impact the TBS, so little, if any, evaluation would be necessary to demonstrate the acceptability of such changes. However, some changes, such as power uprates, have the potential to affect the TBS by increasing operating temperatures, coolant flow rate, and neutronic flux.

Guidance for conducting the plant-specific evaluations to demonstrate the initial applicability of the TBS and the subsequent applicability after implementing changes under this proposed rule is provided in DG–1428.

(v) Alternative ECCS Analysis Requirements and Acceptance Criteria

For breaks at or below the TBS, proposed 10 CFR 50.46a(e)(2)(ii) would specify that acceptance criteria be satisfied to a high level of probability (*i.e.,* 95 percent probability level, as explained in RG 1.157, ''Best-Estimate Calculations of Emergency Core Cooling System Performance''), which is currently required for all breaks under 10 CFR 50.46. Commensurate with the lower probability of breaks larger than the proposed TBS, 10 CFR 50.46a(e)(3) of the proposed rule would specify alternative ECCS analysis requirements in addition to the current 10 CFR 50.46 for breaks larger than the proposed TBS. Therefore, proposed 10 CFR 50.46a(e)(3)(ii) would require entities to analyze ECCS cooling performance for breaks up to and including a double-ended rupture of the largest pipe in the RCS using a relaxed set of criteria compared to current LOCA requirements. These analyses would need to be performed by methods acceptable to the NRC and would need to demonstrate that ECCS cooling performance conforms to the acceptance criteria set forth in the proposed rule.

Additionally, the proposed rule would modify the ECCS acceptance criteria from the current 10 CFR 50.46 to be more performance-based and would address the research findings in RIL–0801 for all breaks. The proposed rule would establish two ECCS performance criteria in proposed 10 CFR 50.46a(e)(1) and fuel system requirements in proposed 10 CFR 50.46a(f).

(a) ECCS Performance Criteria

The SSCs of the ECCS are designed to provide residual heat removal during and following a postulated LOCA. Failure of the ECCS to perform its intended function would result in a loss of coolable geometry followed by core reconfiguration. While the principal ECCS performance requirements are simple in nature (*i.e.,* remove residual heat and maintain a coolable geometry), the system must be designed to achieve specified performance objectives, taking into consideration all degradation mechanisms and any unique performance features of the particular fuel system that the ECCS is intended to cool. Sufficient empirical data must be available for the particular fuel system to enable the entity to identify all degradation mechanisms (*e.g.,* embrittlement, loss of structural integrity) and any unique performance features (*e.g.,* eutectic or exothermic reactions, combustible gas generation). Consideration of applicable degradation mechanisms would in turn allow specification of limits for key parameters (*e.g.,* cladding or fuel temperatures) that would establish the duration for which the ECCS must remove residual heat and ensure that a coolable geometry is maintained. In addition, fuel-specific analytical requirements may be necessary to accurately or conservatively model unique phenomena that impact the ECCS performance demonstration (*e.g.,* fuel rod balloon and burst, cladding inside-diameter oxygen ingress).

Section 50.46a(e)(1) of the proposed rule would establish the following principal ECCS performance requirements:

• Sufficient coolant so that the fuel remains in a coolable geometry during and following the LOCA heatup and quench.

• Sufficient long-term cooling so that decay heat will be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel.

Compliance with these performance requirements would provide reasonable assurance that the overall objective of maintaining a coolable fuel geometry during and after a LOCA. In addition, the proposed rule would dictate specific analytical requirements for demonstrating compliance with the ECCS performance requirements. For instance, to demonstrate compliance with these system performance requirements, ECCS performance would be evaluated using fuel-specific performance objectives and associated analytical limits that take into consideration all known degradation mechanisms and unique performance features of the particular fuel system, along with an acceptable evaluation model.

In previous comments, Framatome suggested changes to the draft final 10 CFR 50.46c rule to make it more performance based. Those changes included two ECCS performance criteria that, according to Framatome, would support new fuel types. The NRC agreed that the performance criteria suggested by Framatome would have benefits such as making those performance requirements more performance based. The two performance criteria in proposed 10 CFR 50.46a(e)(1) align closely with Framatome's recommended performance criteria. The difference between the proposed rule and Framatome's suggestion is also a change from the draft final 10 CFR 50.46c rule (see section XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' of this document). In that draft rule, core temperature was the first ECCS performance requirement. In this proposed rule, the NRC replaced core temperature with fuel coolability to potentially allow for a demonstration of coolability and safety of fuel outside of a fuel rod, such as dispersed fine fuel fragments resulting from FFRD.

(b) Fuel Coolability

As explained in section XXXV.C.(v)(a), ''10 CFR 50.46 and Fuel Dispersal,'' of this document, since 1973, the AEC and NRC position has been that the objective of the coolable geometry criterion in 10 CFR 50.46(b)(4) is to maintain fuel pellets within the cladding and fuel rods within the fuel bundle lattice. While fuel dispersal is not explicitly addressed in the NRC's current regulations, the objective of the coolability criterion indicates that significant fuel dispersal during a LOCA is not permitted, as fuel leaving the fuel rod leads to loss of the fuel rod structure and loss of fuel bundle configuration. However, the state-of-knowledge surrounding LOCAs and the ability to simulate complex phenomena during a LOCA have drastically improved since 1973 and is expected to continue to do so. Therefore, it is appropriate to update the understanding of coolability. Based on the conclusions in NUREG/CR–7307, which describes the NRC-sponsored fuel dispersal consequences PIRT exercise, it is reasonable to conclude that some amount of fuel dispersal could be coolable, and it is expected that this can be demonstrated with the tools and experimental capabilities available today. The PIRT expert panel believed that relatively simple bounding calculations can be performed to address the primary downstream consequences of dispersal.

While core configuration, fuel bundle array geometry, and fuel rod structure have traditionally been considered to be challenged by any significant amount of fuel dispersal, the NRC is open to the possibility that core configuration, fuel bundle array geometry, and fuel rod structure could be shown to remain generally intact even if some amount of fuel is dispersed. While simple bounding calculations may be possible at the present time, the models and testing necessary to perform a more detailed analysis and a more detailed demonstration in support of reactor safety analyses have not been developed and specific limits concerning how much dispersed fuel would be acceptable have not been defined. Therefore, similar to any other LOCA phenomena, prior to approving LOCA analysis methods involving fuel dispersal under both the existing regulations and the proposed rule, the NRC would review the relevant modeling approaches, including their underlying validation and experimental basis, to ensure their credibility. Should fuel dispersal be calculated to occur, an entity would need to provide a technical basis addressing the coolability of both fuel retained in the core and fuel dispersed into the reactor vessel or containment.

The proposed 10 CFR 50.46a provides an explicit risk-informed framework for treatment of breaks above the TBS that could relax required analytic assumptions. The proposed risk-informed framework is not the only permissible way to use risk insights in addressing the ECCS requirements. The NRC will continue to assess regulatory compliance consistent with the existing regulatory framework on risk-informed regulation, including regulatory guidance such as RG 1.174. An acceptable level of defense-in-depth and safety margins should continue to be maintained when applying risk insights. As a result of addressing coolability in a more performance-based way and treating dispersal as not being incompatible with coolability, other licensing pathways may be made possible to address coolability, such as other alternatives postulated in the regulatory basis for this rulemaking or proposed by industry in topical reports.

This proposed rule would represent a change in the Commission's position on coolability to allow for demonstrations of fuel dispersal. This proposed change could result in questions on when the core geometry would no longer be considered coolable. The proposed requirements to demonstrate fuel coolability (in proposed 10 CFR 50.46a(e)(1)(i) and (f)(3)) and address cladding degradation phenomena (in proposed 10 CFR 50.46a(f)(1)) in the ECCS performance analyses would provide reasonable assurance that unacceptable scenarios would not occur. Unacceptable scenarios would include, but would not be limited to the following:

• Widespread brittle cladding failure. Brittle failure of the cladding during a LOCA could lead to the shattering of the cladding and the release of much of the fuel in the rod. While fuel may be dispersed out of a rupture opening of a fuel rod when considering FFRD, less fuel is expected to be dispersed than if PQD is not preserved. Additionally, the general fuel bundle configuration of the core would be lost in the case of widespread brittle cladding failure, which would have major deleterious effects on core coolability. For these reasons, the NRC would maintain PCT and PQD criteria for zirconium-alloy and UO_2 fuel systems in 10 CFR 50.46 but include them in guidance (*i.e.,* DG–1263) to support proposed 10 CFR 50.46a. The PCT and PQD criteria in DG–1263 would address proposed 10 CFR 50.46a(f)(1), which states that cladding degradation phenomena must be addressed.

• Fuel/cladding melt. In addition to ensuring PQD, emergency coolant provided by the ECCS is intended to prevent the fuel from melting during a LOCA. If the ECCS is unable to provide sufficient cooling to prevent the fuel from melting, then this situation could lead to an outcome where the fuel becomes uncoolable. While this rulemaking proposes to recategorize LOCAs above the TBS as beyond-design-basis, the NRC continues to find that avoidance of fuel melting during a LOCA is appropriate to ensure a coolable geometry. Similarly, the fuel dispersal PIRT identified fuel accumulation on the spacer grids as a concern. If fuel particles settle on spacer grids and there is two-sided heating of the cladding, then it could potentially cause the cladding to melt and therefore damage the configuration of the core. This postulated scenario must be avoided. For zirconium-alloy and UO_2 fuel systems that retain their fuel, the PCT criteria in DG–1263, which would address the proposed 10 CFR 50.46a(f)(1) requirement to have NRC-approved limits that address cladding degradation phenomena, would prevent fuel melt during a LOCA.

(c) Acceptable Methodologies and Analysis Assumptions

Proposed 10 CFR 50.46a(e) would retain the requirement in existing 10 CFR 50.46 that ECCS cooling performance must be calculated in accordance with an acceptable evaluation model. Acceptable evaluation models are currently of two types: those that realistically describe the behavior of the RCS during a LOCA, and those that conform with the required and acceptable features specified in appendix K to 10 CFR part 50. Appendix K to 10 CFR part 50 evaluation models incorporate conservatism as a means to justify that the acceptance criteria are satisfied by an ECCS design. In contrast, the realistic or best-estimate models attempt to accurately simulate the expected phenomena while accounting for uncertainty such that there is a high level of probability that the ECCS acceptance criteria will not be exceeded. As a result, comparisons to applicable experimental data must be made and uncertainty in the evaluation model and inputs must be identified and assessed. All these existing requirements are included in proposed 10 CFR 50.46a(e)(2) for breaks at or below the TBS.

As currently required under 10 CFR 50.46, the ECCS analysis performed with realistic modeling must demonstrate with a high level of probability that the acceptance criteria will not be exceeded. The NRC position in RG 1.157 is that 95 percent probability constitutes an acceptably high probability. Section 50.46a(e)(2) of the proposed rule retains this high level of probability as the statistical acceptance criterion for breaks below the TBS. For breaks at or above the TBS, proposed 10 CFR 50.46a(e)(3) would depart from the requirement of high probability to state that assurance to at least a best-estimate level is acceptable. For these breaks, best-estimate would refer to nominal and unbiased analyses. Thus, for realistic evaluation models for breaks above the TBS, entities would not be required to account for the uncertainty. The best-estimate analyses could also take credit for offsite power, as stated in proposed 10 CFR 50.46a(e)(3).

Proposed 10 CFR 50.46a(e)(2) and (e)(3) would each require a separate determination of the most limiting break scenarios within each of the two break-size regions: (1) breaks at or below the TBS and (2) breaks larger than the TBS up to and including a double-ended rupture of the largest pipe in the RCS. Different methodologies, analytical assumptions, and acceptance criteria could be used for each break size region. Consistent with current 10 CFR 50.46 requirements, entities would be required to analyze breaks at or below the TBS by assuming the worst single failure concurrent with a loss-of-offsite power and only crediting the mitigative capability of safety-related SSCs. For breaks larger than the TBS, entities could credit operation of both safety and non-safety-related SSCs (subject to system availability as supported by plant-specific data or analysis) provided that onsite power could be readily provided to that equipment through manual actions after a loss-of-offsite power (*e.g.,* within approximately 30 minutes). This requirement for non-safety-related equipment would be a defense-in-depth consideration for severe accident management. The SSCs that are credited for such accidents should have at least a pedigree similar to that of the equipment credited in other beyond-design-basis accidents. All non-safety equipment that is credited for analyses of breaks larger than the TBS would need to be identified as such and evaluated whether they should be listed in the plant technical specifications in order to satisfy criterion 4 of 10 CFR 50.36(c)(2)(ii). Criterion 4 of 10 CFR 50.36(c)(2)(ii) states that a technical specification limiting condition for operation must be established for a ''structure, system, or component which operating experience or probabilistic risk assessment has shown to be significant to public health and safety.'' Despite the recategorization of LOCAs greater than the TBS as beyond-design-basis, the NRC still believes that it is significant to public health and safety that such events are able to be mitigated. Criterion 4 of 10 CFR 50.36(c)(2)(ii) is the basis for the establishment of technical specifications for equipment that are used in the mitigation of another beyond-design-basis accident, anticipated transient without scram. For example, in the BWR/6 standard technical specifications in Volume 2 of Revision 5.0 of NUREG–1434, ''Standard Technical Specifications—General Electric BWR/6 Plants,'' the typically non-safety-related anticipated transient without scram recirculation pump trip system is stated as satisfying criterion 4 of 10 CFR 50.36(c)(2)(ii).

(d) Fuel-Specific Performance and Analytical Requirements

Section 50.46a(f) of the proposed rule would include performance requirements for fuel designs. The fuel designs would be required to have NRC-approved limits that do the following:

• Address cladding degradation phenomena.
• Maintain fuel coolability.
• Avoid explosive concentration of combustible gas.
• Demonstrate that, after any calculated successful initial operation of the ECCS, the ECCS must provide sufficient coolant to remove decay heat and prevent further cladding failure for the extended period of time required by the long-lived radioactivity remaining in the fuel.

Means of meeting the requirement to address cladding degradation criteria are provided in DG–1263 for fuel designs consisting of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium-alloy cladding. Under this requirement, entities should address the research findings discussed in section XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' of this document when establishing criteria on PCT, PQD, and breakaway oxidation, as detailed in DG–1263. The NRC is proposing to not include PCT and PDQ requirements in the proposed 10 CFR 50.46a, unlike the current 10 CFR 50.46(b)(1) and (b)(2). Instead, the NRC proposes to include PCT and PQD criteria in guidance to enable regulatory flexibility. For example, additional criteria for fuel performance above 2200 °F (1204 °C) may be needed to address other high-temperature failure mechanisms that may not occur below 2200 °F (1204 °C). Including the PCT, the maximum local oxidation, and maximum hydrogen generation criteria in DG–1263 rather than codified in proposed 10 CFR 50.46a would provide this flexibility.

Exemptions from proposed 10 CFR 50.46a would not be needed for new fuels to which the current criteria may not be applicable, such as non-zirconium-alloy cladded fuel, since the criteria would be located in guidance. The NRC did not include guidance for fuel designs that do not consist of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium-alloy cladding as a part of this rulemaking due to a lack of operational experience on which to base specific criteria and to accelerate the rulemaking schedule. The NRC has determined that these new fuels should be able to be licensed based on technical justifications without the need for exemptions from regulation. For example, since the detailed criteria would be in guidance, justification could be provided for alternative criteria for PCT that exceed the 2200 °F (1204 °C) limit in 10 CFR 50.46(b)(1) and has historically been used for fuel designs consisting of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium alloy cladding.

As discussed in section XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' of this document, some amount of fuel dispersal could be shown to be coolable and therefore acceptable under proposed 10 CFR 50.46a. During FFRD, fuel is dispersed following ductile failure of the cladding (*i.e.,* ballooning and burst) and also can be dispersed from brittle failure of the cladding. Historically, brittle failure of even a single rod has been prevented by ensuring compliance with 10 CFR 50.46(b), as described in section XXXV.C.(v)(a), ''10 CFR 50.46 and Fuel Dispersal,'' of this document. Under this proposed rule, the NRC may review applications for safety demonstrations of FFRD during breaks above the TBS, so it is logical to consider safety demonstrations of fuel dispersed from brittle failure for LOCAs above the TBS. Such brittle failures should be limited so that there is not a widespread loss of the general fuel rod bundle configuration in the core, as widespread destruction of the fuel rod bundle configuration would have significant deleterious effects on core coolability.

There has been little research on the amount of fuel dispersal expected to occur due to brittle failure, but if coolability and safety can be ensured following brittle failure of the cladding, then the NRC may find it to be acceptable for breaks above the TBS. Entities would need to justify the safety case for permitting brittle failure of fuel rods and the resulting fuel dispersal.

Additionally, the criteria in proposed 10 CFR 50.46a(f) may be used as an alternative to the criteria in proposed 10 CFR 50.46(b), as applicable, without having to adopt the rest of proposed 10 CFR 50.46a, as stated in proposed 10 CFR 50.46(a)(3)(i).

The existing regulation in 10 CFR 50.46(b)(5) requires that, for long-term cooling, the calculated core temperature be maintained at an acceptably low value following any calculated successful initial operation of the ECCS. It also requires that decay heat be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel. Section 50.46a(f)(4) of the proposed rule would retain these requirements from 10 CFR 50.46(b)(4) and specify that cladding failure should be prevented in the extended period of time required by the long-lived radioactivity remaining in the fuel.

(e) Restriction of Reactor Operation

Proposed 10 CFR 50.46a(i) would allow the Director of the NRC's Office of Nuclear Reactor Regulation to impose restrictions on reactor operation if the NRC determines that the evaluations of ECCS cooling performance are not consistent with the requirements for evaluation models and analysis methods specified in proposed 10 CFR 50.46a(e)(1) through (e)(3) and 10 CFR 50.46a(f). Non-compliance could be due to factors such as lack of a sufficient database upon which to assess model uncertainty, use of a model outside the range of an appropriate data base, use of models inconsistent with the requirements of appendix K to 10 CFR part 50, or discovery of phenomena unknown at the time of approval of the methodology. Lack of compliance with methodological requirements would not necessarily mean that the ECCS capability is unacceptable, but only that the analysis results using the methodology in question cannot be relied upon to demonstrate compliance with the appropriate acceptance criteria. Thus, depending upon the specific circumstances, it might be necessary for the NRC to impose restrictions on operation until these issues are resolved. This requirement would be consistent with the current ECCS regulations in existing 10 CFR 50.46(a)(2).

(vi) Risk-Informed Changes to the Facility, Technical Specifications, or Procedures

The proposed 10 CFR 50.46a would designate LOCAs above the TBS as beyond-design-basis, allowing for best-estimate analysis for such LOCAs. The proposed flexibility in ECCS analyses for LOCAs above the TBS would enable a wide range of changes that could be implemented at facilities seeking to apply the proposed 10 CFR 50.46a.

Entities that would request approval to use 10 CFR 50.46a would use a risk-informed evaluation to demonstrate that facility changes would satisfy the risk-informed acceptance criteria in proposed 10 CFR 50.46a(h). Changes that would need to be evaluated would be specified in proposed 10 CFR 50.46a(d)(3) and would include all ''enabled'' changes (*i.e.,* changes that would be permissible if the NRC were to approve the entity's request to use proposed 10 CFR 50.46a) that satisfy the alternative ECCS analysis requirements in proposed 10 CFR 50.46a but do not satisfy the ECCS analysis requirements in current 10 CFR 50.46.

Proposed 10 CFR 50.46a(h)(1), (2) and (3) would require entities to demonstrate in their risk-informed evaluations that increases in plant risk (if any) would meet appropriate risk acceptance criteria, defense-in-depth would be maintained, adequate safety margins would be maintained, and adequate performance-measurement programs would be implemented. All changes to a plant, its technical specifications, or its procedures that would be based upon the analyses of ECCS performance permitted under proposed 10 CFR 50.46a(e)(3)–except for those changes made under proposed 10 CFR 50.46a(h)(1)–would need to be reviewed and approved by the NRC. A wide range of changes could be implemented under proposed 10 CFR 50.46a that, if improperly implemented by entities, could result in significant adverse impacts on public health and safety or common defense and security. NRC review and approval would provide verification that an entity has properly evaluated each proposed change against the acceptance criteria in proposed 10 CFR 50.46a. Existing 10 CFR 50.36(b) requires each license authorizing operation of a production or utilization facility of a type described in 10 CFR 50.21, ''Class 104 licenses; for medical therapy and research and development facilities,'' or 50.22, ''Class 103 licenses; for commercial and industrial facilities,'' to include technical specifications, so changes to the technical specifications require the license to be amended. However, 10 CFR 50.36 does not provide risk thresholds, nor does it require a risk-informed evaluation to demonstrate that the proposed change does not result in significant adverse impacts on public health and safety or common defense and security. Therefore, for technical specifications changes proposed under 10 CFR 50.46a, 10 CFR 50.46a(h)(2) would provide the risk acceptance criteria necessary for entities to evaluate each proposed change, beyond that required in 10 CFR 50.36. Accordingly, the NRC's proposed rule would require NRC review and approval of all changes initiated under proposed 10 CFR 50.46a(h)(2).

An entity other than a design certification applicant or holder of an ML who sought to make certain changes that would be enabled by the proposed rule without prior NRC review and approval would need to submit for NRC review its risk-informed process that would be used in evaluating the acceptability of these changes as described in proposed 10 CFR 50.46a(c)(1)(v). The entity's process would also need to include a means to evaluate the continued applicability of the TBS with the acceptance criteria used in the evaluation described in proposed 10 CFR 50.46a(c)(1)(i) for plants authorized to operate under 10 CFR part 50 on December 31, 2015 or as described in proposed 10 CFR 50.46a(c)(2) for entities other than those authorized to operate under 10 CFR part 50 on December 31, 2015. An entity who would make only a single or a few changes enabled by the rule would not need to submit a risk-informed evaluation process. Instead, that entity would submit only its risk-informed evaluation of each change it has requested. Proposed 10 CFR 50.46a(h)(1) would contain acceptance criteria for self-made changes enabled by the rule. Under the proposed framework, if an entity's initial application to implement proposed 10 CFR 50.46a does not include a risk-informed evaluation process, then that entity could, at any later time, submit another license amendment requesting approval of a risk-informed evaluation process. The DG–1426 would provide guidance for the risk-informed evaluation specified in proposed 10 CFR 50.46a(c)(1)(iv) and the risk-informed evaluation process specified in proposed 10 CFR 50.46a(c)(1)(v).

(a) Requirements for the Risk-Informed Evaluation

The acceptability of all entity-initiated changes made under the rule would be judged in a risk-informed manner. The risk-informed assessment process would include methods for evaluating compliance with the risk criteria, defense-in-depth criteria, safety margin criteria, and performance measurement criteria in proposed 10 CFR 50.46a(h). These attributes have been identified by the NRC in RG 1.174 as a set of risk evaluation tools to ensure that changes to the facility do not endanger public health and safety.

Compliance with the risk criteria would play a key role in the regulatory structure of the proposed rule. Entities would be required to use a risk assessment to determine the change in risk associated with facility changes. Inasmuch as the Commission's final policy statement on the ''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities'' (60 FR 42622; August 16, 1995) sets forth the Commission's intention to encourage the use of PRA and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the-art in PRA methods and data, 10 CFR 50.46a(h)(4) of the proposed rule would require that a technically acceptable PRA be used to demonstrate compliance with the requirements of proposed 10 CFR 50.46a if the change being assessed could substantively increase risk. Proposed 10 CFR 50.46a(h)(4)(i) through (iv) set forth the four general attributes of an acceptable PRA for the purposes of this proposed -rule. However, the NRC recognizes that nonquantitative PRA assessment methodologies and approaches could also be used to complement or supplement the quantitative aspects of a PRA, especially when performance of a quantitative PRA methodology of the level needed to support a particular plant modification decision would not be justifiable because the safety significance of the decision would not warrant the level of technical sophistication inherent in a PRA. Accordingly, proposed 10 CFR 50.46a(h)(5) would establish the minimum requirements for risk assessment methodologies other than PRA. This proposed requirement would provide flexibility for entities to use the nonPRA risk methodology (or combination of different methodologies) when these methodologies produce results that are sufficient to -determine that the risk acceptance criteria in the proposed rule have been met.

(b) Aggregation of Plant Changes When Evaluating Changes in Risk

Entities often make changes to their facilities, technical specifications, and procedures. Some changes that entities would be able to make after being approved to use this proposed rule would not have been permitted without the proposed 10 CFR 50.46a ECCS requirements (*i.e.,* enabled changes). Other changes would be unrelated insofar as the basis of the changes and NRC approval, when necessary, would rely on regulations, guidelines, or facility priorities that would not depend on the proposed 10 CFR 50.46a ECCS requirements. Unrelated changes would indirectly influence the change in risk of the proposed 10 CFR 50.46a related changes because they would change the risk profile of the facility. If unrelated changes were combined (bundled) with enabled changes in evaluating the proposed 10 CFR 50.46a change in risk estimates, the result would typically be different than if the unrelated changes were considered as part of the baseline risk associated with the current design and operation of the facility. Regulatory guide 1.174 permits bundling changes (referred to as combined changes in RG 1.174) and provides additional acceptance guidelines when combining unrelated plant changes that might decrease risk together with a group of enabled changes to evaluate the total change in risk for comparison to the acceptance guidelines.

Allowing the bundling of unrelated changes into the proposed 10 CFR 50.46a change in risk estimates would encourage entities to use risk-informed methods to take advantage of opportunities to reduce risk. However, in some situations, bundling could mask the creation of significant risk outliers. To ensure that outliers would not be created, the proposed rule would not permit bundling of unrelated changes with enabled changes without NRC review and approval. Specifically, proposed 10 CFR 50.46a(h)(2)(i) and (iii) would allow changes not enabled by proposed 10 CFR 50.46a to be bundled with changes enabled by proposed 10 CFR 50.46a in the calculation of the change in risk when an entity would submit an application for a change under 10 CFR 50.90, ''Application for amendment of license, construction permit, or early site permit.''

(c) NRC approval of an Entity Process for Making Changes to an Entity's Facility or Procedures Without NRC Review and Approval

As a general matter, the proposed rule would require an entity to obtain NRC review and approval through an application for any changes to its facility, technical specifications, or procedures that may be implemented under proposed 10 CFR 50.46a. However, the proposed rule would allow an entity, other than a design certification applicant or holder of an ML, to make a subset of plant and procedure changes without NRC approval if the changes would involve minimal changes in risk and no significant impact upon defense-in-depth capabilities, safety margins, or performance monitoring. Prior NRC review and approval of these changes on an individual basis would be unnecessary if the NRC had previously concluded that the entity other than a design certification applicant or holder of an ML had an adequate technical process for appropriately identifying this subset of changes. Plant changes that would involve minimal changes in risk and have no significant impact upon defense-in-depth, safety margins, and performance monitoring (and do not involve a change to the technical specifications), would not result in significant issues involving public health and safety or common defense and security.

Expending entity resources to prepare, and NRC resources to review and approve, an application for approval of plant changes involving minimal changes in risk would not be efficient uses of resources. Rather, if the NRC would review and approve in advance the entity's processes (including the acceptability of the entity's PRA and other risk assessment methods) and criteria for identifying changes that would have minimal impact on risk and would not significantly affect defense-in-depth, safety margin, performance monitoring, or plant physical security, then there would be no need for the NRC to review and approve each of the individual changes. Accordingly, the NRC is proposing an approach in 10 CFR 50.46a(h)(1) that would allow an entity other than a design certification applicant or holder of an ML to obtain ''pre-approval'' of a process for identifying minimal plant and procedure changes made possible under proposed 10 CFR 50.46a.

Proposed 10 CFR 50.46a(h) would enable an entity other than a design certification applicant or holder of an ML to make changes based upon the provisions of proposed 10 CFR 50.46a, without prior NRC approval, if the requirements in proposed 10 CFR 50.46a(h)(1) and (h)(3) were met. The proposed rule also would require that the change be permitted under the 10 CFR 50.59, ''Changes, tests and experiments.'' Compliance with the 10 CFR 50.59 requirements would be necessary to ensure that facility changes made without NRC approval would not result in plant conditions that could impact public health and safety. Compliance with the proposed 10 CFR 50.46a(h) requirements for risk assessments would be required to ensure that facility changes would result in acceptable changes in risk, that adequate defense-in-depth would be maintained, that safety margins would be maintained, and that adequate performance-measurement programs would be implemented.

Design certification applicants would not be subject to the change process in proposed 10 CFR 50.46a(h)(1), either before or after NRC certification of the design. An applicant for a design certification that has not been approved by the NRC would not need this provision because it could change the design specified in its application before NRC issuance of a final standard design certification rule for its design. The NRC also has determined that design certification applicants whose designs have been certified should not be allowed to change the certified designs without NRC review and approval via rulemaking. Allowing the design certification applicant to make changes to the certified design without NRC approval through proposed 10 CFR 50.46a(h)(1) would be inconsistent with the purpose of certifying the design in a rulemaking and would effectively reduce the NRC's regulatory control over the design certification. The NRC would review any deviations from the certified design when reviewing the COL application. The NRC also would exclude ML holders from this option to avoid a reduction of NRC regulatory control over the approved manufacturing design, consistent with the requirement in existing 10 CFR 52.171(b)(1) that holder of an ML may not make changes to the design of the nuclear power reactor authorized to be manufactured without NRC approval.

(d) Risk Acceptance Criteria for Plant Changes

To make changes to the facility, technical specifications, or procedures not permitted by proposed 10 CFR 50.46a(h)(1), proposed 10 CFR 50.46a(h)(2) would require the submission of information from the risk-informed evaluation demonstrating, among other things, that the total increases in risk from the proposed change would be very small and that the overall plant risk would remain small. These characterizations of ''very small'' and ''small'' are intended to be consistent with their use in RG 1.174, which introduces surrogate guidelines that provide assurance that overall plant risks remain bounded by the Commission's Policy Statement on ''Safety Goals for the Operations of Nuclear Power Plants'' (51 FR 28044; August 4, 1986).

1. Risk Estimate

To satisfy the Commission's requirement in proposed 10 CFR 50.46a(h)(2)(ii) that the total increases in risk are very small, an entity would need to evaluate the change in risk for each facility change and show that the change meets the acceptance guidelines. If a series of changes were made over time, proposed 10 CFR 50.46a(h)(2)(iii) would require that the cumulative effect of these changes be evaluated and shown to meet the acceptance criteria. Proposed 10 CFR 50.46a(h)(2)(iii) also would permit an entity to combine changes in risk from facility changes not enabled by proposed 10 CFR 50.46a with changes in risk from facility changes that would be enabled by proposed 10 CFR 50.46a for the purposes of meeting the acceptance guidelines. Taken together, this bundled group of enabled changes and unrelated changes would be referred to as the ''changes made under'' proposed 10 CFR 50.46a.

For each change requiring a risk-informed evaluation, the total change in risk from all facility changes made under the proposed 10 CFR 50.46a would need to be evaluated and compared to the ''very small'' acceptance criterion when the change is first made and then with each subsequent enabled change that would result in a greater than minimal increase in risk. Requiring that the total change in risk from all facility changes made under the proposed 10 CFR 50.46a be compared to the proposed 10 CFR 50.46a acceptance criteria instead of allowing the changes in risk to be partitioned and individually compared to the acceptance criteria would ensure that the total risk increase for all changes, as they are implemented over time, would not constitute more than a very small increase in risk. If the total increase in the applicable risk metrics were not compared to the acceptance criteria, then several changes in which each individual change's risk increase was kept below the proposed rule's risk acceptance criteria could, considered cumulatively, result in a significant increase in risk. A significant increase may not satisfy the Commission's proposed criterion that the overall plant risk remains small. Also, comparing the risk increase from each change to the acceptance criteria independently of all previous changes would render the use of the ''very small'' criterion inadequate to monitor and control increases in risk from a series of plant changes implemented over time.

Comparing the total risk increase to the risk increase criterion, and allowing bundling of unrelated changes in the change in risk estimate, would support the NRC's position as stated in RG 1.174 that, consistent with the key principles of risk-informed integrated decision-making, entities should have a risk management approach in which risk insights are not just used to systematically increase risk, but also to help reduce risk where appropriate and where it is shown to be cost effective.

2. Acceptance Criteria

The risk acceptance guidelines proposed in 10 CFR 50.46a(h)(2)(ii) use CDF and large early release frequency (LERF) risk metrics. As discussed in SRM–SECY–98–015, ''Staff Requirements—SECY–98–015—Final General Regulatory Guide and Standard Review Plan for Risk-Informed Regulation of Power Reactors,'' dated May 20, 1998, the Commission approved the use of RG 1.174, which incorporated Commission direction in the March 19, 1998, SRM issued for SECY–97–287, ''Final Regulatory Guidance on Risk-Informed Regulation: Policy Issues,'' dated December 12, 1997. Based on proposals made by the staff, the Commission approved the use of very small increases in CDF and LERF independent of the baseline calculated CDF/LERF, provided that licensees track and NRC staff monitor the cumulative effect of changes. These risk metrics are based on subsidiary objectives derived from the NRC's safety goals and their quantitative health objectives. In particular, the CDF risk metric is used as a surrogate for the individual latent cancer fatality risk, and the LERF risk metric is used as a surrogate for the individual early fatality risk. The NRC has used CDF and LERF in making regulatory decisions for more than 30 years. The NRC endorsed the use of CDF and LERF as appropriate measures for evaluating risk and ensuring safety in nuclear power plants when it adopted RG 1.174 in 1998. Since the adoption of RG 1.174, the NRC has had 27 years of experience in applying risk-informed regulation to support a variety of applications, including amending facility procedures and programs (*e.g.,* inservice testing and inservice inspection programs), amending facility OLs, making changes to the FSAR, and implementing risk-informed technical specifications. Based on this experience, the NRC has determined that CDF and LERF are acceptable measures for evaluating changes in risk as the result of changes to a facility, technical specifications, and procedures, except for certain changes that affect containment performance but do not affect CDF or LERF. Changes that affect containment performance are considered as part of the defense-in-depth evaluation.

In SRM–SECY–07–0082, ''Staff Requirements—SECY–07–0082—Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,' '' dated August 10, 2007, the Commission concluded that, to more closely follow the approach presented in RG 1.174, the staff, in the 10 CFR 50.46a draft final rule, should restrict changes to a plant to very small risk increases. As discussed in RG 1.174, a very small risk increase is independent of a plant's overall risk as measured by the current CDF and LERF. Increases in CDF of 10^{-6} per reactor year or less and increases in LERF of 10^{-7} per reactor year or less are very small risk increases for existing reactor facilities. Limiting the acceptance criteria for plant changes enabled under proposed 10 CFR 50.46a to very small risk increases ensures that significant plant changes will not be enabled strictly due to the initiating event frequency for a LOCA greater than the TBS, which is on the order of 10^{-5} and the same as the criteria for small risk increases. In SRM–SECY–12–0081, ''Staff Requirements—SECY–12–0081—Risk-Informed Regulatory Framework for New Reactors'' dated October 22, 2012, the Commission approved the staff's recommendation to transition new reactors from large release frequency to LERF at or before initial fuel load and discontinue regulatory use of large release frequency. Applicants for new reactor OLs under 10 CFR part 50 or COLs under 10 CFR part 52 may need to transition to LERF to demonstrate in the risk-informed evaluation that the proposed changes meet the requirements in proposed 10 CFR 50.46a(h).

Since adopting RG 1.174 in 1998, the NRC has applied the quantitative change in risk guidelines to individual plant changes and to sequences of plant changes implemented over time. The NRC has found these guidelines and the CDF and LERF values (when used together with the defense-in-depth, safety monitoring, and performance measurement criteria) to be capable of differentiating between changes, and sequences of changes, that are not expected to endanger public health and safety and those that might.

When the change does not significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the applicant's facility and the change is permitted under 10 CFR 50.59, 10 CFR 52.98(b), 10 CFR 52.98(c), and 10 CFR 52.98(d), as applicable, proposed 10 CFR 50.46a(h)(1) would permit entities other than a design certification applicant or holder of an ML to make changes without prior NRC approval if the changes involve minimal increases in risk that also have no significant impact upon defense-in-depth capabilities, safety margins, and performance monitoring. A minimal risk increase is one that, when considered qualitatively by itself or in combination with all other minimal increases, would never become significant. A minimal increase in risk is an increase less than 10 percent of the risk increases that would be very small for any licensee. Therefore, a minimal increase is an increase of less than 10^{-7} per reactor year for CDF and an increase in LERF of less than 10^{-8} per reactor year. These values are two orders of magnitude below the maximum allowed risk increase guidelines in RG 1.174 and one order of magnitude less than the very small criterion. Although multiple changes, when evaluated separately, could each be a minimal increase in risk, when combined and evaluated together, they could exceed the very small criterion. Most of these changes would have a much smaller (and, in some cases, an unmeasurable) increase in risk. If an entity other than a design certification applicant or holder of an ML were to implement an unexpectedly large number of minimal risk changes, then the periodic reporting requirements in proposed 10 CFR 50.46a(j)(3) would provide adequate notice to ensure that the NRC is aware of potentially significant changes (or any collective impact), so that the NRC could undertake additional oversight actions as deemed necessary and appropriate.

(e) Defense-in-Depth

Section 50.46a(h)(3)(i) of the proposed rule would require that the risk-informed evaluation demonstrate that defense-in-depth is maintained. Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. As conceived and implemented by the NRC, defense-in-depth provides, among other things, redundancy in addition to a multiple barrier approach against fission product releases. Defense-in-depth continues to be an effective way to account for uncertainties in equipment and human performance. The NRC has determined that retention of adequate defense-in-depth must be ensured in all risk-informed regulatory activities.

(f) Safety Margins

Proposed 10 CFR 50.46a(h)(3)(ii) would require that adequate safety margins be retained to account for uncertainties. These uncertainties include phenomenology, modeling, plant construction, and plant operation. Without this proposed provision, entities could make plant changes that would inappropriately reduce safety margins, resulting in an unacceptable increase in risk or challenge to plant SSCs. This proposed requirement would ensure that an adequate safety margin exists to account for these uncertainties, such that there would be no unacceptable results or consequences (*e.g.,* structural failure) if an acceptance criterion or limit is exceeded.

(g) Performance Measuring Programs

Section 50.46a(h)(3)(iii) of the proposed rule would require entities to implement adequate performance-measurement programs and feedback strategies to ensure that the risk-informed evaluation continues to reflect actual plant design and operation. The risk-informed evaluation would include the risk assessment, maintenance of adequate defense-in-depth, and maintenance of adequate safety margins. This proposed requirement would require that the monitoring programs be designed to detect degradation of SSCs before plant safety is compromised.

(vii) Leak Detection Requirements

In its SRM on SECY–07–0082, the Commission directed the NRC staff to increase the defense-in-depth against large pipe breaks provided by the 10 CFR 50.46a draft final rule. The SRM also directed the NRC staff to evaluate various approaches for enhancing that draft final rule with requirements for improved leak detection methods. The NRC determined that adequate leak detection capability meeting this direction could enhance defense-in-depth for LOCAs larger than the TBS by reducing the likelihood of pipe breaks in the large break region. Thus, proposed 10 CFR 50.46a(d)(2) would require that licensees have leak detection systems available at the facility and implement actions as necessary to identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS.

Because proposed 10 CFR 50.46a would not change the design basis of piping and components that are smaller than the TBS, the requirements of proposed 10 CFR 50.46a(d)(2) would apply only to piping and components that are larger than TBS. The NRC recognizes that leakage detection methods that satisfy these proposed requirements may not be capable of determining whether the source of leakage is from piping or a component that is larger or smaller than the TBS.

Discrimination between leaks in pipes larger or smaller than the TBS would be unnecessary as long as adequate leak detection would be provided for all beyond-TBS piping.

(viii) Programmatic Requirements

The proposed rule would include several specific programmatic requirements in proposed 10 CFR 50.46a(d) that would apply to entities who are approved to implement proposed 10 CFR 50.46a. These requirements would remain applicable to such an entity as long as the entity is subject to the proposed 10 CFR 50.46a alternative ECCS requirements until such time as the licensee permanently ceases operations by submitting the certifications required under 10 CFR 50.82(a). The proposed programmatic requirements would require entities implementing proposed 10 CFR 50.46a to do the following:

(a) Maintain ECCS models and/or analysis methods that demonstrate compliance with the ECCS acceptance criteria.

(b) Maintain adequate reactor coolant leak detection equipment available at the facility and identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS.

(c) Perform a risk-informed evaluation for each potentially risk-significant change (or group of changes) to the facility enabled by proposed 10 CFR 50.46a.

(d) Perform an evaluation to determine the effect of all planned nuclear power plant changes and do not implement any facility change that would invalidate the applicability of the TBS to the facility.

(e) Within 120 days after the outage in which the inspection required in proposed 10 CFR 50.46a(b)(3) has been performed, submit to the NRC a report that details the results of the inspection and any impact these results have on the TBS in accordance with proposed 10 CFR 50.46a(b)(3).

The following discussion describes each of the programmatic requirements.

(a) Maintain ECCS Models and/or Analysis Methods That Demonstrate Compliance With the ECCS Acceptance Criteria

Section 50.46a(d)(1) of the proposed rule would require that calculated results of entity ECCS models and/or analysis methods must demonstrate compliance with the ECCS acceptance criteria as long as the entity is subject to the requirements in proposed 10 CFR 50.46a. Entities also would be required to update ECCS models and/or analysis methods by modifying them as needed to address any error corrections and plant design changes affecting ECCS performance during this time period.

(b) Maintain Adequate Reactor Coolant Leak Detection Equipment Available at the Facility and Identify, Monitor, and Quantify Leakage To Ensure That Adverse Safety Consequences Do Not Result From Leaking Primary Pressure Boundary Components That Are Larger Than the Transition Break Size

The requirement for adequate leak detection capability would be in proposed 10 CFR 50.46a(d)(2) and was discussed in section XXXVI.F.(vii), ''Leak Detection Requirements,'' of this document. Adequate leak detection would be required for all primary coolant pressure boundary piping and other components whose rupture could result in a break larger than the TBS.

(c) Perform a Risk-Informed Evaluation for Each Change (or Group of Changes) to the Facility Enabled by Proposed 10 CFR 50.46a

In addition to meeting all other applicable requirements, entities would be required by proposed 10 CFR 50.46a(d)(3) to perform a risk-informed evaluation for changes enabled by proposed 10 CFR 50.46a. If an entity had a change methodology that was submitted under proposed 10 CFR 50.46a(c)(1)(iv) and approved by the NRC, that licensee would be able to make some changes without NRC approval as long as the acceptance criteria in proposed 10 CFR 50.46a(h)(1) were met. Otherwise, the entity would be required to submit the results of its risk-informed evaluation for NRC review and approval. The entity would need to retain the results of all risk-informed evaluations made under proposed 10 CFR 50.46a(h)(1) and periodically submit a summary of the results to the NRC as required under proposed 10 CFR 50.46a(j)(3).

(d) Perform an Evaluation To Determine the Effect of All Planned Facility Changes and Do Not Implement Any Facility Change That Would Invalidate the Applicability of the TBS to the Facility

For the TBS as defined in 10 CFR 50.46a(a)(9) to properly apply to an entity's facility, that entity would be required to perform an evaluation to demonstrate that the TBS is applicable to that particular facility. For those entities that decide to propose an alternate TBS, a similar evaluation would be needed as part of the basis for the proposed TBS. But after the initial evaluation has demonstrated the applicability of the TBS, an entity could make significant facility changes that would invalidate the initial evaluation. Therefore, after a facility has been approved to use proposed 10 CFR 50.46a, the proposed rule would require the entity to ensure that the TBS remains applicable to the facility by reviewing all subsequent plant changes to ensure that the facility is not modified to the extent that the results impact the applicability of the TBS. Licensees' existing configuration management programs, which contain a process to control plant changes made under 10 CFR 50.59, could be modified, through screening or evaluation, to identify future plant changes that may invalidate the applicability of the NRC's generic studies. Most anticipated plant changes should not impact the TBS, so little, if any, evaluation would be necessary to demonstrate the acceptability of such changes. However, some changes, such as power uprates, would have the potential to affect the TBS by increasing operating temperatures, coolant flow rate, and neutronic flux.

(e) Submit to the NRC a Report Within 120 Days After the Outage When the Inspection Occurred Detailing the Results of the Inspections and Any Impact These Results Have on the TBS in Accordance With Proposed 10 CFR 50.46a(b)(3)

Under proposed 10 CFR 50.46a(b)(3), for RCPB piping whose inner diameter is greater than the TBS, licensees would be required to inspect an NRC-approved risk-informed sample of the similar metal piping circumferential welds in a PWR and the Category A welds (as defined in Generic Letter 88–01) in a BWR in accordance with 10 CFR 50.55a(g) before implementing proposed 10 CFR 50.46a and in every subsequent inservice inspection interval (as defined in 10 CFR 50.55a(y)). Any indications found during this inspection should be dispositioned according to ASME section XI requirements and the effects of any indications on the continued applicability of the TBS should be evaluated.

(ix) Reporting Requirements

(a) ECCS Reporting Requirements

The ECCS reporting requirements currently provided in 10 CFR 50.46(a)(3) were added during the 1988 revision to 10 CFR 50.46 (53 FR 35996; September 16, 1988). The proposed rule (52 FR 6334; March 3, 1987) preceding that final rule prompted several public comments on the reporting requirements, some of which suggested that the reporting requirements be relaxed or even eliminated (see NRC Summary of Public Comments, ''PR–050—52FR06334—Emergency Core Cooling Systems: Revisions to Acceptance Criteria,'' March 3, 1987).

In response to these comments, the NRC identified several reasons for requiring reporting of changes to, or errors in, ECCS evaluation models or in the applications thereof. First, the Commission believed that significant changes or errors raise potential questions about the adequacy of an evaluation model as a whole. Second, the Commission noted that even minor or inconsequential errors and changes constituted a deviation from what previously had been reviewed and accepted. Finally, the Commission also noted that applications of models to areas not contemplated during initial review of the model could result in errors by extending a model beyond its intended range. The Commission stated that, overall, the reporting requirements were a clarification and relaxation of the then-existing requirements.

More than 20 years later, in its rulemaking efforts for 10 CFR 50.46c, the NRC again received numerous public comments about reporting requirements, some of which suggested that the reporting requirements should be relaxed or eliminated. In response to those public comments, the NRC is proposing in the new 10 CFR 50.46a several relaxations to, and clarifications of, the reporting requirements compared to what currently appears in 10 CFR 50.46(a)(3). However, the NRC proposes to leave the deterministic reporting requirements under the 1988 revision to the ECCS regulations largely intact, with the addition of reporting requirements for changes and error corrections affecting the integral time-at-temperature (*i.e.,* ECR) calculation.

Reporting remains necessary for changes to, or errors in, ECCS evaluation models, and applications thereof, for several reasons. First, considering all safety analyses for DBEs, LOCA analysis requires substantially more complex thermal-hydraulic calculations. The reporting requirements allow minor changes to, and error corrections for, these calculations. Second, the reporting requirements provide a regulatory framework for communicating, and addressing the effects of, these changes and errors. And finally, reporting requirements are less burdensome than an alternative that would include topical report revisions and license amendments to address changes and errors. The NRC considered these benefits, in addition to the original, safety-related justification for the reporting requirements set forth in the 1988 rulemaking, when deciding to retain reporting requirements in proposed 10 CFR 50.46a.

The ECCS reporting criteria in proposed 10 CFR 50.46a(j) generally match the criteria in the 10 CFR 50.46c draft final rule in SECY–16–0033. One of the primary differences would be that an entity could propose an alternative definition for a ''significant change'' for breaks above the TBS. Furthermore, proposed 10 CFR 50.46a(j)(1)(iii) would relax the reporting requirements for applicants for a standard design certification (including applicants after the Commission has adopted a final design certification regulation) or applicants for or holders of a standard design approval under 10 CFR part 52 that are approved to use proposed 10 CFR 50.46a. Under proposed 10 CFR 50.46a(j)(1)(iii), standard design approval holders and applicants and standard design certification applicants that are approved to use the alternative ECCS criteria in proposed 10 CFR 50.46a would be required to internally document the nature and estimated effect of all changes and errors affecting ECCS evaluation models. This documentation would be subject to NRC inspection. Also, if the cumulative effect of changes or errors would result in an inability to ensure compliance with the alternative ECCS criteria in proposed 10 CFR 50.46a(f), then proposed 10 CFR 50.46a(j)(1)(iv) 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 standard design approval or standard design certification.

Instead of the existing requirement for the applicant for or holder of a standard design approval or applicant for a standard design certification to report this information to the NRC, the CP, OL, or COL applicant would be responsible for providing an acceptable analysis of the ECCS in its application submitted to the NRC under proposed 10 CFR 50.46a(j)(1)(i)–(iii). The proposed relaxation for applicants for or holders of standard design approvals and applicants for standard design certifications is justified because reporting changes and errors to the NRC before the design is referenced in an application for a CP, OL, or COL would not produce a tangible public health and safety benefit, provided that the changes or errors would not create the potential for the standard design approval or standard design certification to become noncompliant with NRC requirements. There would be no public health and safety benefit because the change or error would not impact the operation of an operating reactor or even the NRC's safety review of an application.

Moreover, instead of the existing 30-day reporting requirements that are in 10 CFR 50.46(a)(3)(ii), the reporting requirements proposed in 10 CFR 50.46a(j)(1)(ii), (j)(1)(iv), (j)(2)(ii), and (j)(2)(iii) would require reports to be submitted to the NRC within 60 days of discovery to better align with the 10 CFR 50.73, ''Licensee event report system,'' report timeframe. As stated in 10 CFR 50.46(a)(3)(ii), discovery of a change or error that exceeds the 10 CFR 50.46 acceptance criteria would be a reportable event as described in paragraph (e) of 10 CFR 50.55, ''Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses''; 10 CFR 50.72, ''Immediate notification requirements for operating nuclear power reactors''; and 10 CFR 50.73. Likewise, discovery of a change or error that exceeds the criteria in proposed 10 CFR 50.46a would also be a reportable event under 10 CFR 50.55(e), 10 CFR 50.72, and 10 CFR 50.73. Since exceeding the proposed 10 CFR 50.46a criteria would be reportable under those regulations, the NRC proposes to align the report required under proposed 10 CFR 50.46a(j)(1) and (2) with the 60-day timeframe in 10 CFR 50.73. The additional time permitted relative to 10 CFR 50.46 would be based on the low initiating event frequency for many of the limiting LOCAs, which would be confirmed on a plant-specific basis in order to employ the proposed 10 CFR 50.46a. The additional time may also result in increased accuracy in the information provided to the NRC in the report required under proposed 10 CFR 50.46a.

The 10 CFR 50.46a proposed rule would clarify existing reporting and corrective action requirements. Proposed 10 CFR 50.46a(j)(1) would distinguish four possible combinations of reporting criteria based upon predicted response, level of significance (*i.e.,* significant or not significant, as defined by the proposed rule), and whether the error, change, or operation would result in any exceedance of acceptance criteria. For each scenario, the proposed rule would provide the required actions, reports, and a time frame for providing the necessary reports.

Presently, the reporting requirements in 10 CFR 50.46(a)(3) require that entities report changes to, or errors in, an ECCS evaluation model, or in the application of the evaluation model, and the estimated effect of the changes or errors on predicted PCT. Proposed 10 CFR 50.46a would expand the definition of a significant change or error to include integral time-at-temperature (*i.e.,* ECR). Any changes or errors that prolong the temperature transient may further challenge the PQD analytical limits; however, they may not significantly change the predicted PCT. As such, this change or error would not be captured in the existing reporting requirements. The NRC would include the reporting requirements for changes and errors in integral time-at-temperature in proposed 10 CFR 50.46a to improve the content and communications of reports submitted to the NRC. The NRC also proposes this requirement to inform the agency's response to future changes to, or errors discovered in, ECCS evaluation models or in the applications thereof.

A significant change or error would occur when the sum of the absolute magnitudes of the respective changes is greater than 50 °F (10 °C) PCT or 1.0 percent ECR for breaks at or below the TBS, as defined in proposed 10 CFR 50.46a(k)(1). A change of 1.0 percent ECR is correlated to a change in calculated ECR for a 50 °F (10 °C) change in cladding temperature for a typical analysis of record PCT. The definition of significant change in proposed 10 CFR 50.46a(k)(1) would be specific to zirconium-alloy cladding. A new definition of significant change or error may be necessary for other cladding materials. In addition, proposed 10 CFR 50.46a(k)(1)(ii) would require the use of maximum local oxidation (*i.e.,* percent ECR) to evaluate the impact of a change or error on the predicted integral time-at-temperature. In proposed 10 CFR 50.46a(k)(2), for breaks above the TBS, the significant change or error is one that results in a significant reduction in the capability to meet the requirements of proposed 10 CFR 50.46a(e)(1) and (f). For LOCAs above the TBS, this significant change or error is higher level than the criteria for LOCAs at or below the TBS to allow for an entity to define alternative criteria for a significant change. If alternative criteria are not defined, then the same reporting criteria in proposed 10 CFR 50.46(k)(1) would be applied.

Existing reporting requirements in 10 CFR 50.46(a)(3) with respect to any ''change to or error discovered in an acceptable evaluation model or in the application of such a model'' have been a source of confusion. Two areas of common misconceptions are related to (1) the baseline PCT and integral time-at-temperature values when estimating a significant change or error (*i.e.,* greater than 50 °F (10 °C)), and (2) the 30-day reporting requirement including ''a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements.'' Similar to the 10 CFR 50.46c draft final rule, the NRC is proposing in this rulemaking to revise the existing reporting requirements to (1) identify more clearly the baseline values to be used in reporting pursuant to the requirements of proposed 10 CFR 50.46a(j), (2) require under proposed 10 CFR 50.46a(j)(1)(ii) and (iv) that entities include, in a report describing a significant change, a proposed scope and schedule for providing a reanalysis, and (3) distinguish between the requirements for proposing a reanalysis scope and schedule, and for proposing to implement corrective action as may be needed to show compliance with proposed 10 CFR 50.46a(e) requirements.

As is the case with 10 CFR 50.46(a)(3), flexibility would exist in terms of the scope of reanalysis that would be required to comply with proposed 10 CFR 50.46a(j)(1)(ii) and (iv), and with the schedule that the reporting entity may propose. Since the promulgation of the 1988 revision to 10 CFR 50.46, the NRC has accepted multiple evaluations, which have been performed within a scope that has been significantly limited when compared to full-scale implementation of an ECCS evaluation model. In these cases, the NRC has concluded that such evaluations satisfied the requirements of 10 CFR 50.46(a)(3)(ii). The Commission does not propose to change its approach in this regard. In addition, a proposed schedule for reanalysis may also incorporate appropriate flexibility. The NRC has accepted proposed schedules that extend as far as four years into the future and that are managed using regulatory commitments that can be changed or updated as operating conditions require and nuclear safety considerations permit. Proposed 10 CFR 50.46a(j)(1)(ii) and (iv) would retain this flexibility.

Proposed 10 CFR 50.46a(k)(1) would provide threshold values for PCT and integral time-at-temperature for entities to use when estimating the effect of a significant change or error. The baseline predictions used to assess a significant change or error should be the PCT and integral time-at-temperature values documented in a plant's updated final safety analysis report (UFSAR). These values should represent the latest LOCA analyses that were submitted and reviewed by the NRC as part of a license amendment request (*e.g.,* power uprate, fuel transition) or as incorporated into the facility licensing basis in accordance with NRC-approved methods, as amended by subsequent annual reports.

Existing 10 CFR 50.46(a)(3) requires entities to include, in a report describing the nature of a significant error or change and its estimated effect on the predicted PCT, a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with 10 CFR 50.46. This requirement has led to a misconception that, when a significant error is reported that does not cause the predicted PCT to exceed its 2200 °F (1204 °C) acceptance criterion, a proposed schedule for providing a reanalysis is not required and taking other action is not needed to show compliance with the requirements. As explained in the preamble to the 1988 revision of 10 CFR 50.46, it has long been the NRC's position that facility operation in excess of the 10 CFR 50.46 acceptance criteria is an immediate safety concern that requires prompt corrective action and the ''taking other action'' language in the rule was intended to address that concern. This position is underscored by the final sentence of the existing 10 CFR 50.46(a)(3)(iii): ''The affected applicant or holder shall propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.'' Therefore, the reporting and reanalysis requirements would be further separated into proposed 10 CFR 50.46a(j)(1) and 10 CFR 50.46a(j)(2) to distinguish the requirements that apply when a significant change or error is identified that results in facility operation in excess of the proposed 10 CFR 50.46a acceptance criteria, from the requirements that apply when a significant change or error is identified that does not result in facility operation in excess of the proposed 10 CFR 50.46a acceptance criteria.

When a change to, or error in, an ECCS evaluation model, or in the application of such a model, is discovered, the entity would be responsible for estimating the magnitude of changes in predicted results to (1) determine if immediate steps are necessary to demonstrate compliance or bring plant design or operation into compliance with proposed 10 CFR 50.46a(e) requirements, and (2) identify reporting requirements. Under proposed 10 CFR 50.46a(j), an entity's obligation to report and take corrective action would vary depending upon whether the licensee's situation falls into one of the following three possible scenarios:

1. *Change or error that does not result in any predicted response that exceeds any acceptance criteria and is itself not significant.*

In this scenario, proposed 10 CFR 50.46a(j)(1)(i) would require the entity to do the following:

a. Submit an annual report documenting the change(s) and/or error(s), along with the estimated magnitudes of changes in predicted results, and the basis for the entity's determination that the change or error is not significant.

b. Revise the UFSAR in accordance with paragraph (e) of 10 CFR 50.71, ''Maintenance of records, making of reports.''

c. Use the revised UFSAR PCT/ECR predictions as a baseline for future evaluations.

2. *Change or error that does not result in any predicted response that exceeds any acceptance criteria but is significant.*

In this scenario, proposed 10 CFR 50.46a(j)(1)(ii) would require the entity to do the following:

a. Within 60 days of making a change, discovering an error, or both, submit a report documenting the change, error, or both, estimated magnitudes of changes in predicted results, the proposed scope and schedule for providing a reanalysis, and a description of and schedule for implementing corrective actions. The reanalysis must be performed within a scope of detail appropriate to address the reported, significant change to, or error in, the ECCS evaluation model, or in its application. The proposed reanalysis schedule should reflect consideration for both the magnitude of the change or error and the available margin to NRC acceptance criteria, once the estimated effect of the change or error is applied to the existing results.

b. In accordance with the schedule proposed in paragraph a., provide the reanalysis to the NRC. This may be accomplished by submitting a subsequent report, pursuant to proposed 10 CFR 50.46a(j)(1), describing the reanalysis and providing the updated results. The reanalysis may be limited in scope but must otherwise be performed using an acceptable evaluation model.

c. Revise the UFSAR to include new evaluation model results in accordance with 10 CFR 50.71(e).

d. Use the revised UFSAR evaluation model results as a baseline for the future evaluations.

3. *Change or error that results in any predicted response that exceeds any of the four acceptance criteria in proposed 10 CFR 50.46a(f).*

In this scenario, proposed 10 CFR 50.46a(j)(1)(iv) and 10 CFR 50.46a(j)(2)(i) would require the entity to do the following:

a. Take immediate actions to bring the plant into compliance with the acceptance criteria.

b. Within 60 days of making a change, discovering an error, or both, submit a report documenting the change, error, or both, estimated magnitudes of changes in predicted results, description of corrective actions and/or compensatory measures, and the proposed scope and schedule for providing a reanalysis, and a description of and schedule for implementing corrective actions. The reanalysis must be performed within a scope of detail appropriate to address the reported change to, or error in, the ECCS evaluation model, or in its application. The proposed reanalysis schedule should reflect consideration for both the magnitude of the change or error and the fact that the change or error has caused the NRC's acceptance criteria to be exceeded. The entity may also need to submit this information in the reports required under 10 CFR 50.55(e), 10 CFR 50.72, and 10 CFR 50.73, as applicable.

c. Provide the reanalysis to the NRC in accordance with the schedule submitted to the NRC. This may be accomplished by submitting a subsequent report, pursuant to proposed 10 CFR 50.46a(j)(1), describing the reanalysis and providing the updated results. The reanalysis must be performed using an acceptable evaluation model. Revise the UFSAR to include new evaluation model results in accordance with 10 CFR 50.71(e).

d. Use the revised UFSAR evaluation model results as the baseline for future evaluations.

As described in scenario 3, proposed 10 CFR 50.46a(j)(1)(iv) and (j)(2)(i) would apply to changes to, or errors in, ECCS evaluation models, or the applications thereof, that affect the predicted performance relative to all of the acceptance criteria contained in proposed 10 CFR 50.46a(f). For example, an error or change in a PWR boron precipitation calculation that invalidates the timing for emergency operating procedures is considered a condition in which a plant's conformance to proposed 10 CFR 50.46a(f)(4) would be uncertain. In this circumstance, the NRC would consider this a potentially serious safety issue in need of immediate attention and potential correction. In proposed 10 CFR 50.46a(j)(2)(i), if a licensee with a COL identifies a change or error that results in the acceptance criteria in proposed 10 CFR 50.46a(f) being exceeded before the Commission has made a finding under paragraph (g) of 10 CFR 52.103, ''Operation under a combined license,'' immediate action to bring a facility into compliance would not be required due to the low safety significance of exceeding the acceptance criteria before the initial startup of the plant. Similarly, in proposed 10 CFR 50.46a(j)(2)(ii) and (iii), for design certification applicants (including an applicant after the Commission has adopted a final design certification regulation) and applicants and holders for standard design approvals, if a change or error correction results in calculated ECCS performance that does not conform to the criteria in proposed 10 CFR 50.46a(e), immediate action would not be required. In this situation, the affected applicant or holder would need to propose appropriate steps to the Commission within 60 days to demonstrate compliance with proposed 10 CFR 50.46a 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.

Based upon the complexity of the ECCS performance demonstration, entities may need to report multiple estimated effects on PCT and integral time-at-temperature to assess available margin to analytical limits under the proposed rule. For example, if the fuel rod population in a reactor core is subdivided, analyzed, and judged against different analytical limits (*e.g.,* burnup-dependent fuel rod populations), the entity may need to report multiple estimated effects and estimated available margin to PCT and integral time-at-temperature analytical limits. This would enhance communication with the NRC, especially for understanding the proposed scope and schedule for reanalysis, if required.

(b) Risk-Informed Evaluation Process Reporting

Section 50.46a(j)(3) of the proposed rule would require periodic reports of changes that required a risk-informed evaluation under proposed 10 CFR 50.46a(d)(3) and were implemented without prior NRC approval under proposed 10 CFR 50.46a(h)(1). Proposed 10 CFR 50.46a(j)(3) would not require the submission of a report if no changes involving minimal changes in risk were made under proposed 10 CFR 50.46a(h)(1) during the reporting period.

(c) TBS Applicability Requirements

Section 50.46a(j)(3) of the proposed rule would require an entity to provide a brief summary of the basis for the entity determination under proposed 10 CFR 50.46a(h)(1)(iii) that each change made under proposed 10 CFR 50.46a(h)(1) would not invalidate the TBS applicability evaluations made under proposed 10 CFR 50.46a(c)(1)(i) for an operating reactor authorized to operate under 10 CFR part 50 on December 31, 2015, or under proposed 10 CFR 50.46a(c)(2) for entities other than those authorized to operate under 10 CFR part 50 on December 31, 2015.

Proposed 10 CFR 50.46a(j)(4) would include reporting requirements for the periodic inspections used to provide assurance that no significant degradation would be occurring in piping systems with an inner diameter greater than the TBS that could undermine the technical basis of the TBS. During each inservice inspection interval, the licensee would be required to submit a summary report within 120 days after completing the outage when the inspections specified in proposed 10 CFR 50.46a(b)(3) are completed. If any reportable indications were found during these inspections, then the licensee's summary report would need to include an evaluation of the impact of these indications on the TBS as well as any other ASME section XI requirement. This report could be combined with the summary report required by 10 CFR 50.55a(b)(2)(xxxii), which has an identical reporting time requirement. The level of detail in the report specified in proposed 10 CFR 50.46a(j)(4) would be consistent with the report specified in 10 CFR 50.55a(b)(2)(xxxii).

(x) Documentation Requirements

Section 50.46a(l) of the proposed rule would require that entities maintain records sufficient to demonstrate compliance with proposed 10 CFR 50.46a requirements. When making changes under proposed 10 CFR 50.46a(h), entities would be required to document the bases for concluding that the acceptance criteria in proposed 10 CFR 50.46a(h)(1) and (h)(2) would be satisfied and would continue to be satisfied as long as the entity is subject to the proposed 10 CFR 50.46a. Entities would be required under proposed part II of appendix K to 10 CFR part 50 to document the bases of evaluation models used to perform ECCS calculations. Entities also would be required to document plant design changes made under proposed 10 CFR 50.46a by updating the FSAR in accordance with the requirements in 10 CFR 50.71(e). All documentation could be reviewed during NRC inspections and/or audits.

(xi) Submittal and Review of Applications

(a) Initial Application for Implementing Proposed 10 CFR 50.46a Requirements

When an entity would first apply to use the proposed 10 CFR 50.46a requirements, that entity would need to submit an application under 10 CFR 50.34, 10 CFR 50.90, or 10 CFR part 52 for NRC review and approval. The initial application would need to contain the information specified in proposed 10 CFR 50.46a(c)(1)(i) through (vii), as applicable. This would include information related to the applicability of the TBS to the facility (if the entity desires to develop an alternate TBS, the information needed in the application would include those items discussed in section XXXVI.F.(xii), Applicability to New Reactor Designs,'' of this document); information identifying the ECCS analysis methods to be used; information describing the risk-informed evaluation for all changes enabled by the proposed rule and proposed in the application; information describing the proposed process for making risk-informed changes without prior NRC approval (if the applicant would seek approval of such a process); information describing non-safety equipment to be credited for compliance with the ECCS acceptance criteria in proposed 10 CFR 50.46a(e); and information describing how the leak detection program would satisfy the criteria in proposed 10 CFR 50.46a(d)(2).

An entity's initial change from its existing ECCS analysis would not need to be reviewed by the entity under the provisions of 10 CFR 50.59 because the proposed rule would require NRC review and approval of the initial application to implement the proposed 10 CFR 50.46a requirements. After the proposed 10 CFR 50.46a evaluation models and initial ECCS LOCA analyses were established by approval of the proposed 10 CFR 50.46a application, subsequent changes to ECCS analyses would be controlled by the process in 10 CFR 50.59 (which provides criteria for determining which changes are within the licensee's authority to make) and the requirements in proposed 10 CFR 50.46a(j) for reporting changes to evaluation models and analysis methods (whether from correction of errors or changes). The initial application could request one or more facility changes.

The initial application also would include a request for NRC approval of a process for evaluating the acceptability of future facility changes enabled by proposed 10 CFR 50.46a using the provisions in proposed 10 CFR 50.46a(h)(1). If approval of a process for evaluating future changes were requested, the application would need to include the information described in proposed 10 CFR 50.46a(c)(1)(iv).

(b) Subsequent Applications for Changes Under Proposed 10 CFR 50.46a

After NRC approval of an entity's initial application addressing ECCS analyses and the risk-informed evaluation processes under the proposed rule, the entity could submit applications for proposed changes under 10 CFR 50.90. These license amendment applications would need to contain the following:

- For licensees, the information required by 10 CFR 50.90;
- Information from the risk-informed evaluation demonstrating that the risk criteria, defense-in-depth criteria, safety margins, and performance monitoring criteria in proposed 10 CFR 50.46a(h)(2) and (h)(3) would be met;
- Information demonstrating that the ECCS acceptance criteria in proposed 10 CFR 50.46a(e)(1) would be met; and
- Information demonstrating that the proposed change would not increase the LOCA frequency of the facility by an amount that would invalidate the applicability of the TBS to the facility.

After reviewing the application with the proposed change, the NRC could approve the change if it complies with the criteria in proposed 10 CFR 50.46a(h)(2) and (h)(3) and all other applicable NRC regulations, including the current requirements for plant physical security. In addition, the NRC would evaluate potential impacts of the proposed change on facility security to ensure that the change would not significantly reduce the ''built-in capability'' of the plant to resist security threats, thus ensuring that the change would not be inimical to the common defense and security and would provide adequate protection to public health and safety.

Entities who would not submit a request for NRC approval of a process for evaluating the acceptability of future changes enabled by proposed 10 CFR 50.46a using the provisions in proposed 10 CFR 50.46a(h)(1) could make such a request at any time by submitting the application containing the information described in proposed 10 CFR 50.46a(c)(1)(iv).

(xii) Applicability to New Reactor Designs

As discussed in sections XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' and (iii), ''Determining the Ongoing Validity of the Transition Break Size,'' of this document, the TBS was established in NUREG–1829, which was based on the commercial LWR designs authorized to operate under 10 CFR part 50 on December 31, 2015. LWRs authorized to operate under 10 CFR part 52 or after that date may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and thus the TBS. New LWR reactor designs (*i.e.,* the class of commercial LWR reactors authorized to operate under 10 CFR part 50 after December 31, 2015, or under 10 CFR part 52) may have similar piping materials, service conditions and operational programs, piping designs, and mitigation and control of age-related degradation programs as those found in currently operating plants. There are several new LWR designs for which the NRC expects that the frequency of LOCAs above the TBS could be as low as it is at current LWRs. Thus, applicants can apply the proposed 10 CFR 50.46a requirements to these new reactor designs with adequate justification. New large LWR or small modular reactor entities under 10 CFR part 50 or part 52 who wish to apply proposed 10 CFR 50.46a would have to submit an analysis for NRC approval, as specified in proposed 10 CFR 50.46a(c)(2), demonstrating why it would be appropriate to apply the alternative ECCS requirements and what the appropriate TBS would be in order for the new design to meet the proposed 10 CFR 50.46a rule.

In its analysis, the entity would be required to demonstrate that the proposed reactor facility is similar to reactors authorized to operate under 10 CFR part 50 on December 31, 2015. In addressing similarity of the proposed design to reactors authorized to operate under 10 CFR part 50 on December 31, 2015, the entity should address design, construction and fabrication, and operational factors that include, but are not limited to:

- The similarity of the piping materials of construction and construction techniques for new reactors to those in the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- The similarity of service conditions and operational programs (*e.g.,* in-service inspection and testing, leak detection, QA, etc.) for new reactors to those for the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- The similarity of piping design (*e.g.,* pipe sizes and pipe configuration) for new reactors to those found in the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- Adherence to existing regulatory requirements, regulatory guidance, and industry programs related to mitigation and control of age-related degradation (*e.g.,* aging management, fatigue monitoring, water chemistry, stress corrosion cracking mitigation, etc.); and
- Any plant-specific attributes that may increase LOCA frequencies compared to those used to support the development of the proposed TBS.

Proposed 10 CFR 50.46a(c)(2) would also require that the analysis include a recommendation for an appropriate TBS and a justification that the proposed TBS is consistent with the technical basis for the proposed 10 CFR 50.46a (*i.e.,* the TBS would include sufficient margin to provide assurance that, when considering the limited availability of operating experience data and the uncertainty in the estimation of LOCA frequency, the estimated frequency of breaks larger than the TBS for all initiators would not exceed 10^{-5} per year). For those new reactor (large LWR and small modular reactor) designs that employ design features that effectively increase the break size via opening of specially designed valves to rapidly depressurize the RCS during any size LOCA, justification of the acceptability of a TBS would also be necessary. The justification should consider the integral impacts of fluid conditions such as flow quality at the discharge node(s), which can substantially affect the temperature transient experienced by the fuel. The methodology used to determine the proposed TBS should be described in the justification.

(xiii) Changes to 10 CFR 50.46

The NRC is proposing several changes to 10 CFR 50.46. Proposed 10 CFR 50.46(a) would include a pointer to proposed 10 CFR 50.46a as a voluntary alternative. Proposed 10 CFR 50.46(a)(3)(i) would be revised to permit use of the ECCS criteria in proposed 10 CFR 50.46a(f) instead of 10 CFR 50.46(b). To align with these changes, the applicable ECCS reporting requirements from proposed 10 CFR 50.46a would be added as proposed 10 CFR 50.46(a)(iv) and 50.46(a)(v) for entities that are approved to use proposed 10 CFR 50.46a(f). These changes would not invalidate current exemptions from 10 CFR 50.46 and could reduce the number of exemptions for non-zircaloy and non-ZIRLO claddings due to the allowance to use the fuel technology-neutral proposed 10 CFR 50.46a(f) criteria in place of the prescriptive 10 CFR 50.46(b) criteria.

(xiv) Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis

In the public comments on the regulatory basis, representatives of the nuclear power industry did not present a unanimous recommendation among the alternatives provided by the NRC. Alternative 5 would have had the NRC pursue rulemaking to modify 10 CFR 50.46 to allow for insights from piping fracture mechanics to be used to disposition large-break LOCAs and, thus, fuel dispersal during large-break LOCAs. NEI and Westinghouse supported a modified version of alternative 5 that would have aligned with EPRI's ''Alternate Licensing Strategy.'' The EPRI Alternate Licensing Strategy proposed to utilize piping fracture mechanics to show that leaks in large pipes can be detected and operator action taken with sufficient probability before the pipe breaks, such that the larger LOCAs that could challenge fuel integrity would not occur. EPRI submitted its Alternate Licensing Strategy to the NRC via topical reports in April 2024.

NEI also supported, along with the BWR Owners' Group, alternative 4, a rulemaking that would provide a generic bounding assessment of dose and use risk insights for post-FFRD consequences. The former alternative was not viewed by NEI and the BWR Owners' Group as a solution for BWRs since it would utilize the leak-before-break (LBB) concept and LBB has only ever been approved for use in PWRs. Historically, the NRC has not allowed LBB to be applied to ECCS design, containment design, or equipment qualification, as described in the preamble to a 1987 final rule amending GDC 4, ''Environmental and dynamic effects design bases'' (52 FR 41288; October 27, 1987). The PWR Owners' Group and Framatome expressed support for an approach that would employ integrated decision-making as done in the disposition of in-vessel downstream effects associated with generic safety issue (GSI)–191.

Additionally, there was support from NEI, the BWR Owners' Group, and Westinghouse for alternative 2, a rulemaking to recategorize large-break LOCAs as beyond-design-basis accidents, though they recommended that a rulemaking with an updated 10 CFR 50.46c be pursued separately from this increased enrichment rulemaking due to the perceived schedule impact. Aspects of Framatome's response also aligned with this alternative, such as their statement in their proposed path forward that ''the amount of dispersal and coolability evaluation in a [large-break LOCA] would be based on fully best-estimate models (*i.e.,* conditions consistent with expected, nominal operating conditions without biases or uncertainties).'' Moreover, in response to question 2 posed to the public on fuel dispersal in the regulatory basis **Federal Register** notice, NEI, Westinghouse, and Framatome stated that they believed that with a true best-estimate analysis for large-break LOCAs, it would be reasonable to demonstrate that no high burnup rods rupture and, therefore, disperse fuel, especially when combined with the anticipated benefits from ATF.

Industry recommendations stated schedule as a large reason for their support of particular alternatives. The regulatory basis attempted to qualitatively compare the rulemaking schedule impacts of each alternative. After further consideration of these alternatives, the NRC's accuracy of the estimated impacts has improved and the qualitative schedule estimates presented in the regulatory basis have been updated significantly. The NRC now considers that alternative 2 would take less time than alternatives 4 and 5 because the previous work on the draft 10 CFR 50.46a rulemaking could be leveraged. For example, the technical basis and rule language were already developed by the NRC, so most of the work would be in confirming that the technical basis is still applicable, modernizing the rule, and developing guidance. In addition, the previous work performed on the previous 10 CFR 50.46c rulemaking could be leveraged to develop a performance-based rule with guidance that would facilitate future efforts to pursue other licensing pathways. As such, the risk-informed approach in alternative 2 and the performance-based approach in the previous 10 CFR 50.46c rule have been adapted into this proposed rule.

The Union of Concerned Scientists and two members of the public stated that they did not support any approach that allows for fuel dispersal. Another member of the public recommended that the NRC wait until more research and analysis is performed for fuel dispersal. The NRC considered all these comments, among other factors, as discussed in section XXXVI.F.(i), ''Overview,'' of this document, when deciding to pursue a performance-based alternative 2.

XXXVII. Specific Questions

The NRC is seeking advice and recommendations from the public on the proposed rule, draft guidance documents, and a draft regulatory analysis. The NRC is particularly interested in comments and supporting rationale from the public on the following:

Expedited Construction of Certain Structures, Systems, and Components

Question 1: Should the NRC consider granting one or more general licenses to begin construction activities as part of an existing or future standard design certification rule? If the NRC were to issue such a general license, should the NRC require that the general license holder reference another plant that has completed construction (resulting in the general license excluding first of a kind applicants)? If not, what conditions should the NRC include in the general license to ensure that the construction activities authorized by the general license can be completed safely? Please provide a basis for your response.

Question 2: Would it be useful for the NRC to issue regulations to provide for general licenses related to production and utilization facilities for other activities described under section 109 of the AEA, with the exception of import, export, construction, or operation? Please provide a basis for your response.

Question 3: Does the proposed regulatory change achieve its intended objective of allowing applicants to make business decisions on the appropriate balance between expedited construction and the regulatory risk that changes will be necessary to address safety issues? Are there other approaches that can both provide the needed flexibility while better allowing applicants to structure the degree of regulatory risk they take on through interactions with the NRC staff (*e.g.,* hold-points during construction for NRC inspection)?

Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

In accordance with Commission direction in the staff requirements memorandum (SRM), dated July 21, 1993, on SECY–93–087, ''Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs,'' dated April 2, 1993, the NRC staff considers common cause failures (CCFs) in digital instrumentation and controls (DI&C) systems to be beyond design-basis events (BDBEs). In addition, SECY–93–087 states that common mode failures could defeat the redundancy achieved by the hardware architectural structure, and could result in the loss of more than one echelon of defense-in-depth provided by the monitoring, control, reactor protection, and engineered safety functions performed by the DI&C systems. Therefore, a CCF could result in ''a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report'' (see 10 CFR 50.59 (c)(2)(vi)), and a licensee would have to obtain a license amendment pursuant to 10 CFR 50.90 prior to implementing the proposed DI&C modification.

Question 4: In light of these considerations, do the proposed revisions to 10 CFR 50.59 adequately address issues that may arise from facilities that have transitioned to DI&C? If not, please provide specific comments on changes that would be necessary to address these issues.

Updates to Construction Permit Requirements and Related Licenses

Question 5: Are there any additional requirements in 10 CFR 50.34 that the NRC should consider changing to be more technology-inclusive or provide additional clarity? Should conforming changes to 10 CFR 50.67 be made to be consistent with 10 CFR 50.34 wording updates? Please provide a basis for your response.

Question 6: Are there any requirements in 10 CFR 50.34 that the NRC should consider changing that are posing undue barriers to timely and efficient submittal of CP applications, or which are unnecessary at the CP stage? Please provide a basis for your response.

Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Part 52

Question 7: The proposed revisions to the definitions in each of the appendices in 10 CFR part 52 identify the specific sections in the generic DCD that contain the various categories of Tier 1 information (*i.e.,* definitions and general provisions, design descriptions, ITAAC, significant site parameters, and significant interface requirements). The proposed revisions to section VIII in each of the appendices in 10 CFR part 52 describe the change control process associated with each category of Tier 1 information. Will there be adequate regulatory clarity regarding the category of Tier 1 information in the generic DCD such that the change control process can be readily identified? Please provide a basis for your response.

Question 8: The proposed revisions to section VIII.B of appendix D to 10 CFR part 52 would effectively treat Tier 2* information for the AP1000 design as Tier 2 information during construction as well as operation. However, for appendices A (ABWR) and E (ESBWR) Tier 2* information would not be treated as Tier 2 information until after the plant has achieved full power. The basis for this difference is the construction and licensing experience gained from the COLs referencing the AP1000 design which is lacking for the ABWR and ESBWR designs. Should the flexibility provided to the AP1000 design in appendix D during construction also be extended to the ABWR and ESBWR designs in appendices A and E? Please provide a basis for your response.

Question 9: Paragraph (b) of 10 CFR 53.1535 states ''The holder of a COL under this part for which the NRC has not yet made a finding in accordance with 10 CFR 53.1452(g) must request amendments required by 10 CFR 53.1525 or 53.1550 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment will not be granted.'' This differs from provisions in 10 CFR part 52 by adopting requirements that explicitly support a change process described in RG 1.237, ''Guidance for Changes During Construction for New Nuclear Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR part 52.'' Should the provisions in 10 CFR part 52 be revised to also explicitly support this change process? Please provide a basis for your response. Question 10: The proposed revisions to 10 CFR 52.98 and 53.1550 allow holders of an OL or COL that reference a manufacturing license (ML) to make changes to the FSAR without obtaining a license amendment if the changes are identical to changes approved by the Commission by amendment to the ML for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the ML and not involve any additional changes that would require an amendment to its OL or COL. Should this flexibility be provided to COLs that reference a design certification? Please provide a basis for your response.

Question 11: Should the proposed rule changes to 10 CFR 50.59 described in section XII of this document also be applied to the 10 CFR 50.59-like process in the appendices of 10 CFR part 52? Please provide a basis for your response.

Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

Conduct of Exercises

The NRC is considering risk-informed revisions to the conduct of exercises in section F, ''Training,'' of appendix E to 10 CFR part 50. Paragraph IV.F.2.b of appendix E to 10 CFR part 50 requires a biennial exercise of the onsite plan to ensure that emergency response organization (ERO) proficiency in key skills is maintained. The NRC is assessing risk-informed revisions to the conduct of exercises to ensure ERO proficiency is maintained through the appropriate frequency of exercises and performance of the exercise cycle as required by paragraph IV.F.2.j of appendix E to 10 CFR part 50. Licensees conduct drills and exercises to develop and maintain key skills such as timely and accurate classification and notification of events; assessment of radiological releases and development of protective actions; planning, analysis, and implementation of mitigative actions; worker protection during emergency conditions; and coordination with offsite response organizations to include dissemination of information to the public through media channels. Following each exercise, licensees perform a critique of their actions to comply with 10 CFR 50.47(b)(14) which states, in part, ''deficiencies identified as a result of exercises or drills are (will be) corrected.'' In 1996, the NRC revised the emergency plan regulations for exercises from annual to biennial (61 FR 30129; June 14, 1996) to allow greater flexibility in licensee emergency planning training activities while maintaining readiness. The NRC is considering another revision to the frequency to either a triennial, or quadrennial basis. For example, a quadrennial exercise cycle could be supplemented with additional drills to ensure that proficiency is maintained between exercise years. Additionally, the NRC is considering additional language in paragraph IV.F.2.c of appendix E to 10 CFR part 50 to allow for the use of tabletop exercises or other performance enhancing methods when offsite authorities are not participating in the exercise of the onsite emergency plan required by paragraph IV.F.2.b. These potential changes could increase scheduling flexibility and reduce the resource burden while maintaining reasonable assurance that ERO proficiency will be maintained. If the exercise frequency is changed to quadrennial for some sites, the NRC is considering a corresponding change to the exercise cycle from 8 to 16 calendar years in paragraph IV.F.2.j.(iii) of appendix E to 10 CFR part 50 to reflect the proposed change to quadrennial exercises. However, a change to the exercise cycle may impact the ability of the ERO to demonstrate proficiency in the key skills necessary to respond to various emergency events, particularly in sites with increased turnover in ERO members. During the 1996 change from annual to biennial, the NRC received several comments about the ability of licensees to maintain proficiency with a longer gap between exercises and how this increased gap could also affect the performance of State and local responders. These comments were ultimately resolved and the NRC determined that reasonable assurance remained with the change in exercise frequency. With an additional three decades of experience, advances in all-hazards emergency preparedness, and a range of potential new advanced reactor designs in the future, the NRC is again interested in comments on the conduct of exercises. The NRC urges stakeholders to provide comments on the following questions:

Question 12: What are the potential benefits and challenges of a change to the conduct of exercises to applicants and licensees and offsite response organizations? Please provide a basis for your response.

Question 13: What specific criteria related to maintaining onsite ERO proficiency should be considered in evaluating whether a biennial, triennial, or quadrennial exercise is appropriate? Please provide a basis for your response.

Question 14: How would a potential change impact the conduct of exercises of the offsite plans required under paragraph IV.F.2.c of appendix E to 10 CFR part 50? Please provide a basis for your response.

Question 15: If there was a change to the exercise frequency, should the exercise cycle be changed or otherwise be revised to ensure there is adequate opportunity for the ERO to demonstrate adequate performance under paragraph IV.F.2.j of appendix E to 10 CFR part 50? Please provide a basis for your response.

Considerations for Emergency Planning Zones

The proposed change to 10 CFR 50.33(g)(1) would provide certainty for a site-boundary EPZ for facilities less than 300 MWt. This proposed change is based on NRC staff review of available technical analyses that estimate radiological consequences for a variety of reactor designs and design power levels. The NRC is considering factors that may obviate the need for applicants of certain reactor designs to perform detailed analyses to support a site-boundary EPZ determination or reach a determination that no EPZ is needed. Such factors may include use of novel fuel forms or the performance of functional containment that may generically demonstrate that predetermined, prompt protective measures are unwarranted. The NRC is also considering factors that may necessitate additional analysis by the applicant for facilities less than 300 MWt.

Question 16: Are there additional design factors or analyses that should be considered to provide certainty on EPZ determinations? Please address within the comment the technical basis for consideration and how they relate to EPZ determinations and, specifically, the criteria of 10 CFR 50.33(g)(2).

Question 17: Should design features, other than power level, or site attributes be considered for determining when additional analysis by the applicant is necessary to justify site-boundary EPZ for facilities less than 300 MWt? Please provide the basis for your response.

Optional Submittal of Operational Programs

The NRC is proposing to add a new provision in 10 CFR 52.158(c) that will allow an applicant for an ML to voluntarily submit standardized operational program information for approval and to revise 10 CFR 52.171 to provide finality for such information that is approved by the NRC in the ML review. The NRC is proposing these changes in response to stakeholder interest in the context of deployment of factory-fabricated reactors.

Question 18: Should the NRC consider making similar changes to the requirements in 10 CFR 52.47, 52.63, 53.1239, and 53.1263 for design certifications? Please provide a basis for your response.

Question 19: If the NRC were to add a provision for the optional submittal of standardized operational program information in a design certification application, please describe how change control should be accounted for as a part of certifying the design.

Early Site Permit for Nuclear Power Plants

Question 20: With the proposed change to remove the requirement for renewal, all changes to update the early site permit (ESP) must be made by amendment. What other options could the staff consider to increase the useability of an ESP? Could the provisions in the, ''Commission Policy Statement on Deferred Plants,'' (52 FR 38077; October 14, 1987) be applied to ESPs? Please provide a basis for your response.

Question 21: For a COL application that references an ESP, the changes proposed in 10 CFR 52.39 and 53.1188 would limit finality on safety and environmental issues to 20 years following ESP issuance or approval of an update amendment. Because the proposed rule would also retain the requirement for applicants to review for new and significant information when referencing an ESP, the NRC requests input on whether limiting finality to 20 years is necessary to ensure that all relevant environmental information is considered in licensing decisions.

Manufacturing License Term Extension

Question 22: The manufacturing license term extension aligns with the recently promulgated July 2, 2025, direct final rule, ''Revising the Duration of Design Certifications,'' where the NRC replaced the 15-year duration for design certifications with a 40-year duration period. The Commission is interested in determining if a manufacturing license or design certification term limit is necessary. Should the NRC eliminate time limits for manufacturing licenses, design certifications, or both? Please provide a basis for your response.

Nuclear Power Plant License Renewal

Safety Guidance

The NRC currently has separate safety guidance for initial and subsequent renewal to address 40 to 60 years and 60 to 80 years of operation, respectively. In addition, some licensees may soon apply for a third renewal, for which no guidance has yet been developed. One option would be to maintain a single set of safety guidance that represents the state-of-the-art for aging management, covering initial renewal, subsequent renewal, and periods beyond. This guidance would identify an acceptable approach for managing aging and evaluating time-limited aging analyses, regardless of the renewal period. The question below applies to the Generic Aging Lessons Learned Report for initial (NUREG–1801) and subsequent (NUREG–2191) license renewal and the Standard Review Plan for initial (NUREG–1800) and subsequent (NUREG–2192) license renewal.

Question 23: Should the NRC consolidate its safety guidance into one collection that is time-independent (*i.e.,* the same guidance applying to all periods of extended operation), instead of having separate guidance for initial renewal, subsequent renewal, and the upcoming third renewal term? Is there a different approach that should be considered? Please provide a basis for your response.

Implementation of Aging Management

Question 24: With the proposed change to use a 40-year ''tack-on'' license, what regulatory approach should the NRC take with respect to aging management activities that are currently required to be implemented prior to the period of extended operation? Should conditions that are currently included in the renewed license be revised or instead imposed by different means? Please provide a basis for your response.

Considerations for Shorter License Renewal Term

Question 25: Should the NRC retain an option for licensees seeking shorter renewals (those that would not exceed 40 years when combined with the number of years remaining on an existing license) to apply for a ''supersession'' license?

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

Expansion of 10 CFR 71.55(g) Enrichment Levels

The NRC is proposing to change 10 CFR 71.55(g) to expand the exception from 10 CFR 71.55(b) for enrichment levels between 5.0 and 10.0 weight percent U–235. The NRC is not considering expanding the exception for enrichments from 10.0 weight percent U–235 up to but less than 20.0 weight precent U–235 for two reasons: (1) limited technical data with respect to overall mechanisms and consequences of a canister breach allowing water in-leakage that would provide additional risk insights; and (2) the current transportation package certification path using 10 CFR 71.55(c) adequately addresses the potential need to ship UF_6 enriched above 10.0 weight percent U–235, has no enrichment limitation, and is technology neutral.

Question 26: 10 CFR 71.55(c) provides a certification pathway that has limited prescriptive requirements and no enrichment limitations. Should the NRC add another option to the exception in 10 CFR 71.55(g) to account for enrichment levels from 10.0 weight percent U–235 up to but less than 20.0 weight percent U–235? Please provide a basis for your response.

Regulatory Certainty of Performance-Based ECCS Rod Embrittlement Criteria

Question 27: Will there be adequate regulatory certainty if the fuel system criteria for uranium oxide or uranium-plutonium oxide pellets within cylindrical zirconium-based cladding are located in guidance and 10 CFR 50.46a(f) of the proposed rule is performance-based? Please provide a basis for your response.

Inspection Requirements

The NRC is proposing to add non-destructive evaluation inspection requirements for circumferential welds in piping systems with inner diameters that are larger than the TBS to provide assurance that an acceptable level of performance monitoring is maintained in these systems such that breaks larger than the TBS remain highly unlikely.

The NRC has evaluated several sampling schemes to determine the most effective approach for providing assurance against breaks larger than the TBS in these systems. These inspections may support plant-specific applicability of the TBS. The option in this proposed rule is:

- Inspecting a smart sample of those welds with attributes (*e.g.,* operating temperature, type of welding, fabrication history) most conducive to degradation and having the highest failure potential before implementation of the proposed rule and in every subsequent inservice inspection interval thereafter.

Other schemes include:

- Inspecting all welds at least one-time over the plant's remaining licensing period.
- Inspecting a random sample of the weld population before implementation of the proposed rule and in every subsequent inservice inspection interval thereafter.

Question 28: Please provide feedback on the effectiveness of the proposed sampling scheme in providing assurance against breaks larger than the TBS in these systems. Are there pros and cons to the other sampling schemes, an alternative sampling scheme, or a holistic approach relying on existing performance monitoring strategies that the NRC should consider, and why? Should the sampling scheme be required before or as plants enter into extended operation beyond what is currently authorized in the operating fleet (*e.g.,* if authorized beyond 80 years)?

The NRC is also proposing a requirement to evaluate the effect of any identified indications found during inspections required by this proposed rule on the TBS. The NRC recognizes that any such findings must be dispositioned under ASME section XI, which would require a demonstration that the indications remain acceptable for continued service or are repaired before placing the component back into service. However, the NRC has not included criteria in this proposed rule regarding what constitutes an acceptable additional evaluation of any inspection findings. The NRC is considering that an acceptable additional evaluation would consist of two parts. The first part would be a deterministic or probabilistic fracture mechanics analysis to demonstrate that the failure likelihood of any indications identified during the inspection resulting in a likelihood of ruptures greater than the TBS is less than 10^{6} per year. The second part would, if the indications are evidence that active degradation is occurring, recharacterize the risk-informed inspection examination category for the population of all similar welds to be commensurate with the expected degradation mechanism. All future inspections of this weld population would then be performed according to the ASME section XI requirements associated with that inspection category.

Question 29: The NRC is interested in obtaining feedback on the efficacy of this proposed evaluation method and more broadly on what an acceptable additional evaluation of any indications found during the inspection should entail.

DG–1261—Breakaway Oxidation

Question 30: The DG–1261, Revision 1, ''Measuring Breakaway Oxidation Behavior,'' contains breakaway oxidation testing criteria. The NRC is interested in obtaining feedback on this regulatory position. Please provide a basis for your response. The NRC is interested in specific information on how quality assurance practices and industry operating experience have evolved since the underlying research was published, and whether these developments should inform potential adjustments to this provision.

Regulatory Analysis

Question 31: The NRC is interested in feedback on the draft regulatory analysis, in particular, the benefits associated with power uprates under the proposed 10 CFR 50.46a. Please provide a basis for your response.

DG–1426—Risk-Informed Evaluation and Risk-Informed Evaluation Process

An entity that wishes to make changes under the proposed rule would have to perform a risk-informed evaluation and demonstrate that the proposed change meets the acceptance criteria in proposed 10 CFR 50.46a(h). The acceptance criteria in the proposed rule would include that the total increases in core damage frequency (CDF) and large early release frequency (LERF) due to the proposed change are very small and that the overall plant baseline risk remains small. ''Small'' and ''very small'' are defined in RG 1.174 and DG–1426. The acceptance criteria are limited to very small changes instead of small changes, in part, because the TBS initiating event frequency is the same as the limit for small changes (*i.e.,* change in CDF of approximately 1×10^{-5}). If the acceptance criteria were limited to small changes, a PRA would show that not mitigating a TBS or DEGB LOCA is always less than the small threshold, making the risk assessment unnecessary and overly burdensome.

An entity seeking to make changes under the proposed rule without prior NRC approval would have to have an NRC-approved risk-informed evaluation process and demonstrate that any increases in the estimated risk are minimal. The proposed acceptance criteria for proposed changes that may be made without prior NRC approval were chosen to be an order of magnitude lower than the acceptance criteria for changes that require prior NRC approval for consistency with other established risk-informed programs.

The DG–1426 contains draft guidance that would be acceptable to the NRC for performing a risk-informed evaluation and establishing a risk-informed evaluation process that satisfies the requirements of the proposed rule. This DG follows the structure for risk-informed changes in RG 1.174. Entities would be able to leverage changes made for previous risk-informed amendments, such as 10 CFR 50.69, ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,'' or Technical Specification Task Force Traveler 505, ''Provide Risk-Informed Extended Completion Times—RITSTF Initiative 4B,'' when performing the risk-informed evaluation. Therefore, the NRC does not expect that the risk-informed evaluation would be burdensome.

Under current 10 CFR 50.59, ''Changes, tests and experiments,'' a licensee would need to obtain a license amendment if there would be more than a minimal increase in frequency or consequences of accidents or malfunctions. As described in the preamble for the 10 CFR 50.59 final rule (64 FR 53582; October 4, 1999), PRAs (*i.e.,* total increases in CDF and LERF) may not be used to determine if the minimal increase standard is met because 10 CFR 50.59 concerns DBEs, while RG 1.174 includes risk from severe accidents beyond the design basis. Similar to the change in proposed

10 CFR 50.59 as described in section XII, ''Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods,'' of this document, the risk-informed evaluation process in proposed 10 CFR 50.46a would provide additional flexibility by allowing a licensee to use the total increases in CDF and LERF to determine if the increase in risk associated with a change enabled by this proposed rule would be minimal.

In this proposed rule, the NRC is including the risk-informed evaluation and risk-informed evaluation process that were included in the previously proposed but discontinued 10 CFR 50.46a rulemaking in SECY–10–0161. As part of the development of that previous rule, the NRC received comments from the public and the Advisory Committee on Reactor Safeguards on the risk-informed evaluation and risk-informed evaluation process related to, among other things, the use of the ''very small'' threshold for changes, the definition of ''minimal increase in risk,'' PRA maintenance and upgrade, the evaluation of cumulative risk, and the relationship of the risk-informed evaluation process to 10 CFR 50.59. In addition, the NRC staff received direction from the Commission in SRM–SECY–07–0082 to use the ''very small'' threshold for changes. While some of these issues are addressed in this proposed rule, the NRC is seeking additional information to identify if further changes are needed.

Question 32: The NRC is interested in any additional considerations or feedback on the risk-informed evaluation and risk-informed evaluation process proposed in 10 CFR 50.46a and the implementing guidance in DG–1426, including whether they should be modified or removed from the proposed rule in their entirety. Specifically, what are the advantages and disadvantages of including a risk-informed evaluation as a necessary part of implementing the rule? In addition, what are the advantages and disadvantages of restricting all changes to very small risk increases? Would the risk-informed evaluation, restricting changes to very small risk increases, or both, make it burdensome to implement changes under the proposed rule? What are the advantages and disadvantages of removing the risk-informed evaluation and risk-informed evaluation process from the proposed rule? If the NRC removed the risk-informed evaluation and risk-informed evaluation process from the proposed rule, how should changes that could impact the risk calculation be evaluated? Please provide any supporting basis or justification for your response.

New Reactor Applicability

Question 33: The proposed rule would establish a TBS based on nuclear power reactor licensees' operating experience with piping materials, piping designs, service conditions, operational programs, and mitigation and control of age-related degradation programs. The proposed rule would allow new reactors to submit for NRC approval an alternate TBS that includes a demonstration that the proposed reactor design is similar to the designs of reactors authorized to operate under 10 CFR part 50 on December 31, 2015. This provision might not be applicable to some new reactor designs, including small modular reactors, due to fundamental design differences. For example, some of the new reactor designs may have novel LOCA mitigation strategies, such as passive features or use of valves and associated flanges in the piping system to ensure coolant inventory retention. Some applicants may be able to demonstrate that the failure frequencies at particular locations in the piping system are extremely low and can be maintained extremely low during plant operation. In lieu of the TBS, the failure frequencies of the piping system may be established and maintained extremely low during the plant operation to justify relaxation of the required assumptions for the analyses similar to the proposed rule (*e.g.,* a realistic treatment of defense-in-depth features and best-estimate analyses). The NRC is interested in receiving feedback on the applicability of the proposed rule to such new reactor designs. Please include in your feedback whether it is appropriate to risk-inform the LOCA requirements in light of novel design features, and language that would appropriately allow entities to treat breaks at particular locations in the piping systems for new reactor designs similarly to break sizes larger than the TBS in the proposed rule. Please also include in your feedback whether the option for a non-size-based TBS would improve the applicability of the proposed rule to these designs along with any supporting basis or justification for your response.

Alternate Transition Break Size

Question 34: The NRC incorporated in the proposed rule enabling language to allow currently operating power reactor licensees to recommend and justify an alternative TBS. The NRC is interested in feedback on this option. Please include in your feedback the potential advantages that could be realized by this alternative and if potential benefits are more likely to be realized generically or for individual plants. Please also provide any disadvantages that may result from a loss of regulatory consistency if similar plants have different TBS values and any potential impacts on fulfilling the inspection requirements in proposed 10 CFR 50.46a(b)(3). Please also describe the impact of any associated costs necessary to develop a risk-informed technical basis for an alternative TBS and the associated uncertainties due to the lack of current guidance for developing this basis.

Alternative 10 CFR 50.46a Licensing Pathways

Question 35: This proposed rule would add a voluntary alternative to 10 CFR 50.46 designed to provide flexibility by allowing licensees to adopt tailored approaches for ECCS performance evaluations. This flexibility is proposed in 10 CFR 50.46(a)(1), which would provide applicants and licensees the ability to select between two acceptance criteria pathways. The first is presented in proposed 10 CFR 50.46(b), which is the current 10 CFR 50.46 acceptance criteria. The second is presented in proposed 10 CFR 50.46a(f), which contains the new performance-based acceptance criteria. The NRC expects that the performance-based requirements in proposed 10 CFR 50.46a(f) would facilitate implementation of potential alternative approaches to FFRD such as those described in the regulatory basis for this rulemaking, some of which are already being considered by the NRC. These alternatives could be beneficial for licensees that elect not to pursue the remainder of proposed 10 CFR 50.46a. Please comment on any elements of the proposed rule that could have unintended consequences for implementation of these alternatives.

ECCS Reporting Requirements

Question 36: The industry has proposed that a graded approach could be used to relax the ECCS reporting requirements based on context beyond the current 10 CFR 50.46 criteria. Please provide thoughts on how a graded approach could be applied to relax the ECCS reporting requirements in 10 CFR 50.46 and proposed 10 CFR 50.46a. Please provide a basis for your response.

Threshold for Significance Determination

Question 37: The proposed fixed 50-degree peak clad temperature (PCT) threshold for significant errors can either overstate or understate the safety significance of a change depending on available margin to the acceptance criterion. Further, it does not consider designs where a parameter other than PCT is proposed as the acceptance criterion. Alternative approaches, such as a margin-based threshold can more accurately reflect actual risk significance. Please provide your thoughts, with justification and any supporting information, on alternative approaches for determining the significance of errors in the LOCA evaluation model (*e.g.,* percent reduction in the margin between the acceptance criteria and the approved maximum value of the acceptance parameter).

ECCS Performance

Question 38: The proposed rule explicitly only provides the TBS-based approach to address FFRD. The TBS-based approach may not provide enough margin to demonstrate coolability at the upper end of the burnup range allowed by the proposed rule and therefore, could result in implementation and licensing challenges. The NRC previously included a dose consequence-based approach to addressing FFRD in the regulatory analysis for the Increased Enrichment Rule (Docket ID: NRC–2020–0034). What are the advantages and disadvantages of including an explicit option in the performance-based ECCS acceptance criteria in proposed 10 CFR 50.46a(f) that is based on dose-consequence? What implementation challenges (*e.g.,* acceptance threshold) would need to be addressed for such an option? Please provide the rationale and any supporting information for your response.

Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Question 39: Appendix T of 10 CFR is intended to address nuclear supply chain constraints by providing a graded approach for additional QA flexibilities and aligning with international standards. The proposed rule limits the applicability of appendix T to nth-of-a-kind (NOAK) plants referencing a first-of-a-kind (FOAK) plant constructed and operated under appendix B. How can the NRC expand the applicability of appendix T to FOAK plants and existing licensees, including any guardrails or restrictions that may be desirable (*e.g.,* vendor inspections for FOAK and new suppliers for NOAK)? Should the NRC consider alternative approaches to appendix T such as endorsement of ISO 19443 or changes to appendix B? Please provide the basis for your recommendations, including any unintended consequences.

Question 40: The change process for the Quality Management System (QMS) in proposed 10 CFR 50.54(a)(5) requires changes to the QMS be submitted to the NRC for NRC approval prior to implementation. Should the change process have a graded approach or mirror 10 CFR 50.54(a)(4) in which only changes that reduce the commitments be submitted to the NRC for prior approval? Please explain if there is a preferred method.

Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

Question 41: The NRC is seeking views on increasing the flexibility provided by the proposed rule. The rule currently does not include the allowance for a licensee or applicant to adopt a previously approved alternative without submitting an application to the NRC, provided that the basis for the staff's approval is demonstrated and documented to be applicable to the adoptee's plant or facility. Would adding such flexibility increase or accelerate the use of the proposed rule? What are some viable approaches to resolve any conflicts of such flexibility with the requirements in 10 CFR 50.59?

Siting

Question 42: The proposed rule introduces a new graded approach to siting that provides entry criteria for the less restrictive requirements in subpart A to 10 CFR part 100 (*i.e.,* demonstrating an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary) as an alternative to the prescriptive siting requirements in subpart B. The associated draft guidance provides detailed information on how to evaluate this entry criteria. Given the significance of this new graded approach to siting, are there implications in terms of implementation of this new approach that should be further explored in guidance or addressed at the final rule stage?

XXXVIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XXXIX. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

XL. Backfitting and Issue Finality

This section describes the backfitting and issue finality implications of this proposed rule and the draft guidance documents described in section XLVII, ''Availability of Guidance,'' of this document, as applied to pertinent NRC approvals and certain applicants that reference NRC approvals in their applications. The NRC's backfitting provisions associated with nuclear power plants licensed under 10 CFR part 50 appear in 10 CFR 50.109, ''Backfitting.'' Issue finality provisions (analogous to the backfitting provisions in 10 CFR 50.109) for approvals under 10 CFR part 52 are located in various provisions of 10 CFR part 52. The NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,'' describes the Commission's policies on backfitting and issue finality.

Part 53 of 10 CFR contains backfitting and issue finality provisions. Those provisions apply to NRC actions that would affect 10 CFR part 53 licensees and certain applicants that reference NRC approvals under 10 CFR part 53. The NRC has not issued any licenses or other approvals under 10 CFR part 53, so no licensees or applicants under 10 CFR part 53 could be affected by this proposed rule. Therefore, this proposed rule's changes to 10 CFR part 53 would not constitute backfitting under 10 CFR part 53 or affect the issue finality of an approval issued under 10 CFR part 53.

''Backfitting'' is defined in 10 CFR 50.109(a)(1) as, in relevant part, a modification of or addition to the systems, structures, and components or design of a facility; or the design approval or manufacturing license (ML) of a facility; or the procedures or organization required to design, construct, or operate a facility, which results from a new or amended provision in the Commission's regulations. The issue finality provision for combined licenses (COLs) located in 10 CFR 52.98 provides, in relevant part, that the Commission may not modify, add, or delete any term or condition of a COL except in accordance with the provisions of 10 CFR 50.109. Essentially, if a change does not constitute backfitting, then the change does not affect the issue finality of a COL.

Part 52 of 10 CFR contains an issue finality provision for MLs. No entity holds an ML under 10 CFR part 52. Therefore, the proposed changes to 1) amend 10 CFR 52.173 to change the duration of an ML to a maximum of 40 years, 2) amend 10 CFR 52.181 to change the duration of a renewed ML to a maximum of 40 years, 3) amend 10 CFR 50.71(f) regarding final safety analysis report (FSAR) updates by ML holders, and 4) amend 10 CFR 52.171(b)(1) to allow the holder of an ML to use the regulations in 10 CFR 50.59 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval of an amendment to the ML, would not affect the issue finality of an ML.

Similarly, the proposed change to amend 10 CFR 52.98, which would allow COL holders who reference an ML to use the applicable change processes in 10 CFR part 50 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval, would not affect the issue finality of a COL referencing an ML because there are no MLs for a COL to reference. Also, the proposed change to amend 10 CFR 50.59 to allow the holder of an operating license (OL) under 10 CFR part 50 or a COL under 10 CFR part 52 that references a reactor manufactured under an ML to make changes in the facility or procedures as described in the FSAR without requesting a license amendment if the changes would be the same as changes approved by amendment to the ML and upon a determination that implementing the changes would be consistent with the basis for the Commission's approval of the amendment to the ML and would not involve any additional changes that would require an amendment to the OL or COL, would not constitute backfitting of a 10 CFR part 50 operating license or affect the issue finality of a 10 CFR part 52 COL referencing an ML because there are no MLs for an OL or a COL to reference.

Two sets of proposed changes would affect the issue finality of standard design certifications under 10 CFR part 52. First, the NRC proposes to clarify the definitions of Tier 1 information in section II.D of appendices A, D, E, F, and G to 10 CFR part 52 by identifying specific sections and tables within the generic design certification documents that correspond to each of these categories of Tier 1 information. Second, the NRC proposes to amend sections II.F and VIII.B of appendices A and E to 10 CFR part 52 to revert all Tier 2* information to Tier 2 status after the plant first achieves full power. These proposed changes would modify the certification information of the certified standard designs in those appendices. The issue finality provision for design certifications is in 10 CFR 52.63(a)(1) and prohibits the modification of certification information unless the Commission determines in a rulemaking that certain criteria are met. In this case, the Commission determines that these proposed changes would reduce unnecessary regulatory burden and maintain protection to public health and safety and the common defense and security in accordance with 10 CFR 52.63(a)(1)(iii). Therefore, the NRC may propose to make these changes.

Under 10 CFR 52.63(a)(2), in a rulemaking performed under 10 CFR 52.63(a)(1)(iii), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration. The NRC prepared an analysis addressing whether the benefits of the proposed changes would justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration (see section XXXIX, ''Regulatory Analysis,'' of this document).

Other proposed changes to the standard design certifications under 10 CFR part 52 would not affect the issue finality of those certified designs or COL holders referencing the certified designs because the proposed changes would not amend certification information of the designs. The Commission explained in the 2007 10 CFR part 52 final rule that 10 CFR 52.63(a) applies to changes to the certification information (*i.e.,* the information in the generic design control document incorporated by reference in a design certification appendix in 10 CFR part 52) but does not apply to changes to the certified design rule language (72 FR 49381; August 28, 2007). Therefore, deleting section IX of appendix D to 10 CFR part 52 because it is redundant with 10 CFR 52.99 and 52.103 would not affect the issue finality of the existing design certification or COLs referencing the existing certified design because the proposed change would not amend certification information of the design.

Of the other proposed changes, many would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a COL under 10 CFR part 52 because they would be non-mandatory relaxations of existing requirements. As explained in MD 8.4, non-mandatory relaxations of regulations generally do not meet the definition of ''backfitting'' in 10 CFR 50.109(a)(1). Thus, these proposed changes would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a COL under 10 CFR part 52. The following proposed changes would be non-mandatory relaxations of existing requirements:

- Amending paragraphs IV.F.2.a.(i) through (iii) of appendix E to 10 CFR part 50 and paragraphs 10 CFR 50.160(c)(1) and (c)(2) to remove the requirement to demonstrate compliance within 2 years before issuance of an OL under 10 CFR part 50 or the scheduled date of initial loading of fuel for a 10 CFR part 52 COL. A 10 CFR part 50 OL applicant or 10 CFR part 52 COL holder could conduct the initial exercise within 2 years of the respective milestones and would comply with the proposed rule.
- Amending paragraph IV.D.3 of appendix E to 10 CFR part 50 to revise requirements for when backup alert and notification system methods are required. Licensees could continue to have a single primary method and a single backup method and would comply with the proposed rule.
- Amending 10 CFR 50.33(g), 50.47(c)(2), and 50.160(b)(3) to ensure the plume exposure pathway emergency planning zone (EPZ) is no larger than needed to implement predetermined, prompt protective measures. Licensees could continue to have a plume exposure pathway EPZ of an area about 10 miles (16 km) in radius and would comply with the proposed rule.
- Eliminating the requirement to define an ingestion pathway EPZ by removing references to the ingestion pathway EPZ in 10 CFR 50.33(g)(1), 50.47(b)(10), 50.47(c)(2), and paragraph IV.F.2.a.(i) and footnote 1 of appendix E to 10 CFR part 50. Licensees could continue to have an ingestion pathway EPZ of an area about 50 miles (80 km) in radius and would comply with the proposed rule.
- Amending paragraph IV.E.8.b of appendix E to 10 CFR part 50 to require the emergency plan to specify the location of the emergency operations facility in relation to the EPZ boundary. A licensee could continue to locate its

emergency operation facility between 10 and 25 miles (16 and 40 km) of the nuclear power reactor site, or a primary facility less than 10 miles (16 km) from the nuclear power reactor site and a backup facility between 10 and 25 miles (16 and 40 km) of the nuclear power reactor site, based on the current 10-mile (16-km) EPZ requirement, and would comply with the proposed rule.

- Amending 10 CFR 50.54(t) to eliminate the requirement for licensees to ensure that all program elements are reviewed by people who have no direct responsibility for implementation of the emergency preparedness (EP) program. Licensees could continue to have their EP program elements reviewed by people who have no direct responsibility for implementation of the EP program and would comply with the proposed rule.
- Amending paragraphs IV.5, IV.6, and IV.7 of appendix E to 10 CFR part 50 to eliminate certain requirements related to updates of evacuation time estimates. Licensees could continue to update their EPZ permanent resident population estimates and evacuation time estimate analysis, and would comply with the proposed rule.
- Amending paragraph IV.E.9.d of appendix E to 10 CFR part 50 to eliminate the requirement for monthly tests of communications between the licensee and the appropriate NRC Regional Office Operations Center. Licensees could try to communicate monthly with their NRC Regional Office Operations Center and would comply with the proposed rule.
- Amending 10 CFR 71.55 to expand the exception from 10 CFR 71.55(b) for packages containing enrichment levels between 5.0 and 10.0 weight percent U–235. Packages could contain enrichment levels below 5.0 weight percent U–235 and would comply with the proposed rule.
- Amending 10 CFR 50.67 and General Design Criterion (GDC) 19 of appendix A to 10 CFR part 50 to increase the numerical value of the control room design criteria from 5 to 10 rem (0.05 to 0.10 Sv) and enable a higher control room design criteria, ranging from 10 to 25 rem (0.10 to 0.25 Sv) TEDE, for licensees whose facility-specific risk profiles warrant them. Licensees could meet the current control room habitability design requirements and would comply with the proposed rule.
- Removing the restriction limiting proposed alternatives to paragraphs (b) through (h) of 10 CFR 50.55a so that proposed alternatives would now be permitted for all regulatory requirements in 10 CFR 50.55a using the existing criteria in paragraphs (z)(1) and (2) of 10 CFR 50.55a. Licensees could continue to propose alternatives to only paragraphs (b) through (h) of 10 CFR 50.55a and would comply with the proposed rule.
- Amending appendix A to 10 CFR part 50 to clarify that (1) deviations from GDC could be identified and justified within licensing submittals, with no need for a separate exemption request; and (2) demonstrating compliance with GDC 28 of appendix A to 10 CFR part 50 could be based on a different design basis accident than the control rod ejection or control rod drop accident. Licensees could continue to submit an exemption request or demonstrate compliance with GDC 28 using an evaluation of control rod ejection or control rod drop accidents and would comply with the proposed rule.
- Amending 10 CFR 54.37(b) to only require that the final safety evaluation report include a summary description of aging management activities that addresses newly identified SSCs, as appropriate, consistent with what is required in the renewal application.

Some of the changes in this proposed rule would not constitute backfitting under 10 CFR part 50 or affect the issue finality of an approval under 10 CFR part 52 because the proposed changes would provide a voluntary alternative set of requirements. Licensees could continue to comply with the current applicable requirement and would not be required to comply with the proposed rule. The following proposed changes would not require holders of 10 CFR part 50 or 52 approvals to comply with the proposed rule changes:

- Amending various regulations to allow applicants and licensees under 10 CFR parts 50 and 52 the option to use 10 CFR 50.160.
- Amending 10 CFR 52.26 to remove the requirement for an ESP to include a fixed term and making related conforming changes to subpart A of 10 CFR part 52.
- Amending 10 CFR 50.68(b)(7) to allow enrichment above 5.0 weight percent U–235.
- Amending 10 CFR 50.46a and making conforming changes to provide alternative acceptance criteria for emergency core cooling systems for light-water reactors.
- Adding 10 CFR 50.221 to establish an optional verification, validation, and uncertainty quantification (VVUQ) program.
- Adding appendix T to 10 CFR part 50 to establish an alternative to the current quality assurance requirements in appendix B to 10 CFR part 50.
- Amending various paragraphs in 10 CFR 50.4, 50.34, 50.54, 50.55, and 52.79 to make conforming changes to reflect the addition of appendix T to 10 CFR part 50.
- Adding 10 CFR 50.220 and 52.220 to allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed, or performance-based acceptance criteria as alternatives to existing prescriptive requirements.

Several of the proposed changes would apply to only future applicants and to current licensees at their discretion, and therefore would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 approval. Applicants and potential applicants (for licenses, permits, and other regulatory approvals) generally are not within the scope of the backfitting or issue finality regulations. Those regulations include language delineating when those provisions begin; in general, the backfitting and issue finality regulations begin upon the issuance of the license, permit, or other approval. The following proposed changes would apply to only future applicants and to current licensees at their discretion:

- Amending paragraph I.5 of appendix E to 10 CFR part 50 to determine the degree to which compliance with the requirements in certain sections of appendix E is necessary on a case-by-case basis for power reactors with a site-boundary EPZ or no EPZ.
- Amending 10 CFR 50.33(g), 50.47(c)(2), and 50.160(b)(3) to simplify EPZ determinations.
- Amending 10 CFR 50.33(g) to eliminate the requirement to submit response plans of State, local, and participating Tribal governmental entities.
- Amending 10 CFR 50.34(a)(10) and sections I.1, I.2, and II of appendix E to 10 CFR part 50 to remove the requirements for applicants to submit preliminary plans for coping with emergencies in the preliminary safety analysis report.
- Amending 10 CFR 52.158 and 52.171 to allow ML applicants the option to submit essentially complete operational program information with their applications and to provide finality to such program information that is reviewed and approved by the NRC as part of the ML review.
- Amending 10 CFR 54.31 to extend the maximum renewal period for a license to 40 years.
- Adding 10 CFR 54.21(a)(4) to allow applicants to voluntarily propose risk-informed and performance-based

alternatives to the current prescriptive requirements of the aging management review.

• Amending 10 CFR 54.17(c) to remove the 20-year limit on applying for license renewal.

• Amending 10 CFR 54.21(c)(2) to remove the requirement to submit a list of plant-specific exemptions granted under 10 CFR 50.12 that are based on time-limited aging analyses and a justification for continuing those exemptions during the extended operating period.

• Amending 10 CFR 54.22 to remove the requirement that applicants include and justify any technical specification changes needed to manage the effects of aging.

• Amending 10 CFR part 100 to allow power reactor applicants under 10 CFR part 50 or 52 to have greater flexibility to determine the appropriate level of site characterization.

• Amending or adding 10 CFR 50.10, 50.34(b), 50.57, 50.58, 51.4, 52.79(a), 52.85, 52.97(d), and 52.98 to revise the definition of construction to better focus the definition on safety-significant matters and reduce the cost impact of the current definition, to allow certain applicants to request generic finality, and to allow certain construction activities under a general license.

• Amending 10 CFR 50.2 to add definitions for the terms ''design basis events'' and ''beyond design basis events'' and making a conforming change to 10 CFR 50.49(b)(1)(ii).

• Adding a new paragraph (b)(2) to 10 CFR 50.75 to allow new reactor applicants and licensees to use an alternative decommissioning funding assurance pathway.

• Amending 10 CFR 50.75(c)(1) to delete language in the table of minimum amounts that requires reactors of less than 1200 MWt to use the certification amount for a 1200 MWt reactor.

• Amending 10 CFR 50.75(e) to include ''applicant or'' in all appropriate places where currently only ''licensee'' is referenced.

• Amending 10 CFR 50.34(a)(4) and (b)(4) and footnote 1 of 10 CFR 50.34(a) regarding construction permit and OL application requirements and making conforming changes to 10 CFR 52.47, 52.79, 52.137, and 52.157.

• Amending paragraph (a)(1)(ii)(D) and footnotes 3 and 6 of 10 CFR 50.34 to use technology-inclusive language and making conforming changes to 10 CFR 52.17, 52.47, 52.79, 52.137, and 52.157.

• Amending footnote 4 of 10 CFR 50.34(a)(1)(ii)(D)(*1*) to remove outdated information regarding recommendations included in a 1959 National Bureau of Standards handbook.

• Amending 10 CFR 52.1 to add the definitions of Tier 1, Tier 2, and Tier 2*, which would apply to design certifications issued after the effective date of the proposed rule (if finalized).

The remaining proposed changes in this proposed rule would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 COL, and they would not be non-mandatory relaxations of existing requirements, voluntary alternative requirements, or applicable to only future applicants. These proposed changes would not require a licensee to modify or add to systems, structures, components, or the design of a facility; or the design approval or ML of a facility; or the procedures or organization required to design, construct, or operate a facility. Therefore, the proposed changes would not meet the 10 CFR 50.109 definition of ''backfitting'' and, thus, would not constitute backfitting and would not affect the issue finality of a 10 CFR part 52 COL. The following proposed rule changes would fall into this category:

• Amending 10 CFR 50.160(b)(1)(iv)(A)(*2*) and paragraph IV.D.2 of appendix E to 10 CFR part 50 to use modern terminology.

• Amending 10 CFR 50.54(q) to revise and risk-inform the emergency plan change process. The criteria to determine whether the licensee's emergency plan change would require prior NRC approval and the process to obtain that approval in 10 CFR 50.54(q) are not within the scope of ''backfitting'' as defined in 10 CFR 50.109(a)(1) because they are part of an NRC-designed administrative change process that is not required to design, construct, or operate a facility. In addition, the procedures a licensee might use to decide whether to change its emergency plan are not required to design, construct, or operate a facility. Other proposed changes that would amend a change process are the following:

○ Adding 10 CFR 50.59(e) to establish a risk-informed alternative to the existing 10 CFR 50.59 change process.

○ Amending 10 CFR 50.59(c)(2)(viii) to allow licensees to implement certain changes to analytical methods described in the FSAR (as updated) without prior NRC approval, provided those changes are undertaken pursuant to an NRC-approved VVUQ program under 10 CFR 50.221.

○ Amending section VIII.A of appendices A, D, E, F, and G to 10 CFR part 52 to revise the change process for licensee-requested changes to Tier 1 design description information and Tier 1 ITACC information, and to revise the change process for changes and departures during commercial operation.

○ Amending section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 to amend the change process criteria used to determine if a proposed departure from Tier 2 information affecting the resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD requires a license amendment.

○ Amending section VIII.B of appendix D to 10 CFR part 52 to allow the use of the 10 CFR 50.59-like criteria in sections VIII.B.5.b and B.5.c to determine if licensees who reference appendix D to 10 CFR part 52 may depart from Tier 2* information without prior NRC approval.

• Amending table S–3 in 10 CFR 51.51(b). The information in table S–3 provides the basis for evaluating the contribution of the environmental effects of the uranium fuel cycle to support the NRC's NEPA obligations at the time of a nuclear reactor licensing action. Because table S–3 only provides information about the environmental effects away from a nuclear reactor, the NRC's proposed revision to table S–3 would not result in a modification or addition that meets the definition of ''backfitting'' in 10 CFR 50.109(a)(1).

• Amending table S–4 in 10 CFR 51.52. The information in table S–4 provides the basis for evaluating the contribution of the environmental impacts of the transportation of fuel and waste to and from a nuclear reactor to support the NRC's NEPA obligations at the time of a nuclear reactor licensing action. Because table S–4 only provides information about the environmental impacts away from a nuclear reactor, the NRC's proposed revisions to table S–4 would not result in a modification or addition that meets the definition of ''backfitting'' in 10 CFR 50.109(a)(1).

• Amending the terminology in 10 CFR 50.67 and GDC 19 of appendix A to 10 CFR part 50 to clarify the regulations.

• Amending current 10 CFR 50.34, 50.46, 50.46a, and 50.69; GDC 17, 35, 38, 41, 44 and 50 of appendix A to 10 CFR part 50; appendix K to 10 CFR part 50; 10 CFR 52.47, 52.54, 52.79, 52.137, and 52.157; and appendix G to 10 CFR part 52 to reflect the proposed 10 CFR 50.46a. Many of these proposed changes would support implementation of the proposed 10 CFR 50.46a, which would offer voluntary alternative criteria for emergency core cooling systems for light-water reactors. These proposed conforming changes would not meet the definition of backfitting for the same reasons why the proposed 10 CFR 50.46a—voluntary alternative requirements—would not meet the definition of backfitting. The other proposed conforming changes would affect regulations for applicants and, therefore, would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 approval.

- Removing footnote 3 from 10 CFR 50.49(b)(1) and redesignating footnote 4 as footnote 1.
- Amending 10 CFR 50.75(e), (g), and (h) to make editorial corrections.
- Amending 10 CFR 52.63(a)(1)(vii) to eliminate ''increased standardization'' as a criterion that the Commission must meet before modifying, rescinding, or imposing new requirements on certification information by rulemaking.
- Amending 10 CFR 52.63(a)(4)(ii) to eliminate whether special circumstances outweigh any decrease in safety that may result from a reduction in standardization as a criterion that the Commission must meet before imposing new requirements on a design by plant-specific order.
- Amending 10 CFR 52.63(b)(1) to eliminate the requirement for the Commission to review the impact of a requested exemption on standardization.
- Amending 10 CFR 52.93 and 52.171 to eliminate the requirement for the Commission to discuss the impact of a change on standardization as a criterion for the justification for departures from ML information.

As described in the ''Availability of Guidance'' section of this document, the NRC is issuing 24 draft guidance documents that, if finalized, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. Further, as discussed in the guidance documents, applicants and licensees would not be required to comply with the positions set forth in the guidance. Therefore, issuance of the guidance documents as final guidance would not constitute backfitting under 10 CFR parts 50 and 53 or affect the issue finality of any approval issued under 10 CFR parts 52 and 53.

XLI. Cumulative Effects of Regulation

The NRC seeks to minimize potential negative consequences resulting from the cumulative effects of regulation (CER). The NRC believes that the deregulatory impacts of this rulemaking activity are unlikely to cause implementation challenges for stakeholders. In addition, during the pendency of this rulemaking, the NRC is deprioritizing issuance of regulatory actions that might influence the implementation date for the new rule requirements (*e.g.,* orders, generic communications, license amendment requests, and inspection findings of a generic nature).

To fully understand any potential CER implications that could result from this rulemaking, the NRC is asking the following questions. Response to these questions is voluntary and any input will be considered during development of the final rule.

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.
2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.
3. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

XLII. 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.

XLIII. National Environmental Policy Act

The Commission proposes to determine under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The basis of this proposed determination regarding potential environmental impacts is the implementation of the proposed rule for the regulations described in this **Federal Register** notice would not have a significant impact on the environment. The proposed requirements would be administrative in application or matters of procedure or provide an equivalent level of safety as existing requirements; therefore, there would be similar environmental impacts from the implementation of the regulations in this proposed rule as there are for existing requirements.

The proposed determination of this draft environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the **ADDRESSES** caption. The draft environmental assessment is available as indicated under the ''Availability of Documents'' section of this document. This environmental assessment and proposed finding of no significant impact can be tracked with identification number NEPA ID EAXX–429–00–000–1770782365.

XLIV. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et *seq.*). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission: New.

The title of the information collection: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices.

OMB approval numbers: 3150–0008, 3150–0011, 3150–0093, 3150–0151, 3150–0155, 3150–0264, and 3150–0274.

The form number if applicable: Not applicable.

How often the collection is required or requested: Collections are submitted one-time, on-occasion, and periodically. The frequency of collections changes by adding new periodic reporting under 10 CFR50.46a, introducing event-driven submissions for quality management system (QMS) changes and EP framework transitions, while reducing EP program reviews from annual to biennial under 10 CFR50.54(t). Changes to the QMS must be maintained for three years, while other records are generally required to be maintained for the length of license.

Who will be required or asked to respond: The proposed rule would affect a range of entities that apply for or hold licenses from the NRC. The affected entities encompass both new applicants and current licensees operating under 10 CFR parts 50, 52, 53, 54, 71, and 100 and 10 CFR 50.55a.

An estimate of the number of annual responses: 2,075.1 (2,063.1 reporting responses, 10.3 recordkeeping responses for 10 CFR part 50; 1.7 reporting responses for 10 CFR part 53).

The estimated number of annual respondents: 130 (120 for 10 CFR part 50, 5 for 10 CFR part 53, 5 for 10 CFR part 100).

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 33,321.6 (83,116.6 reporting + 6,150 recordkeeping for 10 CFR part 50; −835 reporting for 10 CFR part 53; −55,110 reporting for 10 CFR part 100).

Abstract: The NRC is proposing to amend its regulations to modernize reactor licensing, safety oversight, and siting practices. The proposed rule introduces voluntary risk-informed and performance-based alternatives, updates EP requirements, streamlines quality assurance criteria through a new appendix T to 10 CFR part 50, and revises siting criteria to incorporate risk insights. These changes affect information collections associated with license applications, license amendment requests, periodic reporting, and recordkeeping. New collections include ECCS evaluation model reporting and monitoring under 10 CFR50.46a, QMS change approvals under 10 CFR50.54(a)(5), 50.55(f)(5), and 53.1565, and EP framework transition requests under 10 CFR50.160. The proposed rule also reduces burden by eliminating duplicative requirements, such as prescriptive EP content in CP applications and ESP renewal provisions, and by simplifying seismic/geologic siting criteria under 10 CFR part 100. Overall, the proposed rule results in a net increase in burden due to additional technical analyses and documentation required for voluntary alternatives, balanced by targeted reductions from modernization and streamlining initiatives.

This proposed action includes amendments to several requirements in 10 CFR 50.55a and parts 50, 52, 53, 54, 71, and 100. The proposed changes to 10 CFR parts 2 and 51 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995.

The NRC is seeking public comment on the potential impact of the information collections 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? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.

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 Office of Management and Budget (OMB) clearance package and proposed rule are available in the ''Availability of Documents'' section of this document 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 on submissions related to the OMB clearance package by searching on *https://www.regulations.gov* under Docket ID NRC–2025–0975.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by the following method:

• *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–0975.

Submit comments by August 17, 2026.

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.

XLV. Executive Orders

The following are Executive orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (as Amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is an economically significant regulatory action under section 3(f) of E.O. 12866. Accordingly, NRC submitted this proposed rule to OIRA for review. NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in section XXXIX, ''Regulatory Analysis,'' of this document.

B. Executive Order 14154: Unleashing American Energy

NRC has examined this proposed rule document and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is tentatively determined to be a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule document can be found in section XXXIX, ''Regulatory Analysis,'' of this document.

D. Executive Order 14267: Reducing Anti-Competitive Regulatory Barriers

Executive Order 14267 requires the NRC to identify anti-competitive regulations for recission or modification.

The NRC identified 10 CFR 50.34, and related portions of 10 CFR part 52, because these regulations could create a barrier to market participation by using language that may not be clear on the minimum level of information needed to be submitted for a construction permit and uses overly prescriptive language that is not technology inclusive. The proposed recission/modification of the regulations would support the objectives of E.O. 14267 by removing regulatory requirements that could create unnecessary barriers to entry for new market entrants. See section XVIII, ''Discussion—Updates to Construction Permit Requirements and Related Licenses,'' of this document for more information.

The NRC identified 10 CFR 50.54 because this regulation has an anticompetitive effect by raising barriers to entry. It also serves an important regulatory goal as many portions of this regulation are necessary for reasonable assurance of adequate protection. The proposed modifications of the regulation would support the objectives of E.O. 14267 by adding alternatives to enhance entry for new market entrants. The proposed amendments to 10 CFR 50.54 would be conforming changes to reflect the addition of performance-based QA criteria in the proposed appendix T to 10 CFR part 50 as an alternative to appendix B to 10 CFR part 50 for eligible applicants. See section XVI, Discussion—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' of this document for more information.

The NRC identified 10 CFR 50.160 because this regulation creates a barrier to market participation by limiting use of performance-based emergency preparedness standards to small modular reactors less than 1000 MWt, non-light water reactors, and other new technologies. The proposed modification of the regulation would support the objectives of E.O. 14267 by making performance-based regulations available to all new market entrants. See section XXIV, ''Discussion—Revision of the Emergency Preparedness Regulations for Nuclear Power

Reactors,'' of this document for more information.

The NRC identified 10 CFR 100.3 because this regulation creates a barrier to market participation by limiting available potential facility sites, especially for designs that do not require low population zones beyond site boundaries. The proposed recission/modification of the regulation would support the objectives of E.O. 14267 by removing regulatory requirements that could create unnecessary barriers to entry for new market entrants. See section XXXIV, ''Discussion—Enhancing Flexibility of Reactor Site Criteria,'' of this document for more information.

XLVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 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. In this proposed rule, the NRC would revise the regulations associated with the usage of increased enrichment of conventional and ATF designs for LWRs in 10 CFR parts 50, 51, 52, and 71. This action would not constitute the establishment of a standard that contains generally applicable requirements.

XLVII. Availability of Guidance

The NRC is issuing for comment 24 draft guidance documents to support the implementation of the proposed requirements in this rulemaking. You may obtain information and comment submissions related to the draft guidance by searching on *http://www.regulations.gov* under Docket ID NRC–2025–0975. You may submit comments on these draft guidance documents by the methods outlined in the **ADDRESSES** section of this document.

1. The DG–1261, Revision 1, ''Measuring Breakaway Oxidation Behavior,'' would be a new regulatory guide.
2. The DG–1262, Revision 1, ''Determining Post-Quench Ductility,'' would be a new regulatory guide.
3. The DG–1263, Revision 1, ''Establishing Analytical Limits for Zirconium-Based Alloy Cladding,'' would be a new regulatory guide.
4. The DG–1425, ''Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors,'' would be Revision 2 to the existing RG 1.183.
5. The DG–1426, ''An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors,'' would be a new regulatory guide.
6. The DG–1428, ''Plant-Specific Applicability of the Transition Break Size,'' would be a new regulatory guide.
7. The DG–1430, ''Performance-Based Emergency Preparedness,'' would be Revision 1 to the existing RG 1.242.
8. The DG–1434, ''Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents,'' would be a new regulatory guide.
9. The DG–1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' would be a new regulatory guide.
10. The DG–1456, ''Emergency Response Planning and Preparedness for Nuclear Power Reactors,'' would be Revision 8 to the existing RG 1.101.
11. The DG–1457, ''Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors,'' would be Revision 2 to the existing RG 1.219.
12. The DG–1460, ''Applications for Nuclear Power Plants,'' would be Revision 2 to the existing RG 1.206.
13. The DG–1461, ''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,'' would be Revision 1 to the existing RG 1.237.
14. The DG–1462, ''A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,'' would be Revision 1 to the existing RG 1.208.
15. The DG–1463, ''Meteorological Monitoring Programs for Nuclear Power Plants,'' would be Revision 2 to the existing RG 1.23.
16. The DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' would be a new regulatory guide.
17. The DG–1465, ''Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' would be Revision 1 to the existing RG 1.253.
18. The DG–1466, ''Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,' '' would be Revision 4 to the existing RG 1.187.
19. The DG–1467, ''Assuring the Availability of Funds for Decommissioning Nuclear Reactors,'' would be Revision 3 to the existing RG 1.159.
20. The DG–1468, ''Guidance for Implementation of 10 CFR 50.221, 'Credibility Requirements for Modeling and Simulation,' '' would be a new regulatory guide.
21. The DG–4036, ''Graded Approach to Site Characterization for New Reactor Applications,'' would be a new regulatory guide.
22. The DG–4037, ''Preparation of Environmental Reports for Nuclear Power Stations,'' would be Revision 5 to the existing RG 4.2.
23. LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' would be new interim staff guidance.
24. NUREG–0800, Chapter 14, Section 14.3, ''Inspections, Tests, Analyses, and Acceptance Criteria,'' would be a revision to the existing standard review plan (issued March 2007).

Draft regulatory guide updates beyond this rulemaking are included in DG–1425. These additional updates to DG–1425 include the following:

- Updated steady-state release fractions for accidents other than the maximum hypothetical accident (loss-of-coolant accident), based on American National Standards Institute/American Nuclear Society 5.4, ''Method for Calculating the Fractional Release of Volatile Fission Products from Oxide Fuel,'' May 2011, extending the applicability to higher burnups and increased enrichments;
- Additional guidance for modeling BWR main steam isolation valve (MSIV) leakage and fission product removal by suppression pool scrubbing;
- Guidance for crediting holdup and retention of MSIV leakage within the main steamlines and condenser for BWRs; and
- Guidance for use of best estimate plus uncertainty approaches to determining inputs to radiological models.

XLVIII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

BILLING CODE 7590–01–P

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION
Proposed Rule Documents	
Regulatory Analysis for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26181A099
Environmental Assessment for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26181A100
OMB Supporting Statement for Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML25328A182
OMB Burden Tables for Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26034C042
Unofficial Redline Rule Language for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices (NRC-2025-0975; RIN 3150-AL44) dated July 2026	ML26029A079
Draft Guidance Documents	
DG-1261, Revision 1, "Measuring Breakaway Oxidation Behavior," July 2026	ML24284A338
DG-1262, Revision 1, "Determining Post-Quench Ductility," July 2026	ML24284A340
DG-1263, Revision 1, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding," July 2026	ML24304A946
DG-1425, "Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors," July 2026	ML24185A179
DG-1426, "An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors," July 2026	ML24284A342
DG-1428, "Plant-Specific Applicability of the Transition Break Size," July 2026	ML24341A154
DG-1430, "Performance-Based Emergency Preparedness," July 2026	ML25289A302
DG-1434, "Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents," July 2026	ML24304A951
DG-1454, "Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments," July 2026	ML25283A021
DG-1456, "Emergency Response Planning and Preparedness for Nuclear Power Reactors," July 2026	ML25289A309
DG-1457, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," July 2026	ML25289A351
DG-1460, "Applications for Nuclear Power Plants," July 2026	ML25255A088
DG-1461, "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," July 2026	ML25258A248
DG-1462, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," July 2026	ML25259A323

DG-1463, "Meteorological Monitoring Programs for Nuclear Power Plants," July 2026	ML25259A209
DG-1464, "Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria," July 2026	ML25258A147
DG-1465, "Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," July 2026	ML25260A526
DG-1466, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,'" July 2026	ML25272A138
DG-1467, "Assuring the Availability of Funds for Decommissioning Nuclear Reactors," July 2026	ML25273A081
DG-1468, "Guidance for Implementation of 10 CFR 50.221, 'Credibility Requirements for Modeling and Simulation,'" July 2026	ML25269A145
DG-4036, "Graded Approach to Site Characterization for New Reactor Applications," July 2026	ML25272A272
DG-4037, "Preparation of Environmental Reports for Nuclear Power Stations," July 2026	ML25268A122
LR-ISG-2026-01, "Updated Review Criteria for License Renewal," July 2026	ML25258A002
NUREG-0800, Chapter 14, Section 14.3, "Inspections, Tests, Analyses, and Acceptance Criteria," July 2026	ML25276A087
Other References	
Expedited Construction of Certain Structures, Systems, and Components	
Federal Register Notice, Final Rule – "Limited Work Authorizations for Nuclear Power Plants," dated October 9, 2007	72 FR 57416
Federal Register Notice, Final Rule – "Limited Work Authorizations for Nuclear Power Plants," Description of Supplemental Proposed LWA Rule, dated October 9, 2007	72 FR 57429
RG 1.233, Revision 0, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," dated June 2020	ML20091L698
Determinate and Data-Backed Thresholds for Reactor Safety Assessments	
NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"	https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/index
RG 1.76, Revision 1, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants," dated March 2007	ML070360253
RG 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," dated March 2007	ML070310619
RG 1.221, "Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants," dated October, 2011	ML110940300
Removal of IEEE-323-1974 Reference in Footnote 3 of 10 CFR 50.49	
Federal Register Notice – Final Rule, "Environmental Qualification of Electric Equipment	48 FR 2733

Important to Safety for Nuclear Power Plants," dated January 21, 1983	
IEEE Std 308-2020, "IEEE Standard Criteria for Class 1E Power Systems for Nuclear Power Generating Stations," dated March 2020	https://store.accuristech.com/standards/ieee-308-2020?product_id=2033437
IEEE Std 323-1974, "IEEE Standard for Qualifying Class IE Equipment for Nuclear Power Generating Stations," dated September 1974	https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=6568022
RG 1.32, "Criteria for Power Systems for Nuclear Power Plants," dated January 2025	ML24306A036
Expanded Alternative Requests under 10 CFR 50.55a(z)	
Federal Register Notice – Final Rule, "American Society of Mechanical Engineers Code Cases and Update Frequency," dated July 17, 2024	89 FR 58039
Federal Register Notice – Final Rule, "Approval of American Society of Mechanical Engineers' Code Cases," dated November 5, 2014	79 FR 65776
Federal Register Notice – Final Rule, "Codes and Standards for Nuclear Power Plants," dated March 15, 1984	49 FR 9711
Federal Register Notice Final Rule, "Codes and Standards for Nuclear Power Plants," dated June 12, 1971	36 FR 11423
SECY-23-0061 "Clarification of the Staff's Position on Certain American Society of Mechanical Engineers Code Alternatives For More Than One 10-Year Inservice Inspection Interval Under Title 10 of the *Code of Federal Regulations* 50.55a," dated July 21, 2023	ML23094A178
Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods	
Federal Register Notice – Final Rule, "Changes, Tests, and Experiments," dated October 4, 1999	64 FR 53582
Federal Register Notice – Final Rule, "Changes, Tests, and Experiments," Final Rule Language, dated October 4, 1999	64 FR 53598
NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," dated 2025	https://www.nfpa.org/product/nfpa-805-standard/p0805code
RG 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
SECY-97-035, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments)," dated February 12, 1997	https://www.nrc.gov/sites/default/files/doc_library/cdn/legacy/reading-rm/doc-collections/commission/secys/1997/secy1997-035/1997-035scy.pdf
FDA-2021-D-0980, "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions," dated November 17, 2023,	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions
Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors	
Federal Register Notice - Final Rule, "General Requirements for Decommissioning Nuclear Facilities," dated June 27, 1988	53 FR 24018
SRM-SECY-23-0021: Enclosure 4, "Table of Typographical errors and Inconsistencies," dated March 4, 2024	ML24064A052
Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	

ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," dated 2024	https://www.asme.org/codes-standards/find-codes-standards/quality-assurance-requirements-for-nuclear-facility-applications
Federal Register Notice – Final Rule, "Quality Assurance Criteria for Nuclear Power Plant," dated June 27, 1970	35 FR 10498
ISO 19443, "Quality management systems – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety [ITNS]," Edition 1, 2018	https://www.iso.org/standard/64908.html
ISO 9001, "Quality Management System - Requirements," Edition 5, 2015	https://www.iso.org/standard/62085.html
Updates to Construction Permit Requirements and Related Licenses	
Federal Register Notice – Final Rule, "Technical Specifications for Facility Licenses; Safety Analysis Reports," dated December 17, 1968	33 FR 18610
Federal Register Notice – Proposed Rule, "Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses," dated April16, 1969	34 FR 6540
Federal Register Notice – Final Rule, "Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses," dated March 31, 1970	35 FR 5317
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
Federal Register Notice – Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49352
Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52	
Federal Register Notice – Final Rule, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors," dated November 22, 2004	69 FR 68008
SRM-SECY-98-144, "Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999	ML003753601
Establishing Thresholds for Changes to Reactor Designs During Construction and Operation under 10 CFR Part 52	
SECY-17-0075, "Planned Improvements in Design Certification Tiered Information Designations," dated July 24, 2017	ML16196A321
SECY-19-0034, "Improving Design Certification Content," dated April 8, 2019	ML19080A032
Nuclear Energy Institute (NEI) 96-07, Appendix C, "Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed under 10 CFR Part 52," Revision 0-Corrected, dated March 2014	ML14091A739
"10 CFR Part 52 Construction Lessons Learned Report," dated January 16, 2024	ML23325A202
Submittal of NEI 15-02, Draft A of Revision 0, Industry Guideline for the Development of Tier 1 and ITAAC Under 10 CFR Part 52, dated May 27, 2015	ML15147A670

Summary of September 20, 2023, Meeting with Southern Nuclear Operating Company, dated October 12, 2023	ML23275A088
1-15-2025 Public Meeting - Options for Regulatory Flexibility in Part 52 during Construction and Operational Phases	ML24358A012
SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150 AI66), dated June 6, 2022	ML21159A055
SRM-SECY-22-0052, "Staff Requirements – SECY-22-0052 – Proposed Rule: Alignment of Licensing Processes and Lessons Learned From New Reactor Licensing (Rin 3150-AI66), dated November 20, 2024	ML24326A003
SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," dated June 6, 2012	ML12117A012
SRM-SECY-12-0081, "Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012	ML12296A158
NRC Letter, "Vogtle Electric Generating Plant, Units 3 and 4 — Issuance of Amendments and Granting of Exemptions Re: Changes to the Tier 2* Departure Evaluation Process (LAR 17-037) (EPID L-2017-LLA-0421)," dated September 20, 2018	ML18235A030
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Request for Exemption and License Amendment regarding Changes to Tier 2* Information (LAR 14-008)," dated August 7, 2014	ML14219A579
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Withdrawal of Request for Exemption and License Amendment Regarding Changes to Tier 2* Information (LAR 14-008)," dated December 15, 2014	ML14349A624
NRC Letter, "Issuance of Combined Licenses and Limited Work Authorizations for Vogtle Electric Generating Plant (VEGP) Units 3 and 4," dated February 10, 2012	ML113540620
NRC Letter, "Issuance of Tier 2 License Amendment No. 44 (LAR 15-007) for Vogtle, Units 3 and 4," dated February 1, 2016	ML15191A128
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Request for License Amendment and Exemption: Changes to Tier 2* Departure Evaluation Process (LAR-17-037)," dated December 21, 2017	ML17355A416
NRC Letter, "Vogtle Electric Generating Plant, Units 3 and 4 - Issuance of Amendments 142 and 141 and Granting of Exemptions RE: Changes to The Tier 2* Departure Evaluation Process (LAR 17-037)," dated September 20, 2018	ML18235A029
Southern Nuclear Operating Company Vogtle Units 3 and 4, "License Amendment Request and Exemption Request: Remove Tier 1 and Tier 2* Requirements," dated July 25, 2024	ML24207A108
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SECY-97-155, "Staff's Action Regarding Exemptions from 10 CFR 70.24 for Commercial Nuclear Power Plants," dated July 21, 1997	ML20211L130
SECY-R-143, "Amendment to 10 CFR 50—General Design Criteria for Nuclear Power Plants," dated January 28, 1971	ML072420278
SRM-SECY-07-0082, "Staff Requirements – SECY-07-0082 – Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,'" dated August 10, 2007	ML072220595
SRM-SECY-10-0161, "Staff Requirements – SECY-10-0161 – Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a) (RIN-3150-AH29)," dated April 26, 2012	ML12117A121
SRM-SECY-12-0081, "Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012	ML12296A158
SRM-SECY-16-0033, "Staff Requirements – SECY-16-0033 – Draft Final Rule – Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria," dated April 11, 2024	ML24102A281
SRM-SECY-21-0109, "Staff Requirements – SECY-21-0109 Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated March 16, 2022	ML22075A103
SRM-SECY-97-287, "Staff Requirements – SECY-98-287 – Final Regulatory Guidance On Risk-Informed Regulation: Policy Issues," dated March 19, 1998	ML003753490
SRM-SECY-98-015, "Staff Requirements – SECY-98-015 – Final General Reg Guide & Std Review Plan for Risk-Informed Regulation of Power Reactors," dated May 20, 1998	ML20248A848
SRM-SECY-98-144, "Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999	ML003753601
Technical Report, "Method for Graded Risk-Informed Performance-Based Control Room Design Criteria Framework," dated September 2024	ML24150A080

TLR-RES/DE/REB-2021-09, "Probabilistic Leak-Before-Break Evaluation of Westinghouse Four-Loop Pressurized-Water Reactor Primary Coolant Loop Piping using the Extremely Low Probability of Rupture Code," dated August 13, 2021	ML21217A088
TLR-RES/DE/REB-2021-14, "Probabilistic Leak-Before-Break Evaluations of Pressurized-Water Reactor Piping Systems using the Extremely Low Probability of Rupture Code," dated September 28, 2021	ML21266A045
TSTF-18-07, Revision 2, "TSTF Comments on Draft Safety Evaluation for Traveler TSTF-505, 'Provide Risk-Informed Extended Completion Times' and Submittal of TSTF-505," dated July 2, 2018	ML18183A493
Other Documents	
Executive Order 12866, "Regulatory Planning and Review," October 4, 1993	58 FR 51735
Executive Order 14154, "Unleashing American Energy," January 29, 2025	90 FR 8353
Executive Order 14192, "Unleashing Prosperity Through Deregulation," February 6, 2025	90 FR 9065
Executive Order 14215, "Ensuring Accountability for All Agencies," February 24, 2025	90 FR 10447
Executive Order 14267, "Reducing Anti-Competitive Regulatory Barriers," April 15, 2025	90 FR 15629
Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," May 29, 2025	90 FR 22587
Presidential Memorandum, "Plain Language in Government Writing," June 10, 1998	63 FR 31885

BILLING CODE 7590–01–C

The NRC prepared an unofficial redline strikeout version of the proposed changes to regulatory text that is intended to help the readeridentifythe changes. The NRC is providing the unofficial redline as a reader tool only, and this document is listed in the ''Availability of Documents'' section of this document. Comments on the rule text should be made in this proposed rule.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2025–0975. 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–2025–0975); (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 50

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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

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10 CFR Part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, Inspection, Intergovernmental relations, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR Part 54

Administrative practice and procedure, Age-related degradation, Backfitting, Classified information, Criminal penalties, Environmental protection, Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Packaging and containers, Penalties, Radioactive materials, Reporting and recordkeeping requirements.

10 CFR Part 100

Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

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 amend 10 CFR parts 2, 50, 51, 52, 53, 54, 71, and 100:

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 Sec. 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note).

§ 2.109 [Amended]

■ 2. In § 2.109, remove and reserve paragraph (c).

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 3. 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; ADVANCE Act of 2024, sec. 301 (42 U.S.C. 2133 note).

■ 4. In § 50.2, add in alphabetical order the definitions ''*Beyond design basis event*'' and ''*Design basis event*'' to read as follows:

§ 50.2 Definitions.

* * * * *

Beyond design basis event means an initiating event with a frequency below the threshold for a design basis event, but greater than or equal to a threshold for credibility that provides an appropriate level of safety and is deemed acceptable by the NRC, or an event (other than a design basis event) that is specifically required by regulation to be considered in the licensing basis. This definition, along with the corresponding definition of ''design basis event,'' applies to applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for construction permits and operating licenses under this part, as well as for early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses under part 52 of this chapter. Applicants for or holders of licenses, permits, standard design certifications, or standard design approvals under this part or part 52 of this chapter who are not subject to this requirement may propose to adopt this definition and the corresponding definition of ''design basis event'' by submitting a request for NRC approval in an application, through a license amendment request under § 50.90, or through the applicable change process under part 52 of this chapter.

* * * * *

Design basis event means an initiating event with a frequency greater than or equal to a determinate, data-backed threshold that provides an appropriate level of safety and is deemed acceptable by the NRC. This definition, along with the corresponding definition for ''beyond design basis event,'' applies to applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for construction permits and operating licenses under this part, as well as for early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses under part 52 of this chapter. Applicants for or holders of licenses, permits, standard design certifications, or standard design approvals under this part or part 52 of this chapter who are not subject to this requirement may propose to adopt this definition and the corresponding definition of ''beyond design basis event'' by submitting a request for NRC approval in an application, through a license amendment request under § 50.90, or through the applicable change process under part 52 of this chapter.

* * * * *

■ 5. In § 50.4, add paragraph (b)(7)(iii) to read as follows:

§ 50.4 Written Communications.

* * * * *

(b) * * *

(7) * * *

(iii) A change to the Safety Analysis Report quality management system under § 50.54(a)(5) or § 50.55(f)(5), or a change to a licensee's NRC-accepted quality management system topical report under § 50.54(a)(5) or § 50.55(f)(5), must be submitted to the NRC's Document Control Desk, 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. If the communication is on paper, the signed original must be sent.

* * * * *

■ 6. In § 50.10, revise paragraphs (a) and (c), and add paragraph (h) to read as follows:

§ 50.10 License required; limited work authorization.

(a) *Definitions.* As used in this section, *construction* means the activities in paragraph (a)(1) of this section.

(1) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which may impact the required functions of:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in § 50.2;

(ii) SSCs that perform safety-significant functions; and

(iii) SSCs necessary to comply with part 73 of this chapter.

(2) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under section 104a. or section 104c. of the Act, construction does not include the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (*e.g.,* the construction of a college laboratory building with space for installation of a training reactor).

(3) Any activities that are determined to be outside the scope of those defined in § 50.10(a)(1) and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and has no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

* * * * *

(c) *Requirement for construction permit, early site permit authorizing limited work authorization activities, combined license, or limited work authorization.* Except as provided in paragraph (h) of this section, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under this part, a combined license under part 52 of this chapter, an early site permit authorizing the activities under paragraph (d) of this section, or a limited work authorization under paragraph (d) of this section.

* * * * *

(h) *Issuance of general license.* A general license is hereby issued to an applicant for a construction permit or combined license for a utilization facility under 10 CFR part 50 or 52 for construction activities on a site that is specified in the application, subject to the following conditions:

(1) The applicant has submitted and the Commission has docketed a construction permit or combined license application for a utilization facility under 10 CFR part 50 or 52 that meets the following criteria:

(i) The application references a reactor design for which the Commission issued an operating license or issued a combined license and made the finding under § 52.103(g) of this chapter and for which the Commission afforded generic finality under § 50.57(d) or § 52.97(d);

(ii) The operating license or combined license described in paragraph (h)(1)(i) of this section met the criteria for a categorical exclusion or resulted in a finding of no significant impact from an environmental assessment in accordance with part 51 of this chapter;

(iii) The application utilizing the general license includes a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary; and

(iv) The application must contain information demonstrating that the site characteristics are bounded by the site parameters postulated for the approval of generic finality.

(2) The applicant may perform construction only upon notification to the NRC Director of NRR using instructions in § 50.4 before the start of construction. The notice must state that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action have been obtained. The notice may be in the form of a letter, but must contain the applicant's name, address, and the name and means of contacting a person responsible for providing additional information concerning construction under this general license.

(3) All applicable Federal environmental consultations have been completed.

(4) The general license authorizes construction of those generic aspects of the design of the commercial nuclear plant for which the Commission afforded generic finality and does not authorize installation of the reactor vessel, the reactor coolant system, or associated reactivity control and heat removal systems;

(5) The applicant must allow for NRC inspections that the Commission deems necessary related to activities performed under the general license.

(6) Any activities undertaken by the applicant or on its behalf under the general license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

■ 7. In § 50.33, remove footnotes 1 and 2 and revise paragraph (g) to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(g)(1) If the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant must coordinate radiological emergency preparedness activities with offsite organizations with responsibilities for coping with emergencies including State, local, and Tribal governmental agencies, as applicable. Specifically, the applicant must ensure that these response organizations are aware of the potential radiological consequences of the facility and have been consulted on appropriate protective measures including the extent of any emergency planning zone (EPZ) for implementing predetermined, prompt protective measures. The application must include information that describes the extent of the applicant's interaction with these response organizations. If the application is for an early site permit that, under § 52.17(b)(2)(i) of this chapter, proposes major features of the emergency plans describing the EPZ, then the description of the EPZ must meet the requirements of this paragraph (g)(1). Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 50.33(g)(2). The exact size and configuration of the EPZ surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

(2) For a case-by-case EPZ determination, the applicant or licensee must submit an analysis used to determine whether the criteria in § 50.33(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Dose to an individual is projected to exceed 1 rem (10 mSv) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) [Reserved]

* * * * *

■ 8. In § 50.34,

■ a. Remove the text ''LOCA's'' wherever it appears, and add, in its place, the text ''LOCAs'';

■ b. Remove the text ''PWR's'' wherever it appears, and add, in its place, the text ''PWRs'';

■ c. Remove the text ''BWR's'' wherever it appears, and add, in its place, the text ''BWRs'';

■ d. Revise paragraphs (a)(1) introductory text, (a)(1)(ii)(D), (a)(7), (b)(6)(ii), (b)(6)(v), (b)(10), (b)(11), and footnotes 1, 3, 4, and 6;

■ e. Remove the last sentence of paragraphs (a)(4) and (b)(4);

■ f. Remove and reserve paragraph (a)(10);

■ g. In paragraph (a)(12), remove the phrase ''On or after January 10, 1997, stationary power'' and add in its place ''Power''.

■ h. Add paragraph (b)(14); and

■ i. Revise paragraph (f)(3)(ii).

The revisions and additions are to read as follows:

§ 50.34 Contents of applications; technical information.

(a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The minimum information [1] to be included shall consist of the following:

(1) Power reactor applicants for a construction permit shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.

* * * * *

(ii) * * *

(D) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [3] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [4] (0.25 Sv) total effective dose equivalent (TEDE).

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

(7) A description of the quality assurance program or a quality management system to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth the requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants. Appendix T to this part, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants that an eligible construction permit applicant may voluntarily use as an alternative to appendix B to this part. The description of the quality assurance program for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied or for eligible construction permit applications, the quality management system for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T will be satisfied.

* * * * *

(10) [Reserved]

* * * * *

(b) * * *

(6) * * *

(ii) Managerial and administrative controls to be used to assure safe operation. Appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth the requirements for such controls for nuclear power plants and fuel reprocessing plants. Appendix T to this part, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for such controls for nuclear power plants and fuel reprocessing plants that an eligible operating license applicant may voluntarily use as an alternative to appendix B to this part. The information on the controls to be used for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B to this part will be satisfied or, for eligible operating license applications, the quality management system for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to this part will be satisfied.

* * * * *

(v) Plans for coping with emergencies. The applicant must provide the offsite response organizations that are expected to respond in an emergency with the opportunity to provide input on the emergency plan before submitting it to the NRC. The application must contain any input on the emergency plan received from offsite response organizations.

* * * * *

(10) Power reactor applicants who apply for an operating license, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part.

(11) Power reactor applicants who apply for an operating license shall provide a description and safety assessment of the site and of the facility as in § 50.34(a)(1)(ii).

* * * * *

(14) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for an operating license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

* * * * *

(f) * * *

(3) * * *

(ii) Ensure that the quality assurance (QA) list required by Criterion II of appendix B and appendix T of 10 CFR part 50 includes all structures, systems, and components important to safety. (I.F.1)

* * * * *

[1] This paragraph specifies the minimum required technical information to be included in a preliminary safety analysis report, while §§ 50.35(a)(1) through (4), 50.40, and 50.50 specify required findings for issuance of a construction permit. The level of detail provided in a preliminary safety analysis report to satisfy the minimum technical information requirements in paragraph (a) of this section will be deemed sufficient if the provided information enables the Commission to make the findings for issuance of a construction permit in §§ 50.35(a)(1) through (4), 50.40, and 50.50. The applicant may provide information

required by this paragraph in the form of a discussion, with specific references, of similarities to and differences from, facilities of similar design for which applications have previously been filed with the Commission.

* * * * *

[3] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[4] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that such designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

* * * * *

[6] 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 to bound a broad range of design basis accidents. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

■ 9. Revise and republish § 50.46 to read as follows:

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

(a) Each boiling or pressurized light-water nuclear power reactor must be provided with an emergency core cooling system (ECCS) that is designed under requirements described in this paragraph.

(1) The requirements of this section or § 50.46a must be satisfied for:

(i) Holders of an operating license under this part authorized to operate on December 31, 2015;

(ii) Holders of an operating license under this part authorized to operate after December 31, 2015, and whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a construction permit issued under this part whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the design of reactors authorized to operate under this part on December 31, 2015;

(iv) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(v) Applicants for a construction permit or operating license under this part whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015; and

(vi) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is demonstrated under § 50.46a(c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(2) The requirements of this section must be satisfied for:

(i) Holders of an operating license under this part that were authorized to operate after December 31, 2015, and whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(ii) Holders of a construction permit issued under this part whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the design of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iv) Applicants for a construction permit or operating license under this part whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015; and

(v) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(3) (i) The ECCS system must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents (LOCAs) conforms to the criteria set forth in paragraph (b) of this section or § 50.46a(f). ECCS cooling performance must be calculated in accordance with an acceptable evaluation model and must be calculated for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs are calculated. Except as provided in paragraph (a)(3)(ii) of this section, the evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section or § 50.46a(f), as applicable, there is a high level of probability that the criteria would not be exceeded. Section II, ''Required Documentation,'' of appendix K to this part, sets forth the documentation requirements for each evaluation model. This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted.

(ii) Alternatively, an ECCS evaluation model may be developed in conformance with the required and acceptable features of appendix K to this part, ''ECCS Evaluation Models.''

(4) The Director of Nuclear Reactor Regulation may impose restrictions on reactor operation if it is found that the submitted evaluations of ECCS cooling performance are not consistent with paragraphs (a)(3)(i) and (ii) of this section.

(5) (i) Each applicant for or holder of an operating license or construction permit issued under this part, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final design certification regulation), or an applicant for or holder of a standard design approval, a combined license, or a manufacturing license issued under part 52 of this chapter, must 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 which 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.

(ii) 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 of a construction permit, operating license, combined license, or manufacturing license must report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4 or § 52.3 of this chapter, as applicable. If the change or error is significant, the applicant or licensee must provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC-approved integrated scheduling system, a schedule will be established by the NRC within 60 days of receipt of the proposed schedule. 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 is a reportable event as described in §§ 50.55(e), 50.72, and 50.73. The affected applicant or licensee must propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46 requirements.

(iii) 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 of a standard design approval or the applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification rule) must report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission and to any applicant or licensee referencing the standard design approval or standard design certification at least annually as specified in § 52.3 of this chapter. If the change or error is significant, the applicant or holder of the standard design approval or the applicant for the standard design certification must provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. The affected applicant or holder must propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.

(iv) For entities that are approved to use § 50.46a(f) instead of paragraph (b) of this section, changes or errors discovered in an acceptable evaluation model should be reported in accordance with § 50.46a(j)(1) and (2).

(b) The ECCS system of each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding must be designed so that its calculated cooling performance following postulated LOCAs conforms to the following criteria:

(1) *Peak cladding temperature.* The calculated maximum fuel element cladding temperature must not exceed 2200 °F.

(2) *Maximum cladding oxidation.* The calculated total oxidation of the cladding may nowhere exceed 0.17 times the total cladding thickness before oxidation. As used in this subparagraph total oxidation means the total thickness of cladding metal that would be locally converted to oxide if all the oxygen absorbed by and reacted with the cladding locally were converted to stoichiometric zirconium dioxide. If cladding rupture is calculated to occur, the inside surfaces of the cladding must be included in the oxidation, beginning at the calculated time of rupture. Cladding thickness before oxidation means the radial distance from inside to outside the cladding, after any calculated rupture or swelling has occurred but before significant oxidation. Where the calculated conditions of transient pressure and temperature lead to a prediction of cladding swelling, with or without cladding rupture, the unoxidized cladding thickness must be defined as the cladding cross-sectional area, taken at a horizontal plane at the elevation of the rupture, if it occurs, or at the elevation of the highest cladding temperature if no rupture is calculated to occur, divided by the average circumference at that elevation. For ruptured cladding, the circumference does not include the rupture opening.

(3) *Maximum hydrogen generation.* The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam must not exceed 0.01 times the hypothetical amount that would be generated if all of the metal in the cladding cylinders surrounding the fuel, excluding the cladding surrounding the plenum volume, were to react.

(4) *Coolable geometry.* Calculated changes in core geometry must be such that the core remains amenable to cooling.

(5) *Long-term cooling.* After any calculated successful initial operation of the ECCS, the calculated core temperature must be maintained at an acceptably low value and decay heat must be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(c) As used in this section:

(1) LOCAs are hypothetical accidents that would result from the loss of reactor coolant, at a rate in excess of the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary up to and including a break equivalent in size to the double-ended rupture of the largest pipe in the reactor coolant system.

(2) An evaluation model is the calculational framework for evaluating the behavior of the reactor system during a postulated LOCA. It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(d) The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part. The criteria set forth in paragraph (b) of this section, with cooling performance calculated in accordance with an acceptable evaluation model, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including, in particular, criterion 35 of appendix A to this part.

■ 10. Revise § 50.46a to read as follows:

§ 50.46a Alternative acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a) *Definitions.* For the purposes of this section:

(1) *Changes enabled by this section* means changes to the facility, technical specifications, and procedures that satisfy the alternative ECCS analysis requirements under this section but do

not satisfy the ECCS requirements under § 50.46.

(2) *Cladding* means the material structure surrounding and containing the fissile material and providing a barrier to prevent fission product transport or release to the coolant.

(3) *Crud* means any foreign substance deposited on the surface of fuel cladding.

(4) *Entity* means an applicant for or a holder of a construction permit, operating license, combined license, standard design approval, or manufacturing license, or an applicant for a standard design certification (including such applicant after NRC issuance of a final standard design certification rule).

(5) *ECCS evaluation model* means the calculational framework for evaluating the behavior of the light-water reactor system (including fuel) during a postulated loss-of-coolant accident (LOCA). It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(6) *Loss-of-coolant accidents (LOCAs)* means the hypothetical accidents that would result from the loss of reactor coolant, at a rate in excess of the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary up to and including a break equivalent in size to the double-ended rupture of the largest pipe in the reactor coolant system. LOCAs involving breaks at or below the transition break size are design basis accidents. LOCAs involving breaks larger than the transition break size are beyond-design-basis accidents.

(7) *Operating configuration* means those plant characteristics, such as power level, equipment unavailability (including unavailability caused by corrective and preventive maintenance), and equipment capability that affect plant response to a LOCA.

(8) *Quench* means the rapid cooling of the fuel cladding by liquid coolant water.

(9) *Transition break size (TBS)* for reactors authorized to operate under this part on December 31, 2015, is a break area equal to the largest cross-sectional flow area of the reactor coolant pressure boundary piping excluding the hot leg, cold leg, or crossover leg piping for a pressurized water reactor; the larger cross-sectional flow area of either the feedwater line or residual heat removal line inside containment for a boiling water reactor; or a plant-specific alternative break area. For reactors that are authorized to operate under this part after December 31, 2015, and for light-water reactors (LWRs) that are authorized to operate under part 52 of this chapter, the TBS will be determined on a plant-specific basis.

(b) *Applicability and scope.*

(1) Those entities listed in subparagraphs (i) through (vi) of this paragraph may apply under paragraph (c) of this section to use the requirements of this section. This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted.

(i) Holders of an operating license under this part authorized to operate on December 31, 2015;

(ii) Holders of an operating license under this part authorized to operate after December 31, 2015, and whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a construction permit issued under this part whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the design of reactors authorized to operate under this part on December 31, 2015.

(iv) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(v) Applicants for a construction permit or operating license under this part whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(vi) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(2) The requirements of this section are in addition to any other requirements applicable to ECCS, with the exception of § 50.46. The criteria set forth in paragraph (e)(1) of this section, with cooling performance calculated in accordance with an acceptable evaluation model or analysis method under paragraphs (e)(2) and (3) of this section, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including, in particular, criterion 35 of appendix A to this part.

(3) A licensee must inspect, under § 50.55a(g), for those reactor coolant pressure boundary piping whose inner diameter is greater than the TBS, an NRC-approved sampling of the similar metal piping circumferential welds in a PWR and the circumferential welds in a BWR that are classified as Category A welds before implementation of this section and in every subsequent in-service inspection interval (as defined in § 50.55a(y)). The sampling must include those circumferential welds with the highest failure potential. Credit may be taken for welds inspected as part of established inspection programs (*e.g.,* risk-informed inservice inspection programs). The effect on the TBS of any degradation identified during these inspections must be evaluated.

(c) *Application.*

(1) An entity seeking to implement this section must submit an application under § 50.34, 50.90, or part 52 of this chapter, as applicable, that contains the following information:

(i) A written evaluation demonstrating applicability of the TBS to the entity's facility or a proposed alternative TBS and a justification that the proposed TBS is consistent with the technical basis for this section. The effects of the initial plant changes proposed in the application must be considered as part of this evaluation.

(ii) As applicable, an inspection report that details the results of the inspection requirements in paragraph (b)(3) of this section and the evaluation of the impact of these results on the TBS.

(iii) Identification of the acceptable analysis method(s) for demonstrating compliance with the ECCS criteria in paragraph (e) of this section.

(iv) A description of the risk-informed evaluation used to demonstrate that the proposed changes to the facility meet the requirements in paragraph (h) of this section.

(v) For an entity other than a design certification applicant or a holder of a manufacturing license that wishes to make changes enabled by this section without prior NRC review and approval, a process to be used for evaluating the acceptability of these changes, including:

(A) A description of the approach, methods, and decision-making process to be used for evaluating compliance with the acceptance criteria in paragraphs (h)(1), (2), and (3) of this section;

(B) A description of the probabilistic risk assessment (PRA) model and/or non-PRA risk assessment methods to be used for demonstrating compliance with paragraphs (h)(4) and (5) of this section; and

(C) A description of the approach, methods, and decision-making process to be used to evaluate the continued applicability of the TBS with the acceptance criteria used in the evaluation from paragraph (c)(1)(i) of this section for plants authorized to operate under this part on December 31, 2015, or from paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(vi) A description of non-safety equipment that is credited for demonstrating compliance with the ECCS acceptance criteria in paragraph (e) of this section.

(vii) A written evaluation demonstrating how the leak detection program in place at the facility satisfies the criteria in paragraph (d)(2) of this section.

(2) Each applicant, other than one authorized to operate under this part on December 31, 2015, seeking to implement the requirements of this section must submit, in addition to the information required by paragraphs (c)(1)(ii) through (vii) of this section, an analysis demonstrating why the proposed reactor design is similar to the designs of reactors authorized to operate under this part on December 31, 2015, such that the provisions of this section may properly apply. The analysis must also include a proposed TBS and a justification that the proposed TBS is consistent with the technical basis for this section. The effects of the initial plant changes proposed in the application must be considered as part of this evaluation.

(3) The NRC may approve an application to use this section if:

(i) The evaluation submitted under paragraph (c)(1)(i) of this section demonstrates the applicability of the TBS to the facility for reactors authorized to operate under this part on December 31, 2015;

(ii) The method(s) for demonstrating compliance with the ECCS acceptance criteria in paragraph (e)(1) of this section meet the requirements in paragraphs (e)(2) and (3) of this section;

(iii) The risk-informed evaluation used to make changes under this section is adequate for determining whether the acceptance criteria in paragraph (h) of this section have been met;

(iv) If applicable, the risk-informed evaluation process proposed for use to make changes under paragraph (h)(1) of this section is adequate for determining whether the acceptance criteria in paragraph (h) of this section have been met;

(v) For each reactor not authorized to operate on December 31, 2015, the evaluation submitted under paragraph (c)(2) of this section demonstrates that the reactor design is similar to the designs of reactors authorized to operate under this part on December 31, 2015, and the applicant demonstrates that its proposed TBS applies to its facility; and

(vi) The applicable standards and requirements of the Act and the Commission's regulations have been met.

(d) *Programmatic requirements.* An entity whose application under paragraph (c) of this section is approved by the NRC must comply with the following requirements as long as the entity is subject to the requirements in this section:

(1) The entity must maintain the ECCS evaluation models meeting the requirements in paragraphs (e)(1), (2), and (3) of this section after implementing any error corrections and changes;

(2) The entity must have leak detection systems available at the facility and must implement actions during operation as necessary to identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS;

(3) Changes made under this section must, in addition to meeting other applicable NRC requirements, be evaluated by a risk-informed evaluation demonstrating that the acceptance criteria in paragraph (h) of this section are met;

(4) The entity must perform an evaluation to determine the effect of all planned facility changes and must not implement any facility change that would significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to determine the plant-specific TBS performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015; and

(5) During operation, the licensees must perform the inspections prescribed in paragraph (b)(3) of this section during every subsequent inservice inspection interval (as defined in § 50.55a(y)) on the same samples inspected to satisfy paragraph (b)(3) of this section. The effect on the TBS of any additional degradation identified since the previous inspection must be evaluated.

(e) *ECCS Performance.*

(1) *Alternative ECCS acceptance criteria.* For each entity approved by the NRC to use this section, its reactor must be provided with an ECCS designed to satisfy the acceptance criteria in this paragraph in the event of, and following, a postulated LOCA. The demonstration of ECCS performance must comply with paragraph (e)(2) of this section for breaks at or below the TBS and paragraph (e)(3) of this section for breaks above the TBS.

(i) The ECCS provides sufficient coolant so that the fuel remains in a coolable geometry during and following the LOCA heatup and quench.

(ii) The ECCS provides sufficient coolant so that decay heat will be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel.

(2) *ECCS evaluation performance demonstration for LOCAs involving breaks at or below the TBS.* ECCS cooling performance at or below the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to appendix K to this part, or for realistic evaluation models, the following requirements.

(i) The evaluation model must be used for a number of postulated LOCAs of different sizes, locations (including LOCAs in piping systems with an inner diameter that is larger than the TBS), and other properties sufficient to provide assurance that the most severe postulated LOCAs involving breaks at or below the TBS are analyzed.

(ii) The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that when the calculated ECCS cooling performance is compared to the ECCS performance criteria set forth in paragraph (e)(1) of this section and addresses the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, there is a high level of probability that the criteria would be met.

(iii) The ECCS evaluation model must address changes in fuel geometry.

(3) *ECCS performance demonstration for LOCAs involving breaks larger than the TBS.* ECCS cooling performance for LOCAs involving breaks larger than the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to appendix K to this part or, for realistic evaluation models, the following requirements. These calculations may take credit for the availability of offsite power and do not require the assumption of a single failure. Availability of safety-related or non-safety-related equipment may be assumed if supported by plant-specific data or analysis, and provided that onsite power can be readily provided through simple manual actions to equipment that is credited in the analysis.

(i) The evaluation model must be used for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the reactor coolant system are analyzed.

(ii) The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made so that there is assurance to at least a best-estimate level that the calculated ECCS cooling performance meets the ECCS performance criteria set forth in paragraph (e)(1) of this section and addresses the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section.

(iii) The ECCS evaluation model must address changes in fuel geometry.

(4) *Required documentation.* The documentation requirements of this paragraph supersede the requirements in section II, ''Required Documentation,'' of appendix K to this part for those entities that are approved to use this section.

(i) (A) A description of the ECCS evaluation model must be submitted to the NRC. The description must be sufficiently complete to permit technical review of the analytical approach, including the equations used, their approximations in difference form, the assumptions made, and the values of all parameters or the procedure for their selection.

(B) A detailed source code of each computer program, in the same form as used in the ECCS evaluation model, must be provided to the NRC upon request.

(ii) For each computer program, solution convergence must be demonstrated by studies of system modeling, noding and calculational time steps, or both.

(iii) Appropriate sensitivity studies must be performed for each ECCS evaluation model to evaluate the effect on the calculated results of variations in noding, phenomena assumed in the calculation to predominate, including pump operation or locking, and values of parameters over their applicable ranges. For items to which results are shown to be sensitive, the choices made must be justified.

(iv) To the extent practicable, predictions of the ECCS evaluation model, or portions thereof, must be compared with applicable experimental information. The technical adequacy of the calculational methods used in the ECCS evaluation models must be documented. For realistic evaluation models, the documentation must demonstrate that the performance criteria of paragraphs (e)(1) and (f) of this section are met. For appendix K models, this documentation must demonstrate compliance with required features of section I of appendix K to this part and must demonstrate that the performance criteria of paragraphs (e)(1) and (f) of this section are met.

(v) The Director of the Office of Nuclear Reactor Regulation may impose restrictions on reactor operation if the NRC finds that the submitted evaluations of ECCS cooling performance are not consistent with paragraph (e) of this section.

(f) *Fuel performance criteria.* Fuel system designs must have NRC-approved limits that:

(1) Address cladding degradation phenomena;

(2) Maintain fuel coolability;

(3) Avoid explosive concentration of combustible gas; and

(4) Demonstrate that, after any calculated successful initial operation of the ECCS, the ECCS must provide sufficient coolant to remove decay heat and prevent further cladding failure for the extended period of time required by the long-lived radioactivity remaining in the fuel.

(g) *Use of NRC-approved fuel in reactor.*

(1) *Fuel load.* A licensee that is approved to use this section may not load fuel into a reactor unless the resulting core design satisfies the ECCS performance requirements of paragraph (e) of this section and the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, or otherwise complies with technical specifications governing lead test assemblies in its license.

(2) *Operation.* If a licensee that is approved to use this section determines that fuel in the reactor no longer complies with the ECCS performance requirements of paragraph (e) of this section and the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, then the licensee must take immediate action to come into compliance with paragraph (e) or (f) of this section, as applicable.

(h) *Changes to facility, technical specifications, or procedures.* An entity that wishes to make changes enabled by this section must perform a risk-informed evaluation.

(1) An entity other than a design certification applicant or holder of a manufacturing license may make changes enabled by this section, other than changes to the technical specifications, without prior NRC approval if:

(i) The change is permitted under § 50.59 for holders of operating licenses, combined licenses that do not reference a standard design certification or standard design approval, or manufacturing license (under § 52.98(b) of this chapter), or combined licenses that reference a standard design approval; or permitted under § 52.98(c) of this chapter for holders of combined licenses that reference a standard design certification; or permitted under § 52.98(d) of this chapter for holders of combined licenses that reference a manufacturing license;

(ii) The risk-informed evaluation process approved in accordance with paragraph (c)(1)(v) of this section demonstrates that any increases in the estimated risk are minimal and the criteria in paragraph (h)(3) of this section are met; and

(iii) The change does not significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the applicant's facility, performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to establish the plant-specific TBS, performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(2) For implementing changes that are not permitted under paragraph (h)(1) of

this section, the entity must submit an application containing the following:

(i) For reactor licensees, the information required under § 50.90;

(ii) Information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large early release frequency are very small, the overall risk remains small, and the criteria in paragraph (h)(3) of this section are met;

(iii) If previous changes have been made under this section, information from the risk-informed evaluation on the cumulative effect on risk of the proposed change and all previous changes made under this section. If more than one plant change is combined, including plant changes not enabled by this section, into a group for the purposes of evaluating acceptable risk increases, then the evaluation of each individual change must be performed along with the evaluation of combined changes;

(iv) Information demonstrating that the criteria in paragraph (e) of this section are met; and

(v) Information demonstrating that the proposed change will not significantly increase the LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the entity's facility, performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to establish the plant-specific TBS, performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(3) All changes made under this section must meet the following criteria:

(i) Adequate defense-in-depth is maintained;

(ii) Adequate safety margins are retained to account for uncertainties; and

(iii) Adequate performance-measurement programs are implemented to ensure the risk-informed evaluation continues to reflect actual plant design and operation. These programs must be designed to detect degradation of the system, structure, or component before plant safety is compromised, provide feedback of information and timely corrective actions, and monitor systems, structures, or components at a level commensurate with their safety significance.

(4) Whenever a PRA is used in the risk-informed evaluation, the PRA must, with respect to the area of evaluation that is the subject of the PRA:

(i) Address initiating events from sources both internal and external to the plant and for all modes of operation, that would affect the regulatory decision in a substantial manner;

(ii) Reasonably represent the current configuration and operating practices at the plant;

(iii) Have sufficient technical acceptability (including consideration of uncertainty) and level of detail to provide confidence that the total risk estimates and the change in total risk estimates adequately reflect the plant and the effect of the proposed change on risk; and

(iv) Be determined, through peer review, to meet industry standards for PRA acceptability that have been endorsed or otherwise found acceptable by the NRC.

(5) Whenever risk assessment methods other than PRAs are used to develop quantitative or qualitative estimates of changes to risk in the risk-informed evaluation, an integrated and systematic process must be used. All aspects of the analyses must reasonably reflect the current plant configuration and operating practices and applicable plant and industry operating experience.

(i) *Authority to impose restrictions on operation.*

The Director of the Office of Nuclear Reactor Regulation may impose restrictions on reactor operation if the NRC finds that the submitted evaluations of ECCS cooling performance are not consistent with the requirements of this section.

(j) *Reporting.* Each entity subject to the requirements of this section must comply with the requirements of this paragraph.

(1) *ECCS evaluation model: reporting.*

(i) If the applicant for or holder of a construction permit, operating license, combined license, or manufacturing license identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section and is itself not significant as defined in paragraph (k) of this section, then each of these entities must prepare a report describing each such change or error, its estimated effect on predicted response, and the basis for the entity's determination that the change or error is not significant. This entity must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, at least annually.

(ii) If the applicant for or holder of a construction permit, operating license, combined license, or manufacturing license identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section but is significant as defined in paragraph (k) of this section, then each of these entities must prepare a report describing each such change or error, its estimated effect on predicted response, proposed corrective actions, and a proposed scope and schedule for providing a reanalysis and for implementing the corrective actions. This entity must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, within 60 days of the change or discovery of the error.

(iii) If an 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 identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section but is significant as defined in paragraph (k) of this section, then each of these entities must document the nature of the change or error and its estimated effect on the limiting ECCS analysis.

(iv) If a licensee identifies any change to, or error in, an ECCS evaluation model or the application of such a model, that results in any of the ECCS acceptance criteria specified in this section to be exceeded at the facility, then the licensee must submit a report describing each such change or error, its estimated effect on predicted response, proposed corrective actions, and a proposed scope and schedule for providing a reanalysis and for implementing the corrective actions. The licensee must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, within 60 days of the change or discovery of the error. The report required by this paragraph is in addition to any reporting required by § 50.72.

(2) *ECCS evaluation model: corrective action.*

(i) If a licensee identifies any change to, or error in, an ECCS evaluation model or the application of such a model, that results in any of the acceptance criteria specified in this section to be exceeded at the facility, then the licensee (in the case of a combined license under part 52 of this chapter, after the Commission has made the finding under § 52.103(g) of this chapter) must take immediate action to bring the facility into compliance with the acceptance criteria. In addition, the corrective action as described in the report required by paragraph (j)(1) of this section must be implemented.

(ii) If a standard design certification applicant (including an applicant after the Commission has adopted a final design certification regulation) is required by paragraph (j)(1)(iv) of this section to submit a reanalysis, or identifies a change to, or error in an ECCS evaluation model, or in the application of such a model, that results in any predicted response that exceeds any of the acceptance criteria specified in this section, then the standard design certification applicant (including an applicant after the Commission has adopted a final design certification regulation) must propose appropriate steps to the Commission, as specified in § 52.3 of this chapter, within 60 days to demonstrate compliance with § 50.46a 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.

(iii) If an applicant for or holder of a standard design approval under part 52 of this chapter is required by paragraph (j)(1)(iv) of this section to submit a reanalysis, or identifies a change to, or error in an ECCS evaluation model, or in the application of such a model, that results in any predicted response that exceeds any of the acceptance criteria specified in this section, then the standard design approval applicant or holder must propose appropriate steps to the Commission, as specified in § 52.3 of this chapter, within 60 days to demonstrate compliance with § 50.46a 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.

(3) *Minimal changes: reporting.* No later than 24 months after NRC approval of the entity's application and every 24 months thereafter, the entity must submit, as specified in § 50.4 or § 52.3 of this chapter, a short description of each change involving minimal changes in risk made under paragraph (h)(1) of this section in the preceding 24 months and a brief summary of the basis for the entity's determination pursuant to paragraph (h)(1)(iii) of this section that the change does not invalidate the applicability evaluation made under paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the plant-specific TBS evaluation made under paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(4) *Inspection: reporting.* Within 120 days after completing the outage when the inspections specified in paragraph (d)(5) of this section were performed, the licensee must submit a summary report detailing the results of the inspections and the evaluation of the effect on the TBS of any additional degradation identified since the previous evaluation. This report can be combined with the summary report required by § 50.55a(b)(2)(xxxii).

(k) *Significant change or error in the ECCS evaluation model.*

(1) For LOCAs at or below the TBS, a significant change or error in the ECCS evaluation model for uranium oxide and mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding is one that results in:

(i) A calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable evaluation 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; or

(ii) A calculated integral time-at-temperature different by more than 1.0 percent equivalent cladding reacted from the oxidation calculated for the limiting transient using the last acceptable evaluation model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective oxidation changes is greater than 1.0 percent equivalent cladding reacted.

(2) For LOCAs above the TBS, a significant change or error in the ECCS evaluation model for uranium oxide and mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding is one that results in a significant reduction in the capability to meet the requirements of paragraphs (e)(1) and (f) of this section.

(3) For fuel that does not consist of uranium or mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding, a significant change in the ECCS evaluation model is one that results in a significant reduction in the capability to meet the requirements of paragraphs (e)(1) and (f) of this section.

(l) *Documentation.* Following implementation of the requirements in this section, each entity subject to this section must maintain records sufficient to demonstrate compliance with the requirements in this section in accordance with § 50.71.

■ 11. Add § 50.46b under the undesignated center heading ''Standards for Licenses, Certifications, and Regulatory Approvals'' to read as follows:

§ 50.46b Acceptance criteria for reactor coolant system venting systems.

Each nuclear power reactor must be provided with high-point vents for the reactor coolant system, for the reactor vessel head, and for other systems required to maintain adequate core cooling if the accumulation of noncondensible gases would cause the loss of function of these systems. High-point vents are not required for the tubes in U-tube steam generators. Acceptable venting systems must meet the following criteria:

(a) The high-point vents must be remotely operated from the control room.

(b) The design of the vents and associated controls, instruments, and power sources must conform to appendix A and appendix B of this part.

(c) The vent system must be designed to ensure that:

(1) The vents will perform their safety functions; and

(2) There would not be inadvertent or irreversible actuation of a vent.

■ 12. In § 50.47,

■ a. In paragraph (b)(10), remove the word ''EPZ'' wherever it appears;

■ b. Revise paragraph (c)(2); and

■ c. Add paragraphs (g) and (h) to read as follows:

§ 50.47 Emergency plans.

* * * * *

(c) * * *

(2) Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 50.33(g)(2). The exact size and configuration of the EPZ surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

* * * * *

(g) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State, local, and Tribal governmental authorities have agreed to the EPZ change.

(h) A licensee desiring to comply with the requirements of § 50.160 in lieu of appendix E to this part, and for nuclear power reactor licensees, the planning standards of § 50.47(b), must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change.

■ 13. In § 50.49, remove footnote 3, redesignate footnote 4 as footnote 1, and revise and republish paragraph (b) to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

* * * * *

(b) Electric equipment important to safety covered by this section is:

(1) Safety-related electric equipment.

(i) This equipment is that relied upon to remain functional during and following design basis events to ensure—

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in § 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(ii) For applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for a license, permit, standard design certification, or standard design approval under this part or part 52 of this chapter, design basis events are defined in § 50.2. This definition also applies to other licenses, permits, standard design certifications, or standard design approvals for which the NRC has approved adopting the § 50.2 definition for design basis events. In all other cases, design basis events are defined as conditions of normal operation, including anticipated operational occurrences, design basis accidents, external events, and natural phenomena for which the plant must be designed to ensure functions (b)(1)(i)(A) through (C) of this section.

(2) Non-safety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions specified in subparagraphs (b)(1)(i)(A) through (C) of this section by the safety-related equipment.

(3) Certain post-accident monitoring equipment.[1]

* * * * *

[1] Specific guidance concerning the types of variables to be monitored is provided in Revision 2 of Regulatory Guide 1.97, ''Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident.'' Copies of the Regulatory Guide may be purchased through the U.S. Government Publishing Office by calling 202–512–1800 or by writing to the U.S. Government Publishing Office, P.O. Box 37082, Washington, DC 20013–7082.

■ 14. In § 50.54, add paragraphs (a)(5) and (q)(1)(v) and revise paragraphs (a)(1), (q)(2), (q)(3), and (t) to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B or T of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program or quality management system, respectively, described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program or quality management system described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

* * * * *

(5) Changes to the quality management system must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 50.4.

(ii) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of this part and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

* * * * *

(q) * * *

(1) * * *

(v) *Risk significant planning standard* means the most essential functions of emergency preparedness to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency. For the purposes of this section, the risk significant planning standards are classification, notification, assessment, protective actions, staffing, and facilities.

(2) A holder of a license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b), or an emergency plan that meets the requirements in § 50.160.

(3) A licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that:

(i) For planning standards that are risk significant, the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the risk significant requirements of § 50.160 or the applicable requirements in appendix E to this part and, for nuclear power reactor licensees, the risk significant planning standards of § 50.47(b); and

(ii) For planning standards that are not risk-significant, the plan, as changed, continues to meet the applicable requirements.

* * * * *

(t) The licensee must provide for annual evaluation of the adequacy of the interfaces between the licensee and the applicable State, local, and Tribal governments, including licensee drills, exercises, capabilities, and procedures. The results of the evaluation, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, retained for a period of 5 years, and must be made available to the appropriate State, local, and Tribal governments.

* * * * *

■ 15. In § 50.55, revise paragraph (f)(1) and add paragraph (f)(5) to read as follows:

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

* * * * *

(f)(1) Each nuclear power plant or fuel reprocessing plant construction permit holder subject to the quality assurance criteria in appendix B or T of this part shall implement, pursuant to § 50.34(a)(7) of this part, the quality assurance program description or quality management system, respectively, described or referenced in the Safety Analysis Report, including changes to that report.

* * * * *

(5) Changes to the quality management system must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 50.4.

(ii) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of this part and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

* * * * *

§ 50.55a [Amended]

■ 16. In § 50.55a, in paragraph (z) introductory text, remove the phrase ''of paragraphs (b) through (h)''.

■ 17. In § 50.57, add paragraph (d) to read as follows:

§ 50.57 Issuance of operating license.[1]

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a utilization facility, including postulated site parameters, and requirements submitted pursuant to § 50.34(b)(14), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

[1] The Commission may issue a provisional operating license pursuant to the regulations in this part in effect on March 30, 1970, for any facility for which a notice of hearing on an application for a provisional operating license or a notice of proposed issuance of a provisional operating license has been published on or before that date.

■ 18. In § 50.58, add paragraphs (b)(7) and (b)(8) to read as follows:

§ 50.58 Hearings and report of the Advisory Committee on Reactor Safeguards.

* * * * *

(b) * * *

(7) If an applicant requests generic finality under § 50.34(b)(14) for an operating license under this part, the Commission will include a request for generic finality as a proposed action in the notice of proposed action required by § 2.105 of this chapter.

(8) In a proceeding for issuance of a construction permit, operating license, or combined license, or in any enforcement hearing other than one initiated by the Commission under § 2.202(e)(1) of this chapter, in which an operating license issued under this subpart is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced operating license, including, if applicable, the adequacy of a reactor design, if the referenced operating license was afforded finality pursuant to § 50.57(d).

■ 19. In § 50.59, revise paragraphs (c)(2)(viii) and (d)(1) and add paragraphs (e) and (f) to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(c) * * *

(2) * * *

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses, unless the licensee has demonstrated through a documented verification, validation, and uncertainty quantification (VVUQ) process, conducted under a VVUQ program that meets the requirements of § 50.221 and has been approved by the NRC for the intended application, that the departure from a method of evaluation described in the FSAR (as updated) meets the criteria established for credibility in the VVUQ program, including implementation of established VVUQ activities and assessments.

* * * * *

(d) (1) The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) or (f) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license amendment pursuant to paragraph (c)(2) or (f) of this section.

* * * * *

(e) For the purposes of criteria § 50.59(c)(2)(i) and (ii), an increase may be demonstrated to not be a ''more than a minimal increase'' using quantitative risk results based on a probabilistic risk assessment of appropriate scope and quality that provides appropriate risk metrics. The change must also maintain defense-in-depth and safety margins.

(f) The holder of an operating license or a combined license that authorizes operation of a manufactured reactor may make changes in the facility as described in the final safety analysis report (as updated) and make changes in the procedures as described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 if the changes are identical to changes approved by the Commission by amendment to the manufacturing license for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the manufacturing license and not involve any additional changes that would require an amendment to its operating license or combined license.

■ 20. In § 50.67, revise and republish paragraph (b) to read as follows:

§ 50.67 Accident source term.

* * * * *

(b) *Requirements.*

(1) A licensee who seeks to revise its current accident source term in design basis radiological consequence analyses must apply for a license amendment

under § 50.90. The application must contain an evaluation of the consequences of applicable design basis accidents [1] previously analyzed in the safety analysis report.

(2) The NRC may issue the amendment only if the applicant's analysis demonstrates with reasonable assurance that:

(i) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(ii) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage), would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE.

(iii) The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without calculated radiation exposures in excess of 10 rem (0.10 Sv) TEDE or a higher design criterion limit established in accordance with paragraph (b)(3) of this section for the duration of the accident.

(3) The licensee may establish a design criterion limit higher than 10 rem (0.10 Sv) TEDE but not greater than 25 rem [3] (0.25 Sv) TEDE for compliance with paragraph (b)(2)(iii) of this section provided the licensee demonstrates that the specified limit is consistent with the plant risk profile or commensurate with the risk of the plant.

[1] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of design analyses 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.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this value constitutes an acceptable limit for emergency doses to the public under accident conditions. Rather, this 25 rem (0.25 Sv) TEDE value has been stated in this section as a reference value, which can be used in the evaluation of proposed design basis changes with respect to potential reactor accidents of exceedingly low probability of occurrence and low risk of public exposure to radiation.

[3] The use of 25 rem (0.25 Sv) TEDE as the control room criterion is not intended to imply that this value constitutes an acceptable limit for emergency doses under accident conditions. Adequate radiological protection for occupationally exposed individuals is provided by the provisions of part 20 of this chapter and § 50.47(b)(11). This criterion is provided only to assess the acceptability of design provisions, in particular engineered safety features that mitigate fission product release, under postulated DBA conditions. The conditions assumed in these analyses, although credible, are of exceedingly low probability of occurrence and do not represent actual accident sequences but are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.

■ 21. In § 50.68, revise paragraph (b)(7) to read as follows:

§ 50.68 Criticality accident requirements.

* * * * *

(b) * * *

(7) The maximum nominal U–235 enrichment of the fresh fuel assemblies is limited to five (5.0) percent by weight or to the value specified in the operating license which must be less than twenty (20.0) percent by weight.

* * * * *

§ 50.69 [Amended]

■ 22. In § 50.69, revise paragraph (b)(1)(ii) by removing the reference ''10 CFR 50.46a(b)'' and adding in its place ''§ 50.46b(b)''.

■ 23. In § 50.71, revise paragraph (f) to read as follows:

§ 50.71 Maintenance of records, making of reports.

* * * * *

(f) Each person licensed to manufacture a nuclear power reactor under subpart F of part 52 of this chapter shall update the FSAR originally submitted as part of the application to reflect the effects[2] of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved amendments to the manufacturing license or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2); and any new analyses of safety issues performed by or on behalf of the licensee at the NRC's request. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee with respect to the modification under § 52.171 of this chapter or the analyses requested by the Commission under § 52.171 of this chapter. The updated information shall be appropriately located within the update to the FSAR.

* * * * *

[2] See footnote 1.

■ 24. In § 50.75,

■ a. Revise paragraphs (b), (c), and (e)

■ b. In paragraph (g)(4)(iii), remove the phrase ''10 CFR Part 20, Subpart E'' and add in its place the phrase ''subpart E to part 20 of this chapter'';

■ c. In paragraph (h)(5), remove the reference ''(h)(3)'' and add in its place ''(3)''.

The revisions are to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

* * * * *

(b) Each power reactor applicant for or holder of an operating license, and each applicant for a combined license under subpart C of part 52 of this chapter for a production or utilization facility shall submit a decommissioning report, as required by § 50.33(k).

(1)(i) For an applicant for or holder of an operating license under this part of a type and power level specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section. For an applicant for a combined license under subpart C of part 52 of this chapter of a type and power level specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be provided no later than 30 days after the Commission publishes notice in the **Federal Register** under § 52.103(a) of this chapter in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section, adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(ii) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(iii) The amount must be covered by one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(iv) The amount stated in the applicant's or licensee's certification may be based on a site-specific cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; *provided, however,* that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

(2)(i) For an applicant for or holder of an operating license under this part or subpart C of part 52 of this chapter of a type and power level other than that specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount that may be based on a design-specific decommissioning cost estimate or the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(ii) A certification relying on a design-specific decommissioning cost estimate must demonstrate that there is reasonable assurance that sufficient funds necessary for safely decommissioning the facility will be available, when needed, and provide the factors used to develop the design-specific decommissioning cost estimate, including reactor technology, power level (in MWt), and costs related to labor, energy, and waste burial. Additionally, design-specific decommissioning cost estimates must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

(iii) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(iv) The amount must be covered by one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(v) The amount stated in the applicant's or licensee's certification may be based on a site-specific cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; *provided, however,* that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

(c) Table of minimum amounts (January 1986 dollars) required to demonstrate reasonable assurance of funds for decommissioning by reactor type and power level, P (in MWt); adjustment factor.[1]

		Millions
(1)(i) For a PWR:	greater than or equal to 3400 MWt	\$105
	between 1200 MWt and 3400 MWt	\$(75+0.0088P)
(ii) For a BWR:	greater than or equal to 3400 MWt	\$135
	between 1200 MWt and 3400 MWt	\$(104+0.009P)

(2) An adjustment factor at least equal to 0.65 L + 0.13 E + 0.22 B is to be used where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG–1307, ''Report on Waste Burial Charges.''

* * * * *

(e)(1) Financial assurance is to be provided by the following methods.

(i) *Prepayment.* Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 50.80 into an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs at the time permanent termination of operations is expected. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by, certificate of deposit, deposit of Government or other securities or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal Government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds based on a site-specific estimate under paragraph (b)(1) or (2) of this section may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2-percent annual real rate of return from the time of future funds' collection through the projected decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination. An applicant or licensee that has prepaid funds based on a design-specific estimate under paragraph(b)(2) of this section or on the formulas in paragraph (c) of this section may take credit for projected earnings on the prepaid decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates or formula amounts (*i.e.,* not a site-specific estimate) can take a pro-rata credit during the immediate dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs.

(ii) *External sinking fund.* An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs at the time permanent termination of operations is expected. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal Government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has collected funds based on a site-specific estimate under paragraph (b)(1) or (2) of this section may take credit for projected earnings on the external sinking funds using up to a 2-percent annual real rate of return from the time of future funds' collection through the decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination. An applicant or licensee that has collected funds based on a design-specific estimate under paragraph (b)(2) of this section or on the formulas in paragraph (c) of this section may take credit for collected earnings on the decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates or formula amounts (*i.e.,* not a site-specific estimate) can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee, whose rates for decommissioning costs cover only a portion of these costs, may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph (e)(1)(ii). This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(A) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by ''cost of service'' or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are assumed to meet this condition.

(B) By an applicant or licensee whose source of revenues for its external sinking fund is a ''non-bypassable charge,'' the total amount of which will provide funds estimated to be needed for decommissioning pursuant to paragraph (b), (c), or (f) of this section, or § 50.82.

(iii) *A surety method, insurance, or other guarantee method.*

(A) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(*1*) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(*2*) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal Government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(B) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to part 30 of this chapter.

(C) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to part 30 of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to part 30 of this chapter. For non-profit entities, such as colleges, universities, and non-profit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to part 30 of this chapter. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(iv) *Statements of intent.* For a Federal applicant for or holder of a power reactor operating license, or for a Federal, State, or local government applicant or holder of an operating license for a non-power production or utilization facility, a statement of intent containing a cost estimate for decommissioning, and indicating that funds for decommissioning will be obtained when necessary.

(v) *Contractual obligations.* Contractual obligation(s) on the part of an applicant's or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant's or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to paragraph (b), (c), or (f) of this section, or § 50.82. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) shall include provisions that the electricity buyer(s) will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed power reactor to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(vi) *Other mechanisms.* Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each application or licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (e)(1)(i) through (v) of this section. Applicants or licensees who do not have sources of funding described in paragraph (e)(1)(ii) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (e)(1)(iii) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

(2) The NRC reserves the right to take the following steps in order to ensure an applicant's or licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds; and, either independently or in cooperation with the FERC and the applicant's or licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of an applicant's or licensee's schedule for the accumulation of decommissioning funds.

(3) Each holder of a combined license under subpart C of part 52 of this chapter shall, 2 years before and 1 year before the scheduled date for initial loading of fuel, consistent with the schedule required by § 52.99(a) of this chapter, submit a report to the NRC containing a certification updating the information described under paragraph (b) of this section, including a copy of the financial instrument to be used. No later than 30 days after the Commission publishes notice in the **Federal Register** under § 52.103(a) of this chapter, the licensee shall submit a report containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification, including a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

* * * * *

[1] Amounts are based on activities related to the definition of ''Decommission'' in § 50.2 of this part and do not include the cost of removal and disposal of spent fuel or of nonradioactive structures and materials beyond that necessary to terminate the license.

■ 25. In § 50.160, revise the section heading and paragraphs (b)(1)(iv)(A)(2), (b)(3), and (c) to read as follows:

§ 50.160 Performance-based emergency preparedness standards.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(A) * * *

(*2*) Implement the emergency plan in response to a security event.

* * * * *

(3) *Emergency planning zone.* Determine and describe the boundary and physical characteristics of the EPZ in the emergency plan as required by § 50.33(g)(1) or 53.1109(g)(1) of this chapter.

* * * * *

(c) *Implementation.*

(1) An applicant for an operating license issued under this part after December 18, 2023, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance before the issuance of an operating license for the facility described in the license application.

(2) A holder of a combined license issued under part 52 or 53 of this chapter before the Commission has made the finding under § 52.103(g) or 53.1452(g) of this chapter, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the approved emergency plan and license, and conduct an initial exercise to demonstrate this compliance before the scheduled date for initial loading of fuel, or for a fueled manufactured reactor, before the scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter.

(3) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State and local governmental authorities have agreed to the EPZ change.

(4) A licensee desiring to comply with the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards in § 50.47(b) in lieu of § 50.160 must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change.

■ 26. Add § 50.220 under a new undesignated heading ''Risk-Informed and Performance-Based Alternatives'' consisting of § 50.220 and § 50.221 to read as follows:

Risk-Informed and Performance-Based Alternatives

§ 50.220 Use of risk-informed and performance-based alternatives to acceptance criteria.

(a) For each regulation in this part that provides specific acceptance criteria, licensees or applicants may propose, either through a license amendment request or as part of an application for an initial license, an alternative under paragraph (b) of this section. If a proposal under paragraph (b) of this section includes alternatives to acceptance criteria in more than one regulation in this part, it must analyze the cumulative effect of those changes to ensure that an appropriate level of safety is maintained.

(b) An applicant for or a holder of a construction permit or operating license under this part; or an applicant for or holder of a design approval, operating license, a combined license, or manufacturing license under this chapter; voluntarily choosing to implement this section must submit a license amendment application that contains the following information or include the following information in the initial application:

(1) The specific regulation and the acceptance criteria for which the alternative criteria are being proposed.

(2) The alternative criteria proposed in place of the acceptance criteria. If applicable, the alternative criteria must include either the selected performance targets or a description of the methodology that will be used to determine the performance targets.

(3) A description of the process followed to develop the alternative acceptance criteria. The process must:

(i) Consider results and insights from the plant- or design-specific probabilistic risk assessment (PRA) or systematic risk assessment or combination thereof to show that the alternate proposed criteria establish an equivalent level of safety to the existing acceptance criteria.

(ii) Reasonably reflect the current plant configuration and operating practices, and applicable plant, facility, and industry operational experience.

(iii) Achieve or maintain adequate defense-in-depth.

(iv) Achieve or maintain sufficient safety margins.

(v) Use an integrated panel of plant- or design-knowledgeable members whose collective expertise supports an integrated evaluation of the alternative criteria.

(vi) Include a performance monitoring program that will be used to periodically evaluate whether the alternative criteria remain valid and make timely adjustments to the design and/or operation of the plant or facility as necessary to maintain the validity.

(vii) Include an evaluation of the cumulative effect of the proposed alternative criteria with relevant NRC-approved alternative criteria.

■ 27. Add § 50.221 under the undesignated center heading ''Risk-Informed and Performance-Based Alternatives'' to read as follows:

§ 50.221 Credibility requirements for modeling and simulation.

(a) *Purpose and scope.*

(1) *Purpose.* This regulation establishes requirements for licensees or applicants to voluntarily adopt a verification, validation, and uncertainty quantification (VVUQ) program that will ensure the credibility of models and simulations (M&S), used to demonstrate compliance with NRC safety criteria for nuclear power plants.

(2) *Scope.* A VVUQ program may apply to any model or simulation whose results inform or directly support nuclear power plant safety assessments, performance criteria, regulatory decisions, or otherwise contribute to demonstrating compliance with regulatory requirements.

(b) *Definitions.* For the purpose of this section:

(1) *Credibility* means the degree to which a model's predictions for a specific purpose can be justifiably trusted such that it can be relied upon.

(2) *Verification, validation, and uncertainty quantification (VVUQ)* means activities related to verification, validation, and uncertainty quantification, as well as all other supporting tools and techniques used to establish and demonstrate the credibility of a model or simulation.

(3) *M&S risk* is defined as the combination of the likelihoods that the M&S is incorrect or misleading and the consequences of relying on the incorrect or misleading result for some decision making purpose. Because simulations inherently include multiple potential sources of error, assessing M&S risk is generally a cumulative process. M&S risk can serve as a basis for establishing a tiered review framework, organized into three levels: low, medium, and high.

(i) *Low risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have low risk may be accomplished using internal quality assurance procedures established by the licensee's or applicant's quality assurance program.

(ii) *Medium risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have medium risk may be provided by an external organization independent of the internal modeling group.

(iii) *High risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have high risk require review and approval by the NRC, generally through the submittal of license amendments or topical reports.

(c) *Credibility requirements.* The VVUQ program must establish credibility requirements. Credibility requirements address two complementary elements: the specific activities performed to establish model or simulation credibility (VVUQ Activities), and the evaluation demonstrating that the outcomes of these activities are sufficient and appropriate for the intended use of the model or simulation (VVUQ Assessments). Licensees and applicants may not adopt or rely on a model or simulation covered by the VVUQ program prior to successful completion of VVUQ activities and VVUQ assessments.

(1) *VVUQ activities.* The VVUQ program must specify the activities necessary to establish and ensure the credibility of M&S used in regulatory or safety applications for that specific VVUQ program. The specific activities required depend on the characteristics of the model or simulation, its intended application, and the associated M&S risk. When considering M&S risk, individual error sources and their associated likelihoods and consequences must be evaluated and then combined to quantify the overall risk. In addition to verification, validation, and uncertainty quantification, VVUQ programs may include a range of supporting activities. These include, but are not limited to, sensitivity analyses, scaling evaluations, comparisons against experimental or operational data, and any other relevant methods or techniques needed to adequately establish credibility.

(2) *VVUQ assessments.* The VVUQ program must require an evaluation of the outcomes of the VVUQ activities performed to determine whether they are sufficient to justify trust in the model or simulation for its specific application. This assessment must consider all relevant uncertainties and potential errors associated with the model or simulation, including but not limited to those stemming from computational methods, numerical approximations, input parameters, modeling assumptions, and comparisons to experimental or operational data. The VVUQ program must require identification of the applicability, limitations, and key assumptions inherent to the modeling or simulation approach, ensuring that the depth and rigor of the assessment appropriately reflect the intended use, scope, and associated risk of the specific model or simulation. Assessments must not only evaluate numerical or quantitative outcomes of the VVUQ activities, but also clearly interpret the significance of these outcomes within the context of their intended regulatory application.

■ 28. In appendix A to part 50,

■ a. Under the heading ''Introduction,'' in the last sentence of the last paragraph, remove the word ''must'' and add in its place the word ''may'' and remove the word ''justified.'' and add in its place the phrase ''justified within the licensing submittal without needing an exemption.''

■ b. Under the heading ''Criteria,'' criteria 17, 19, 28, 35, 38, 41, 44, and 50 are revised to read as follows:

Appendix A to Part 50—General Design Criteria for Nuclear Power Plants

* * * * *

Criterion 17—Electric power systems. An onsite electric power system and an offsite electric power system shall be provided to permit functioning of structures, systems, and components important to safety. The safety function for each system (assuming the other system is not functioning) shall be to provide sufficient capacity and capability to assure that:

(1) specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded as a result of anticipated operational occurrences and

(2) the core is cooled and containment integrity and other vital functions are maintained in the event of postulated accidents.

The onsite electric power supplies, including the batteries, and the onsite electric distribution system, shall have sufficient independence, redundancy, and testability to perform their safety functions assuming a single failure, except for loss-of-coolant accidents involving breaks in the reactor system coolant pressure boundary larger than the transition break size under § 50.46a, where a single failure of the onsite power supplies and electrical distribution system need not be assumed for plants under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

Electric power from the transmission network to the onsite electric distribution system shall be supplied by two physically independent circuits (not necessarily on separate rights of way) designed and located so as to minimize, to the extent practical, the likelihood of their simultaneous failure under operating and postulated accident and environmental conditions. A switchyard common to both circuits is acceptable. Each of these circuits shall be designed to be available in sufficient time following a loss of all onsite alternating current power supplies and the other offsite electric power circuit, to assure that specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded. One of these circuits shall be designed to be available within a few seconds following a loss-of-coolant accident to assure that core cooling, containment integrity, and other vital safety functions are maintained.

Provisions shall be included to minimize the probability of losing electric power from any of the remaining supplies as a result of, or coincident with, the loss of power generated by the nuclear power unit, the loss of power from the transmission network, or the loss of power from the onsite electric power supplies.

* * * * *

Criterion 19—Control room. A control room shall be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions, including loss-of-coolant accidents. The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without calculated radiation exposures in excess of 10 rem (0.10 Sv) whole body, or its equivalent to any part of the body, or a higher design criteria limit established in accordance with paragraph (2) of this section for the duration of the accident. Equipment at appropriate locations outside the control room shall be provided

(1) with a design capability for prompt hot shutdown of the reactor, including necessary instrumentation and controls to maintain the unit in a safe condition during hot shutdown;

(2) with a potential capability for subsequent cold shutdown of the reactor through the use of suitable procedures. Applicants for and holders of construction permits and operating licenses under this part who apply on or after January 10, 1997; applicants for standard design approvals or certifications under part 52 of this chapter who apply on or after January 10, 1997; applicants for and holders of combined licenses or manufacturing licenses under part 52 of this chapter who do not reference a standard design approval or certification; or holders of operating licenses using an alternative source term under § 50.67, shall meet the requirements of this criterion. The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without personnel receiving calculated radiation exposures in excess of 10 rem (0.10 Sv) total effective dose equivalent (TEDE) or a higher design criterion limit established in accordance with paragraph (3) of this section for the duration of the accident; and

(3) with a design criterion limit higher than 10 rem (0.10 Sv) TEDE but not greater than 25 rem [3] (0.25 Sv) TEDE for compliance with paragraph (2) of this section provided the licensee demonstrates that the specified limit is consistent with the plant risk profile or commensurate with the risk of the plant.

* * * * *

Criterion 28—Reactivity limits. The reactivity control systems shall be designed with appropriate limits on the potential amount and rate of reactivity increase to assure that the effects of postulated reactivity accidents can neither

(1) result in damage to the reactor coolant pressure boundary greater than limited local yielding nor

(2) sufficiently disturb the core, its support structures or other reactor pressure vessel internals to impair significantly the capability to cool the core. These postulated reactivity accidents shall include the maximum reactivity insertion and rate resulting from a failure or malfunction of the reactivity control systems, steam line rupture, changes in reactor coolant temperature and pressure, and cold-water addition.

* * * * *

Criterion 35—Emergency core cooling. A system to provide abundant emergency core cooling shall be provided. The system safety function shall be to transfer heat from the reactor core following any loss of reactor coolant at a rate such that

(1) fuel and clad damage that could interfere with continued effective core cooling is prevented and

(2) clad metal-water reaction is limited to negligible amounts.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for loss-of-coolant accidents involving breaks in the reactor coolant system boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 38—Containment heat removal. A system to remove heat from the reactor containment shall be provided. The system safety function shall be to reduce rapidly, consistent with the functioning of other associated systems, the containment pressure and temperature following any loss-of-coolant accident and maintain them at acceptably low levels.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 41—Containment atmosphere cleanup. Systems to control fission products, hydrogen, oxygen, and other substances which may be released into the reactor containment shall be provided as necessary to reduce, consistent with the functioning of other associated systems, the concentration and quality of fission products released to the environment following postulated accidents, and to control the concentration of hydrogen or oxygen and other substances in the containment atmosphere following postulated accidents to assure that containment integrity is maintained.

Each system shall have suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) its safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 44—Cooling water. A system to transfer heat from structures, systems, and components important to safety, to an ultimate heat sink shall be provided. The system safety function shall be to transfer the combined heat load of these structures, systems, and components under normal operating and accident conditions.

Suitable redundancy in components and features, and suitable interconnections, leak detection, and isolation capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 50—Containment design basis. The reactor containment structure, including access openings, penetrations, and the containment heat removal system shall be designed so that the containment structure and its internal compartments can accommodate, without exceeding the design leakage rate and with sufficient margin, the calculated pressure and temperature conditions resulting from any loss-of-coolant accident. This margin shall reflect consideration of

(1) the effects of potential energy sources which have not been included in the determination of the peak conditions, such as energy in steam generators and as required by § 50.44 energy from metal-water and other chemical reactions that may result from degradation but not total failure of emergency core cooling functioning,

(2) the limited experience and experimental data available for defining accident phenomena and containment responses, and

(3) the conservatism of the calculational model and input parameters.

For reactors designed to comply with § 50.46a, the structural and leak tight integrity of the reactor containment structure, including access openings, penetrations, and its internal compartments, shall be maintained for realistically calculated pressure and temperature conditions resulting from any loss-of-coolant accident larger than the transition break size.

* * * * *

[3] The use of 25 rem (0.25 Sv) whole body, or its equivalent to any part of the body as the control room criterion is not intended to imply that this value constitutes an acceptable limit for emergency doses under accident conditions. This criterion is provided only to assess the acceptability of design provisions, in particular engineered safety features that mitigate fission product release under postulated DBA conditions. The conditions assumed in these analyses, although credible, are of exceedingly low probability of occurrence and do not represent actual accident sequences but are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features. Adequate radiological protection for occupationally exposed individuals is provided by the provisions of part 20 of this chapter and § 50.47(b)(11).

■ 29. In appendix E to part 50,

■ a. Revise section I;

■ b. Remove and reserve section II;

■ c. Revise paragraphs IV.3., IV.4., IV.D.2., IV.D.3., IV.E.8.b. introductory text, IV.E.9.d., IV.F.2. introductory text, IV.F.2.a., and IV.F.2.c. second sentence of the introductory text;

■ d. Remove and reserve paragraphs IV.5. through 7.;and

■ c. Revise footnote 1 to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. Introduction

1. Each applicant for an operating license is required by § 50.34(b) or § 53.1369 of this chapter to include in the final safety analysis report plans for coping with emergencies. Each applicant for a combined license under subpart C of part 52 of this chapter or subpart H of part 53 of this chapter is required by § 52.79 or § 53.1416 of this chapter to include in the application plans for coping with emergencies. Each applicant for an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter may submit plans for coping with emergencies under § 52.17 or § 53.1146 of this chapter.

2. This appendix establishes minimum requirements for emergency plans for use in attaining an acceptable state of emergency preparedness. These plans shall be submitted as part of the final safety analysis report for an operating license. These plans, or major features thereof, may be submitted as part of the site safety analysis report for an early site permit.

3. The potential radiological hazards to the public associated with the operation of non-power production or utilization facilities licensed under this part and fuel facilities licensed under part 70 of this chapter involve considerations different than those associated with nuclear power reactors. Consequently, the size of Emergency Planning Zones [1] (EPZs) for facilities other than power reactors and the degree to which compliance with the requirements of this section and sections III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.[2]

4. Notwithstanding the above paragraphs, in the case of an operating license authorizing only fuel loading and/or low power operations up to 5 percent of rated power, no NRC or FEMA review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and the capability to implement State and local offsite emergency plans, as defined in this appendix, are required prior to the issuance of such a license.

5. For power reactors with site-boundary EPZs or no EPZ, the degree to which compliance with the requirements of this section and sections III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.

6. The Tennessee Valley Authority Watts Bar Nuclear Plant, Unit 2, holding a construction permit under the provisions of part 50 of this chapter, shall meet the requirements of the final rule issued November 23, 2011, as applicable to operating nuclear power reactor licensees.

7. For a fueled manufactured reactor licensed under part 53 of this chapter, the date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) is equivalent to the initial loading of fuel in this appendix.

II. [Reserved]

* * * * *

IV. * * *

3. Nuclear power reactor licensees shall use evacuation time estimates (ETEs) and updates to the ETEs in the formulation of predetermined, prompt protective action recommendations and shall provide the ETEs and ETE updates to State and local governmental authorities for use in developing offsite predetermined, prompt protective action strategies.

4. Within 365 days of the date of the availability of the most recent decennial census data from the U.S. Census Bureau, nuclear power reactor licensees shall develop an ETE analysis using this decennial data and submit it under § 50.4 or § 53.040 of this chapter to the NRC. These licensees shall submit this ETE analysis to the NRC at least 180 days before using it to form predetermined, prompt protective action recommendations and providing it to State and local governmental authorities for use in developing offsite predetermined, prompt protective action strategies.

5. [Reserved]

6. [Reserved]

7. [Reserved]

* * * * *

D. * * *

2. Provisions shall be described for yearly dissemination to the public within the plume exposure pathway EPZ of basic emergency planning information, such as the methods and times required for public notification and the protective actions planned if an accident occurs, general information as to the nature and effects of radiation, and a listing of media sources that will be used for dissemination of information during an emergency. Signs or other measures shall also be used to disseminate to any transient population within the plume exposure pathway EPZ appropriate information that would be helpful if an accident occurs.

3. A licensee shall have the capability to notify responsible State and local governmental agencies within 15 minutes after declaring an emergency. The licensee shall demonstrate that the appropriate governmental authorities have the capability to make a public alerting and notification decision promptly on being informed by the licensee of an emergency condition. Prior to initial operation greater than 5 percent of rated thermal power of the first reactor at a site, each nuclear power reactor licensee shall demonstrate that means have been established for alerting and providing prompt instructions to the public within the plume exposure pathway EPZ. The design objective of the alert and notification system (ANS) shall be to have the capability to essentially complete the initial alerting and initiate notification of the public within the plume exposure pathway EPZ within about 15 minutes. The use of this alerting and notification capability will range from immediate alerting and notification of the public (within 15 minutes of the time that State and local officials are notified that a situation exists requiring urgent action) to the more likely events where there is substantial time available for the appropriate governmental authorities to make a judgment whether or not to activate the ANS. The alerting and notification capability shall additionally include means for a backup method of ANS capable of being used in the event the primary method of alerting and notification is unavailable during an emergency to alert or notify all or portions of the plume exposure pathway EPZ population. Alternatively, if the ANS capability, as documented in the ANS Design Report, demonstrates that the primary method of alerting and notifying is robust and has multiple methods implemented in parallel, an independent backup method is

unnecessary. If a backup method is necessary, it shall have the capability to alert and notify the public within the plume exposure pathway EPZ, but does not need to meet the 15-minute design objective for the primary prompt public alert and notification system. When there is a decision to activate the alert and notification system, the appropriate governmental authorities will determine whether to activate the entire alert and notification system simultaneously or in a graduated or staged manner. The responsibility for activating such a public alert and notification system shall remain with the appropriate governmental authorities.

E. * * *

8. * * *

b. For a nuclear power reactor licensee's emergency operations facility required by paragraph 8.a of this section, either a facility located outside the EPZ or a backup facility outside the EPZ if the primary facility is within the EPZ or onsite. An emergency operations facility may serve more than one nuclear power reactor site. A licensee desiring to locate an emergency operations facility more than 25 miles from a nuclear power reactor site shall request prior Commission approval by submitting an application for an amendment to its license. For an emergency operations facility located more than 25 miles from a nuclear power reactor site, provisions must be made for locating NRC and offsite responders closer to the nuclear power reactor site so that NRC and offsite responders can interact face-to-face with emergency response personnel entering and leaving the nuclear power reactor site. Provisions for locating NRC and offsite responders closer to a nuclear power reactor site that is more than 25 miles from the emergency operations facility must include the following:

* * * * *

9. * * *

d. Provisions for communications by the licensee with the NRC Headquarters Operations Center from the nuclear power reactor control room, the onsite technical support center, and the emergency operations facility, as applicable. Such communications shall be tested monthly.

* * * * *

F. * * *

2. The plan shall describe provisions for the conduct of emergency preparedness drills and exercises.[3] Licensees must submit scenarios under § 50.4 or § 53.040 of this chapter no later than 60 days before use in a required drill or exercise. These scenarios must document the applicable regulation(s) the scenario is intended to meet.

a. A full participation [4] exercise which tests as much of the licensee, State, and local emergency plans as is reasonably achievable without mandatory public participation shall be conducted for each site at which a power reactor is located in order to validate the effectiveness of the onsite, and if necessary, the offsite emergency plans and offsite coordination.

(i) For an operating license issued under part 50 or part 53 of this chapter, and if there are no preexisting licensed power reactors at this site, this exercise must be conducted 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 must include participation by each State and local government within the plume exposure pathway EPZ, as applicable. If the applicant currently has an operating reactor at the site with similar onsite and offsite emergency plan elements, this exercise may be included within the operating reactor licensee's existing exercise schedules.

(ii) For a combined license issued under part 52 or part 53 of this chapter, this exercise must be conducted before the scheduled date for initial loading of fuel. 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 or part 53 of this chapter, if the applicant currently has an operating reactor at the site with similar onsite and offsite emergency plan elements, this exercise may be included within the operating reactor licensee's existing exercise schedule. If the onsite emergency plan elements are not similar, then paragraph 2.a.(ii) of this section applies.

* * * * *

c. * * * Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every two years and shall, at least, partially participate in other offsite plan exercises in this period.[5] * * *

* * * * *

[1] EPZs for power reactors are discussed in NUREG–0396; EPA 520/1–78–016, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' December 1978.

[2] Regulatory Guide 2.6, ''Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities,'' may be used as guidance for the acceptability of non-power production or utilization facility emergency response plans.

[3] Use of site-specific simulators or computers is acceptable for any exercise.

[4] Full participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite local and State authorities and licensee personnel physically and actively take part in testing their integrated capability to adequately assess and respond to an accident at a commercial nuclear power plant. Full participation includes testing major observable portions of the onsite and offsite emergency plans and mobilization of State, local and licensee personnel and other resources in sufficient numbers to verify the capability to respond to the accident scenario.

[5] Partial participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite authorities shall actively take part in the exercise sufficient to test direction and control functions; *i.e.,* (a) protective action decision making related to emergency action levels, and (b) communication capabilities among affected State and local authorities and the licensee.

* * * * *

■ 30. In appendix K to part 50,

■ a. Amend section I by revising paragraph C.6. by removing the text ''BWR's'' and adding, in its place, the text ''BWRs''.

■ b. Amend section II by adding paragraph 6 to read as follows:

Appendix K to Part 50—ECCS Evaluation Models

* * * * *

II. * * *

6. If an entity is approved to implement § 50.46a, then the documentation requirements in § 50.46a(e) apply and supersede the requirements of section II of this appendix for that entity and associated regulatory approval.

■ 31. Add appendix T to read as follows:

Appendix T to Part 50—Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

I. Introduction and Scope

Nuclear power plants and fuel reprocessing plants include structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those SSCs for applicants of these facilities that meet certain eligibility criteria. Those applicants may elect to use this appendix as an alternative to the quality assurance requirements in appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.'' To reference this appendix in an application for a construction permit, operating license, or combined license, an applicant must demonstrate it meets the following criteria:

A. The application is for an nth-of-a-kind construction permit, operating license, or combined license that identifies the first-of-a-kind reference plant in the application and any departures from the first-of-a-kind reference plant;

B. Departures from the first-of-a-kind reference plant do not change the classification, design, and method of manufacture, construction, operation, including the design and operational controls, of structures, systems, and components within the scope of this appendix; and

C. Procedures and work processes for implementing the requirements in this appendix, including a mechanism to identify and promptly correct adverse changes in performance reliability of SSCs within the scope of this appendix, have been established and included in the application.

II. Definitions

First-of-a-kind (FOAK) means those nuclear power plants and fuel reprocessing plants that are the initial implementation of a reactor design or technology or fuel reprocessing plant design that has not been previously constructed and operated at commercial scale.

Functional design criteria means metrics for the performance of SSCs. For SR SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.210. For NSRSS SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.220.

Non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) means those SSCs that are not safety-related but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment.

Nth-of-a-kind (NOAK) means those nuclear power plants and fuel reprocessing plants that are subsequent implementations of a reactor design or technology or fuel reprocessing plant design that reference the FOAK plant after the FOAK has been designed, constructed, and operated.

Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system to ensure the material, structure, component, or system will meet predetermined requirements.

Quality assurance program means the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Quality management system means a structured framework that documents an organization's processes, procedures, and responsibilities for ensuring quality.

III. General Requirements

A. *Integrated Quality Assurance Program.* The applicant must establish a quality assurance program, document the quality assurance program in the quality management system, and submit the quality management system to the NRC for review and approval. The quality management system must meet the requirements found in Section IV of this appendix. The applicant must implement the approved quality management system. A quality assurance program must be established that ensures that safety-related SSCs, as defined in § 50.2, and NSRSS SSCs, for applications under parts 50 and 52 of this chapter, and safety-related SSCs, as defined in § 53.020, and NSRSS SSCs, for applications under part 53 of this chapter, are designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those structures, systems, and components perform. In describing the quality assurance program, the quality management system must identify, at the minimum, and explain in detail:

1. All relevant responsibilities and accountabilities of personnel performing functions related to implementation of the quality assurance program, including any delegation of such functions.

2. Measures for ensuring that—

i. the design bases requirements, for those applications under parts 50 and 52 of this chapter, and functional design criteria, for those applications under part 53, of the SSCs within the scope of the quality management system are adequately translated into technical specifications, drawings, procedures, and instructions;

ii. the design is verified to meet technical, quality, and regulatory requirements; and

iii. the as-built and as-operated SSCs are validated to meet the intended function and safety margin.

3. Bidirectional communication pathways for ensuring that all relevant requirements, expectations, concerns, and issues are transmitted through contractual obligations and other means between the applicant or licensee and vendors and third-party suppliers, as appropriate.

4. Measures to—

i. ensure that procured SSCs and related services meet technical and quality requirements; and

ii. to assess the capability of vendors or third-party suppliers that supply the SSCs and related services to meet expectations for product, service, or operational quality.

5. Measures established to—

i. verify and validate that products and services meet the technical and quality requirements of the procured products and services; and

ii. audit the vendors or third-party suppliers that are providing the products and services.

6. Processes implemented to identify, correct, and prevent reoccurrence of issues and failures that could adversely impact quality, safety, and regulatory compliance.

7. Recordkeeping and documentation protocols for the quality assurance program that support demonstrating that SSCs are properly designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those components perform.

B. *Quality Assurance Program Development and Implementation.* The quality assurance program, as documented in the quality management system, must:

1. Contain a graded approach for all quality assurance activities based on the safety significance of the applicable covered SSCs. A graded approach must be used to implement the requirements of the quality assurance program.

i. The implementation of a graded approach must ensure quality assurance efforts are focused in proportion to the risks associated with a product, process, or project.

ii. A graded approach must provide a process for ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with:

a. The relative importance to safety, safeguards, and security of each structure, system, and component that is governed by the quality assurance program.

b. The magnitude of any hazard involved.

c. The life-cycle stage of a facility.

d. The type of facility.

e. The particular characteristics of a facility.

f. The relative importance to radiological hazards.

g. Any other relevant factors.

iii. The basis of any graded approach must be documented for each applicable quality assurance requirement of this regulation and must be submitted as part of an application. The graded approach may not be used to negate any other applicable requirements.

2. The quality management system must describe how the requirements in Section IV of this appendix are met.

3. The applicable quality assurance requirements must be included in procurement documents from the applicant to all relevant contractors, vendors, suppliers, and third-parties.

4. Document the selection of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)–1, "Quality Assurance Requirements for Nuclear Facility Applications" in accordance with § 50.55a(a)(1)(v)(B) or another appropriate industry standard.

i. The necessary level of detail from the standard(s) must be described to achieve quality consistent with regulatory requirements.

ii. Gaps between the selected industry standard(s) and Section IV of this appendix must be addressed within the quality management system.

IV. Quality Assurance Requirements

A. *Quality Assurance Criteria.* For all applications under this appendix, the quality assurance program must establish, identify, and implement processes for meeting the following criteria.

1. Criterion 1—Management: Program.

i. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing quality assurance activities conducted pursuant to this appendix.

ii. Establish management processes, including planning, scheduling, and providing resources, for quality assurance activities conducted pursuant to this appendix.

2. Criterion 2—Management: Personnel Training and Qualification.

i. Ensure that personnel receive training and qualifications to be capable of performing their assigned work for activities covered by this appendix.

ii. Ensure continuing training to personnel to maintain their job proficiency for activities covered by this appendix.

3. Criterion 3—Management: Quality Improvement.

i. Ensure detection and prevention of quality problems for SSCs and activities covered by this appendix.

ii. Identify, control, and correct materials, parts, or components that do not meet established requirements.

iii. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.

iv. Identify and select opportunities for improvement for the quality assurance program.

4. Criterion 4—Management: Documents and the Associated Records.

i. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish designs for SSCs and activities covered by this appendix.

ii. Specify, prepare, review, approve, and maintain these documents as records.

5. Criterion 5—Performance: Work Processes.

i. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory requirements using approved instructions, procedures, or other appropriate means.

ii. Identify and control materials, parts, and components, including partially fabricated assemblies, to ensure proper use.

iii. Maintain material and equipment to prevent damage, loss, or deterioration.

iv. Calibrate and maintain equipment used for activities affecting quality.

6. Criterion 6—Performance: Design.

i. Design of SSCs and design processes using sound engineering or scientific principles and appropriate standards.

ii. Incorporate applicable requirements, design bases, as defined in § 50.2, and functional design criteria in design work and design changes.

iii. Identify and control design interfaces.

iv. Verify and validate the adequacy of the design of structures, systems, and components using individuals or groups other than those who performed the work.

v. Verify the adequacy of the design of structures, systems, and components before approval and implementation of the design.

vi. Validate the design of the structure, system and components before relying on the structures, systems, and components to perform their intended safety function.

7. Criterion 7—Performance: Procurement.

i. Procure items and services that meet established requirements and verify items and services perform as specified.

ii. Evaluate and select prospective suppliers on the basis of specified criteria that will ensure the requirements of this appendix are met.

iii. Ensure that approved suppliers continue to provide acceptable items and services.

8. Criterion 8—Performance: Inspection and Acceptance Testing.

i. Inspect and test specified items, services, and processes using established acceptance and performance criteria.

ii. Calibrate and maintain equipment used for inspections and tests.

9. Criterion 9—Performance: Maintenance of structures, systems, and components. Control the storage of structures, systems, and components consistent with appropriate cleanliness and environmental standards.

10. Criterion 10—Assessment: Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

11. Criterion 11—Assessment: Independent Assessment.

i. Plan and conduct independent assessments to measure item and service quality, the adequacy of work performance, and to promote improvement.

ii. Establish sufficient authority and freedom from line management for independent assessment teams.

iii. Ensure personnel who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

B. *Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety.* Processes for software quality assurance must be identified, established, and implemented within the quality assurance program and documented in the quality management system.

1. Software quality assurance processes must be applied to software used—

i. in digital items for SSCs within the scope of this appendix;

ii. for design verification for SSCs within the scope of this appendix; and

iii. for design analysis of SSCs within the scope of this appendix.

2. Software used for the applications identified in paragraph 1 of this section must be documented, managed, and controlled throughout its life cycle to ensure that the safety functions will be performed under design basis conditions.

3. Appropriate national or international software engineering standard(s) must be used (*e.g.,* ASME, Institute for Electrical and Electronics Engineers (IEEE), National Institutes of Standards and Technology (NIST), American Nuclear Society (ANS), etc.). These standards may include combinations of standards.

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

■ 32. 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 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.

Sections 51.20, 51.30, 51.60, 51.80, and 51.97 also issued under Nuclear Waste Policy Act secs. 135, 141, 148 (42 U.S.C. 10155, 10161, 10168).

Section 51.22 also issued under Atomic Energy Act sec. 274 (42 U.S.C. 2021) and under Nuclear Waste Policy Act sec. 121 (42 U.S.C. 10141).

Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act sec. 114(f) (42 U.S.C. 10134(f)).

■ 33. In 51.4, revise the definition for "*Construction*" to read as follows:

§ 51.4 Definitions.

* * * * *

Construction means:

(1) For production and utilization facilities, the activities in paragraph (1)(i) of this definition.

(i) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(A) Safety-related structures, systems, or components (SSCs) of a facility, as defined in § 50.2 of this chapter;

(B) SSCs that perform safety-significant functions; and

(C) SSCs necessary to comply with part 73 of this chapter.

(ii) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under section 104a. or section 104c. of the Act, construction does not include the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (*e.g.,* the construction of a college laboratory building with space for installation of a training reactor).

(iii) Any activities that are determined to be outside the scope of those defined in the definition of construction in § 51.4 and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and has no bearing on the issuance of an environmental assessment, environmental impact statement or finding of no significant impact with respect to NRC's regulated activities under the requirements of the Act, and rules, regulations issued under the Act.

(2) For materials licenses, taking any site-preparation activity at the site of a facility subject to the regulations in parts 30, 36, 40, and 70 of this chapter that has a reasonable nexus to radiological health and safety or the common defense and security; provided, however, that construction does not mean taking any other action that has no reasonable nexus to radiological health and safety or the common defense and security.

* * * * *

■ 34. In § 51.51, revise table note 1 of table S–3 to read as follows:

§ 51.51 Uranium fuel cycle environmental data—Table S–3.

* * * * *

(b) * * *

TABLE S–3—TABLE OF URANIUM FUEL CYCLE ENVIRONMENTAL DATA [1]

[Normalized to model LWR annual fuel requirement [WASH–1248] or reference reactor year [NUREG–0116]] [See footnotes at end of this table]

* * * * * * *

[1] In some cases where no entry appears it is clear from the background documents that the matter was addressed and that, in effect, the table should be read as if a specific zero entry had been made. However, there are other areas that are not addressed at all in the table. Table S–3 does not include health effects from the effluents described in the table or estimates of releases of Radon-222 from the uranium fuel cycle or estimates of Technetium-99 released from waste management or reprocessing activities. These issues may be the subject of litigation in the individual licensing proceedings.

Data supporting this table are given in the "Environmental Survey of the Uranium Fuel Cycle," WASH–1248, April 1974; the "Environmental Survey of the Reprocessing and Waste Management Portion of the LWR Fuel Cycle," NUREG–0116 (Supp.1 to WASH–1248); the "Public Comments and Task Force Responses Regarding the Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle," NUREG–0216 (Supp. 2 to WASH–1248); and in the record of the final rulemaking pertaining to Uranium Fuel Cycle Impacts from Spent Fuel Reprocessing and Radioactive Waste Management, Docket RM–50–3. The contributions from reprocessing, waste management and transportation of wastes are maximized for either of the two fuel cycles (uranium only and no recycle). The contribution from transportation excludes transportation of cold fuel to a reactor and of irradiated fuel and radioactive wastes from a reactor which are considered in table S–4 of § 51.20(g). The contributions from the other steps of the fuel cycle are given in columns A–E of table S–3A of WASH–1248.

The analysis in NUREG–2249, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors—Final Report," December 2025, extends this table up to an enrichment of 20.0 weight percent uranium-235 for environmental effects of uranium recovery (which replaced uranium mining and milling), the production of uranium hexafluoride, gaseous centrifuge isotopic enrichment (which replaced gaseous diffusion isotopic enrichment), and fuel fabrication. The analysis in NUREG–2266, "Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels," July 2024, extends the assembly averaged level of burnup of the irradiated fuel from the reactor of up to 80,000 megawatt-days per metric ton as related to uranium fuel cycle activities.

* * * * *

■ 35. Revise and republish § 51.52 to read as follows:

§ 51.52 Environmental effects of transportation of fuel and waste—Table S–4.

Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled and other than light-water-cooled nuclear power reactor, and submitted after February 4, 1975, must contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement must indicate that the reactor and this transportation meet either all of the conditions in paragraph (a) of this section or all of the conditions of paragraph (b) of this section.

(a)

(1) The reactor has a core thermal power level not exceeding 3,800 megawatts;

(2) The reactor fuel is in the form of sintered uranium dioxide pellets having a uranium-235 enrichment not exceeding 8% by weight, and the pellets are encapsulated in zircaloy rods;

(3) The average level of irradiation of the irradiated fuel from the reactor does not exceed 80,000 megawatt-days per metric ton, and no irradiated fuel assembly is shipped until at least 90 days after it is discharged from the reactor;

(4) With the exception of irradiated fuel, all radioactive waste shipped from the reactor is packaged and in a solid form;

(5) Unirradiated fuel is shipped to the reactor by truck; irradiated fuel is shipped from the reactor by truck, rail, or barge; and radioactive waste other than irradiated fuel is shipped from the reactor by truck or rail; and

(6) The environmental impacts of transportation of fuel and waste to and from the reactor, with respect to normal conditions of transport and possible accidents in transport, are as set forth in summary table S–4 in paragraph (c) of this section; and the values in the table represent the contribution of the transportation to the environmental costs of licensing the reactor.

(b) For light-water-cooled and other than light-water-cooled reactors not meeting the conditions of paragraph (a) of this section, the statement must contain a full description and detailed analysis of the environmental effects of transportation of fuel and wastes to and from the reactor, including values for the environmental impact under normal conditions of transport and for the environmental risk from accidents in transport. The statement must indicate that the values determined by the analysis represent the contribution of such effects to the environmental costs of licensing the reactor.

(c)

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Summary Table S–4—Environmental Impact of Transportation of Fuel and Waste To and From One Nuclear Power Reactor [1], [2] Normal Conditions of Transport

	Environmental impact
Heat (per irradiated fuel cask in transit)	250,000 Btu/hr
Weight (governed by Federal or State restrictions)	80,000 lb per truck; up to 210 tons per cask per rail car
Traffic density:	
Truck	Less than 1 per day
Rail	Less than 3 per month

Exposed population	Estimated number of persons exposed	Range of doses to exposed individuals[3] (per reactor year)
Transportation workers	200	0.01 to 300 millirem
General public:		
Onlookers	107,000	0.003 to 1.3 millirem
Along Route	1,362,000	0.0001 to 0.06 millirem

Accidents in Transport

	Environmental risk
Radiological effects	Small[4]
Common (nonradiological) causes	1 fatal injury in 100 reactor years; 1 nonfatal injury in 10 reactor years.

[1] Data supporting this table are given in the Commission's "Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants," WASH–1238, December 1972; and Supp. 1 of NUREG–75/038, April 1975. Both documents are available for inspection and copying at the Commission's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852 and may be obtained from National Technical Information Service, Springfield, VA 22161. The WASH–1238 is available from NTIS at a cost of $5.45 (microfiche, $2.25) and NUREG–75/038 is available at a cost of $3.25 (microfiche, $2.25).

[2] The analysis in NUREG-2266, "Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels," July 2024, extends this table up to an enrichment of 8 weight percent uranium-235 and the assembly averaged level of irradiation of the irradiated fuel from the reactor of up to 80,000 megawatt-days per metric ton for UO_2 fuel and increases the estimated number of general public members exposed to radiation for the environmental impact of transportation of fuel and waste to and from one nuclear power reactor. The analysis in NUREG-2249, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors - Final Report," December 2025, extends this table to TRISO fuel with peak pellet burnup of up to133,000 MWd/MTU.

[3] The Federal Radiation Council has recommended that the radiation doses from all sources of radiation other than natural background and medical exposures should be limited to 5,000 millirem per year for individuals as a result of occupational exposure and should be limited to 500 millirem per year for individuals in the general population. The dose to individuals due to average natural background radiation is about 130 millirem per year.

[4] The environmental risk of radiological effects stemming from transportation accidents is small regardless of whether it is being applied to a single reactor or a multireactor site. Radioactive material would not be released in an accident if the fuel is contained in an inner welded canister inside the transport package. Only rail transport packages without inner welded canisters would release radioactive material and only then in exceptionally severe accidents.

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PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

■ 36. 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.

■ 37. In § 52.1, in paragraph (a), add in alphabetical order the definitions ''*Tier 1*'', ''*Tier 2*'', and ''*Tier 2**'' to read as follows:

§ 52.1 Definitions.

(a) * * *

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, including ITAAC, 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 the process set out in 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 the applicable appendix to this part. Regardless of these differences, an applicant or licensee must meet the requirement in 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 containing the qualitative and functional-level portion of design-related information, designated as such in the generic design control document, that is subject to the change process for such information that is specified in a standard design certification rule. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the change and departure provisions for 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.

* * * * *

§ 52.15 [Amended]

■ 38. In § 52.15, in paragraph (c), remove the word ''renewal'' and add in its place the word ''amendment''.

■ 39. In § 52.17, revise paragraph (a)(1)(ix) and footnotes 1 and 2 to read as follows:

§ 52.17 Contents of applications; technical information.

(a) * * *

(1) * * *

(ix) A description and safety assessment of the site on which a facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(ix)(A) and (a)(1)(ix)(B) of this section. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 40. Revise § 52.18 to read as follows:

§ 52.18 Standards for review of applications.

Applications for the initial issuance of an early site permit filed under this subpart will be reviewed according to the applicable standards set out in part 50 of this chapter and its appendices and part 100 of this chapter. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the provisions of part 51 of this chapter. The Commission shall determine, after consultation with Federal Emergency Management Agency, as applicable, whether the information required of the applicant by § 52.17(b)(1) shows that there is not a 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 either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, 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.

§ 52.25 [Amended]

■ 41. In § 52.25, in the first sentence, remove the phrase ''performed and the site is not referenced in an application for a construction permit or a combined license issued under subpart C of this part while the permit remains valid,'' and add in its place the phrase ''performed, and the early site permit holder has applied for termination,''.

■ 42. In § 52.26, revise paragraph (a) and remove and reserve paragraph (b) to read as follows:

§ 52.26 Duration of permit.

(a) An early site permit issued under this subpart will be issued with no fixed term.

(b) [Reserved]

* * * * *

■ 43. Revise § 52.29 to read as follows:

§ 52.29 Application for amendment to update an early site permit.

(a) An early site permit holder may choose to submit an application to amend an early site permit to update the data and information on which the permit is based at any time after issuance of the early site permit. The early site permit holder may provide updated information on as many issues as the early site permit holder chooses and may request to extend the period for which the agency will afford those issues finality up to 20 additional years from the date of the amendment's issuance. The early site permit holder may request such an extension for an already extended permit. The application must meet the requirements of §§ 50.90 and 50.92 of this chapter.

(b) An application submitted under paragraph (a) of this section must contain all information necessary to bring up to date the information and data contained in the previous application for those issues the early site permit holder has chosen to update.

(c) Each application must include an environmental report as required by part 51 of this chapter, or a request and justification for a categorical exclusion under part 51 of this chapter.

(d) Any person whose interest may be affected by the update of the permit may request a hearing on the application for the update. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.309 of this chapter.

■ 44. Revise § 52.31 to read as follows:

§ 52.31 Issuance of amendment to update an early site permit.

The Commission shall grant amendment of an early site permit only if it determines that:

(a) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued, except early site permits issued before [EFFECTIVE DATE OF THE FINAL RULE] are no longer subject to § 52.26(a); and

(b) Any new requirements the Commission may wish to impose are necessary for adequate protection to public health and safety or common defense and security.

§ 52.33 [Removed and Reserved]

■ 45. Remove and reserve § 52.33.

■ 46. Revise § 52.35 to read as follows:

§ 52.35 Use of site for other purposes.

(a) A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 52.39.

(b) If the permit holder no longer intends to use the site for a nuclear power plant or for other reasons no longer wishes to hold the permit, as described in the request, the permit holder may at any time request the Director to terminate the early site permit. The request to terminate the permit must comply with the filing requirements of §§ 52.3 and 50.30 of this chapter, and identify the applicable requirements for site redress of § 52.25. Upon request, the Director may terminate the permit.

(c) Termination of the early site permit does not bar the permit holder or another applicant from filing a new application for the site.

■ 47. In § 52.39,

■ a. In paragraph (a)(1), remove the references ''§§ 52.26 or 52.33'' and add in its place the reference ''§ 52.26'';

■ b. In paragraph (a)(2) introductory text, remove the word ''renewal'' and add in its place the word ''amendment'';

■ c. Revise paragraphs (c)(1)(iv) and (v);

■ d. Add paragraph (c)(1)(vi);

■ e. In paragraph (d), remove the word ''renewed'' and add in its place the word ''amended''; and

■ f. In paragraph (e), remove the references ''10 CFR 50.90 and 50.92'' and add in its place the references ''§§ 50.90, 50.92, and 52.29 of this chapter''.

The revisions and additions are to read as follows:

§ 52.39 Finality of early site permit determinations.

* * * * *

(c) * * *

(1) * * *

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness;

(v) The information as required in the site safety analysis report in accordance with § 52.17(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later; and

(vi) (A) Any significant environmental issue that was not resolved in the early site permit proceeding;

(B) For an application that references an early site permit issued or updated by amendment, whichever is later, no more than 20 years before the submission of the application, any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified; or

(C) For an application that references an early site permit, issued or updated by amendment, whichever is later, more than 20 years before submission of the application, any issue involving the impacts of construction and operation of the facility regardless of whether the early site permit proceeding resolved the issue.

* * * * *

■ 48. In § 52.47,

■ a. Revise paragraph (a)(2)(iv);

■ b. In paragraph (a)(4), remove the last sentence; and

■ c. Redesignate footnotes 3 and 4 as footnotes 1 and 2 and revise footnotes 1 and 2 to read as follows:

§ 52.47 Contents of applications; technical information.

* * * * *

(a) * * *

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE);

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 49. In § 52.54, revise paragraph (a) introductory text and paragraph (b) to read as follows:

§ 52.54 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 52.51 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.53, the Commission may issue a standard design certification in the form of a rule for the design that is the subject of the application, if the Commission determines that:

* * * * *

(b) The standard design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the standard design certification rule. A standard design certification rule that was reviewed and approved as meeting the requirements of § 50.46a of this chapter must specify the criteria governing departures that a referencing combined license must meet. The criteria must ensure that the safety bases for the NRC's approval of the certified design's compliance with § 50.46a of this chapter (including applicability of the transition break size) continue to apply despite the departure.

* * * * *

■ 50. In § 52.63,

■ a. In paragraph (a)(1)(v) at the end of the sentence, add the word ''or'' after ''information;'';

■ b. In paragraph (a)(1)(vi) at the end of the sentence, remove the phrase ''security; or'' and add in its place the word ''security.'';

■ c. Remove paragraph (a)(1)(vii); and

■ d. Revise paragraphs (a)(4)(ii) and (b)(1) to read as follows:

§ 52.63 Finality of standard design certifications.

(a) * * *

(4) * * *

(ii) Special circumstances as defined in § 52.7 are present.

* * * * *

(b)

(1) An applicant or licensee who references a design certification rule may request an exemption from one or more elements of the certification information if one is required by the applicable change process within the referenced design certification rule. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 52.7. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the operating license or combined license hearing.

* * * * *

■ 51. In § 52.79,

■ a. Revise and republish paragraphs (a)(1)(vi), (a)(2)(iv), (a)(5), (a)(21), (a)(25), (a)(27), (a)(36)(i), and (b);

■ b. Add paragraph (a)(48); and

■ c. Redesignate footnotes 5 through 8 as footnotes 1 through 4 and revise footnotes 1 through 4 to read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(1) * * *

(vi) A description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A) and (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE; and

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [3] assuming that the facility is operated at the ultimate power level contemplated;

* * * * *

(5) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety

during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

* * * * *

(21) Emergency plans complying with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter;

* * * * *

(25) A description of the quality assurance program or a quality management system, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. Appendix B to part 50 of this chapter sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter have been and will be satisfied, including a discussion of how the quality assurance program will be implemented or for eligible combined license applications. Appendix T to part 50 of this chapter, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants that an eligible combined license applicant may voluntarily use as an alternative to appendix B to part 50 of this chapter. The quality management system, required by appendix T to part 50 of this chapter, for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to part 50 of this chapter will be satisfied;

* * * * *

(27) Managerial and administrative controls to be used to assure safe operation. Appendix B to part 50 of this chapter sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied. Appendix T to part 50 of this chapter, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for such controls for nuclear power plants and fuel reprocessing plants that an eligible combined license applicant may voluntarily use as an alternative to appendix B to part 50 of this chapter. The quality management system, required by appendix T to part 50 of this chapter, for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to part 50 of this chapter will be satisfied;

* * * * *

(36) (i) A safeguards contingency plan in accordance with the criteria set forth in appendix C to part 73 of this chapter. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license shall include the information contained in the applicant's safeguards contingency plan.[4] (Implementing procedures required for this plan need not be submitted for approval.)

* * * * *

(48) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for a combined license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(b) If the combined license application references an early site permit, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the early site permit, provided, however, that the final safety analysis report must either include or incorporate by reference the early site permit site safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the final safety analysis report does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application shall include a request for a variance that complies with the requirements of §§ 52.39 and 52.93.

(3) If the early site permit site safety analysis report information required by § 52.17(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later, the combined license application shall include updated information and revised analyses, as necessary, in the final safety analysis report. The referencing application need not update the postulated source term stated in the early site permit if it falls within the source term derived from the design. If the postulated source term stated in the early site permit does not fall within the source term derived from the design, the referencing application must propose a variance from the early site permit that complies with the requirements of §§ 52.39 and 52.93.

(4) The final safety analysis report must demonstrate that all terms and conditions that have been included in the early site permit, other than those imposed under § 50.36b of this chapter, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(5) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the final safety analysis report must include any new or additional information that updates and corrects the information that was provided under § 52.17(b), and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a reduction in effectiveness under § 50.54(q) of this chapter.

(6) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(22) of this section are not required.

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad

range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

[3] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[4] A physical security plan that contains all the information required in both § 73.55 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency.

■ 52. Revise § 52.85 to read as follows:

§ 52.85 Administrative review of applications; hearings.

(a) A proceeding on a combined license is subject to all applicable procedural requirements contained in part 2 of this chapter, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses are governed by the procedures contained in part 2 of this chapter.

(b) If an applicant requests generic finality under § 52.79(a)(48), the Commission will include a request for generic finality as a proposed action in the notice of hearing required by § 2.104 of this chapter.

§ 52.93 [Amended]

■ 53. In § 52.93, in paragraph (c) remove the last sentence.

■ 54. In § 52.97, add paragraph (d) to read as follows:

§ 52.97 Issuance of combined licenses.

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a utilization facility, including postulated site parameters, and requirements submitted pursuant to § 52.79(a)(48), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 55. In § 52.98, revise paragraph (b), remove and reserve paragraph (d), and add paragraph (h) to read as follows:

§ 52.98 Finality of combined licenses; information requests.

* * * * *

(b) If the combined license does not reference a design certification, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in part 50 of this chapter (*e.g.*, § 50.54, § 50.59, or § 50.90 of this chapter).

* * * * *

(d) [Reserved]

* * * * *

(h) In a proceeding for the issuance of a construction permit, operating license, or combined license, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which a combined license issued under this subpart is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced combined license, including, if applicable, the adequacy of a reactor design where the referenced combined license was afforded finality pursuant to § 52.97(d).

■ 56. In § 52.137,

■ a. Revise and republish paragraph (a)(2)(iv);

■ b. In paragraph (a)(4), remove the word ''SSC'' and add in its place the word ''SSCs'' and remove the last sentence; and

■ c. Redesignate footnotes 9 and 10 as footnotes 1 and 2 and revise footnotes 1 and 2 to read as follows:

§ 52.137 Contents of applications; technical information.

* * * * *

(a) * * *

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE); and

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 57. In § 52.157,

■ a. Revise and republish paragraph (d);

■ b. In paragraph (f)(1), remove the last sentence;

■ c. Redesignate footnotes 11 and 12 as footnotes 1 and 2 and revise footnotes 1 and 2.

The addition and revisions are to read as follows:

§ 52.157 Contents of applications; technical information in final safety analysis report.

* * * * *

(d) The safety features that are engineered into the reactor and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to reactor design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE); and

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 58. Revise and republish § 52.158 to read as follows:

§ 52.158 Contents of application; additional technical information.

(a) *Inspections, tests, analyses, and acceptance criteria (ITAAC).* (1) The application must contain the proposed inspections, tests, and analyses that the licensee who will be operating the reactor shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformity with the manufacturing license, the provisions of the Act, and the Commission's rules and regulations; and

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The **Federal Register** notification required by § 52.163 must indicate that the application includes this notification.

(b) *Environmental report.* (1) The application must contain an environmental report as required by § 51.54 of this chapter.

(2) If the manufacturing license application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the reactor.

(c) *Optional operational programs.* An applicant may include in its application descriptions of essentially complete programmatic controls, operational programs, or operational requirements beyond those required by § 52.157 in order to satisfy requirements for license applications that may reference a manufacturing license. If approved by the NRC as part of the manufacturing license, such programmatic controls, operational programs, and operational requirements would have finality under § 52.171.

■ 59. In § 52.171, revise paragraphs (a)(1) and (b) to read as follows:

§ 52.171 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in § 50.109 of this chapter, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured; the requirements for the manufacture of the nuclear power reactor; or the programmatic controls, operational programs, or operational requirements; 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.

* * * * *

(b)(1) The holder of a manufacturing license may make a change to the facility or procedures as described in the final safety analysis report (as updated) associated with the manufacturing license without obtaining a license amendment pursuant to § 50.90 of this chapter if the change meets the criteria in § 50.59(c)(1) of this chapter. If needed, applications for amending an ML must be submitted and processed in accordance with §§ 50.90, 50.91, and 50.92 of this chapter.

(2) An applicant who references or uses a nuclear power reactor manufactured under a manufacturing license under this subpart may request a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the construction permit or combined license hearing.

* * * * *

§ 52.173 [Amended]

■ 60. In § 52.173, remove the phrase ''15 years'' and add in its place ''40 years''.

§ 52.181 [Amended]

■ 61. In § 52.181, remove the phrase ''15 years'' and add in its place ''40 years''.

■ 62. Revise subpart G consisting of § 52.220 and add § 52.220 to read as follows:

Subpart G—Risk-Informed and Performance-Based Alternatives

§ 52.220 Use of risk-informed and performance-based alternatives to acceptance criteria.

For each regulation in this part that provides specified acceptance criteria, applicants may propose an alternative following the requirements in § 50.220 of this chapter.

■ 63. In appendix A to part 52, revise paragraphs II.D., II.F., VI.B.4., VI.B.6., VIII.A., and VIII.B. to read as follows:

Appendix A to Part 52—Design Certification Rule for the U.S. Advanced Boiling Water Reactor

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the ABWR Design Control Document, Revision 7: Section 1.0, ''Introduction''; Section 1.1, ''Definitions''; Section 1.2, ''General Provisions''; Appendix A, ''Legend for Figures''; Appendix B, ''Abbreviations and Acronyms Used in the ABWR Certified Design Material''; and Appendix C, ''Conversion to ASME Standard Units'';

2. Design descriptions, which are located in the following sections of the ABWR Design Control Document, Revision 7, and any figures and non-ITAAC tables referenced in these sections: Section 2.0, ''Certified Design for ABWR Systems,'' and Section 3.0, ''Additional Certified Design Material'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the ABWR Design Control Document, Revision 7: Tables 2.1.1d, 2.1.2, 2.1.3, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.2.8, 2.2.9, 2.2.10, 2.2.11, 2.3.1, 2.3.2, 2.3.3, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.5.5, 2.5.6, 2.6.1, 2.6.2, 2.6.3, 2.7.1b, 2.7.3, 2.7.5, 2.8.4, 2.9.1, 2.10.1, 2.10.2a, 2.10.2b, 2.10.4, 2.10.7, 2.10.9, 2.10.13, 2.10.21, 2.10.22, 2.10.23, 2.11.1, 2.11.2, 2.11.3d, 2.11.4, 2.11.5, 2.11.6, 2.11.9, 2.11.10, 2.11.11, 2.11.12, 2.11.13, 2.11.20, 2.11.23, 2.12.1, 2.12.10, 2.12.11, 2.12.12, 2.12.13, 2.12.14, 2.12.15, 2.12.16, 2.12.17, 2.14.1, 2.14.4, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15.3, 2.15.5a, 2.15.5b, 2.15.5c, 2.15.5d, 2.15.5e, 2.15.5f, 2.15.5g, 2.15.5h, 2.15.5i, 2.15.5j, 2.15.5k, 2.15.5l, 2.15.5m, 2.15.6, 2.15.10, 2.15.11, 2.15.12, 2.15.13, 2.15.14, 2.15.15, 2.16.2, 2.17.1, 3.1, 3.2a, 3.2b, 3.3, 3.4, and 3.6.

4. Significant site parameters, which are located in the following section of the ABWR Design Control Document, Revision 7: Section 5.0, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the ABWR Design Control Document, Revision 7: Section 4.0, ''Interface Requirements.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in paragraph VIII.B.6 of this appendix. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the departure provisions in paragraph VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraph A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* Information

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraph B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order, while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of

safety otherwise provided by the design. The granting of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The granting of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section), Tier 2* information, or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a structure, system, or component important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of a structure, system, or component important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design-basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. A proposed departure from Tier 2 information required by § 52.47(a)(28) to address aircraft impacts shall consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by § 50.150(a) of this chapter. The applicant or licensee shall describe, in the plant-specific DCD, how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in § 50.150(a)(1) of this chapter.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to complying with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6. a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with brackets, italicized text, and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and § 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter.

(1) Fuel burnup limit (4.2).

(2) Fuel design evaluation (4.2.3).

(3) Fuel licensing acceptance criteria (Appendix 4B).

(4) ASME Boiler & Pressure Vessel Code, Section III.

(5) ACI 349 and ANSI/AISC N–690.

(6) Motor-operated valves.

(7) Equipment seismic qualification methods.

(8) Piping design acceptance criteria.

(9) Fuel system and assembly design (4.2), except burnup limit.

(10) Nuclear design (4.3).

(11) Equilibrium cycle and control rod patterns (Appendix 4A).

(12) Control rod licensing acceptance criteria (Appendix 4C).

(13) Instrument setpoint methodology.

(14) EMS performance specifications and architecture.

(15) SSLC hardware and software qualification.

(16) Self-test system design testing features and commitments.

(17) Human factors engineering design and implementation process.

c. After the plant first achieves full power, all Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

* * * * *

■ 64. In appendix D to part 52, remove and reserve section IX, and revise paragraphs II.D., II.F., VI.B.4., VI.B.6, VIII.A., and VIII.B. to read as follows:

Appendix D to Part 52—Design Certification Rule for the AP1000 Design

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 1, ''Introduction'';

2. Design descriptions, which are located in the sections of the AP1000 Design Control Document, Revision 19, identified in Table 1 to Paragraph D of this appendix, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0 and any figures and non-ITAAC tables referenced in these sections:

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Table 1 to Paragraph D

Section	Title
2.1.1	Fuel Handling and Refueling System
2.1.2	Reactor Coolant System
2.1.3	Reactor System
2.2.1	Containment System
2.2.2	Passive Containment Cooling System
2.2.3	Passive Core Cooling System
2.2.4	Steam Generator System
2.2.5	Main Control Room Emergency Habitability System
2.3.1	Component Cooling Water System
2.3.2	Chemical and Volume Control System
2.3.3	Standby Diesel Fuel Oil System
2.3.4	Fire Protection System
2.3.5	Mechanical Handling System
2.3.6	Normal Residual Heat Removal System
2.3.7	Spent Fuel Pool Cooling System
2.3.8	Service Water System
2.3.9	Containment Hydrogen Control System
2.3.10	Liquid Radwaste System
2.3.11	Gaseous Radwaste System
2.3.12	Solid Radwaste System
2.3.13	Primary Sampling System
2.3.14	Demineralized Water Transfer and Storage System
2.3.15	Compressed and Instrument Air System
2.3.19	Communication System
2.3.29	Radioactive Waste Drain System
3.1	Emergency Response Facilities
3.2	Human Factors Engineering
3.3	Buildings
3.4	Initial Test Program
3.5	Radiation Monitoring
3.6	Reactor Coolant Pressure Boundary Leak Detection
3.7	Design Reliability Assurance Program

BILLING CODE 7590–01–C

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the AP1000 Design Control Document, Revision 19 and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Tables 2.1.1–1, 2.1.2–4, 2.1.3–2, 2.2.1–3, 2.2.2–3, 2.2.3–4, 2.2.4–4, 2.2.5–5, 2.3.1–2, 2.3.2–4, 2.3.3–2, 2.3.4–2, 2.3.5–2, 2.3.6–4, 2.3.7–4, 2.3.8–2, 2.3.9–3, 2.3.10–4, 2.3.11–2, 2.3.12–1, 2.3.13–3, 2.3.14–2, 2.3.15–2, 2.3.19–2, 2.3.29–1, 3.1–1, 3.2–1, 3.3–6, 3.5–6, 3.6–1, and 3.7–3.

4. Significant site parameters, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 5, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 4, ''Interface Requirements.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1, Tier 2, and Tier 2* under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under

paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* information.

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, or B.5 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 or Tier 2* information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2 or Tier 2*, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address § 50.150 of this chapter, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 or Tier 2* affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If an applicant or licensee proposes to depart from the information required by § 52.47(a)(28) to be included in the FSAR for the standard design certification, then the applicant or licensee shall consider the effect of the changed feature or capability on the original assessment required by § 50.150(a) of this chapter. The applicant or licensee must also document how the modified design features and functional capabilities continue to meet the assessment requirements in § 50.150(a)(1) of this chapter in accordance with Section X of this appendix.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 or Tier 2* information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

* * * * *

■ 65. In appendix E to part 52, revise paragraphs II.D., II.F, VI.B.4., VI.B.6., VIII.A., and VIII.B. to read as follows:

Appendix E to Part 52—Design Certification Rule for the ESBWR Design

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the ESBWR Design Control Document, Revision 10: Section 1, ''Introduction,'' Section 1.1, ''Definitions and General Provisions,'' Section 1.2, ''Figure Legend,'' Section 1.3, ''Table Legend,'' and Section 1.4, ''Design Acceptance Criteria'';

2. Design descriptions, which are located in the following sections of the ESBWR Design Control Document, Revision 10, and any figures and non-ITAAC tables referenced in these sections: Section 2, ''Design Descriptions and ITAAC,'' and Section 3, ''Non-System Based Material'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the ESBWR Design Control Document, Revision 10: Tables 2.1.1–3, 2.1.2–3, 2.2.1–6, 2.2.2–7, 2.2.3–4, 2.2.4–6, 2.2.5–4, 2.2.6–3, 2.2.7–4, 2.2.9–3, 2.2.12–5, 2.2.13–4, 2.2.14–4, 2.2.15–2, 2.2.16–4, 2.3.1–2, 2.3.2–2, 2.4.1–3, 2.4.2–3, 2.5.5–1, 2.5.6–1, 2.5.10–1, 2.6.1–2, 2.6.2–2, 2.10.1–2, 2.10.2–2, 2.10.3–1, 2.11.1–1, 2.11.2–1, 2.11.4–2, 2.11.5–1, 2.11.6–1, 2.11.7–1, 2.12.3–1, 2.12.5–1, 2.12.7–1, 2.13.1–2, 2.13.3–2, 2.13.4–2, 2.13.5–2, 2.13.8–1, 2.13.9–1, 2.15.1–2, 2.15.3–2, 2.15.4–2, 2.15.5–2, 2.15.7–2, 2.15.8–1, 2.16.1–1, 2.16.2–2, 2.16.2–4, 2.16.2–6, 2.16.2–7, 2.16.2–9, 2.16.2–10, 2.16.3–2, 2.16.3.1–1, 2.16.4–1, 2.16.5–2, 2.16.6–2, 2.16.7–2, 2.16.8–1, 2.16.9–1, 2.16.10–1, 2.16.11–1, 2.16.12–1, 2.16.13–1, 2.16.14–1, 2.19–1, 3.1–1, 3.3–2, 3.4–1, 3.6–1, 3.7–1, and 3.8–2.

4. Significant site parameters, which are located in the following section of the ESBWR Design Control Document, Revision 10: Section 5, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the ESBWR Design Control Document, Revision 10: Section 4, ''Interface Material.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in paragraph VIII.B.6 of this appendix. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the departure provisions in paragraph VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* information

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license

hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section), Tier 2* information, or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design-basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. A proposed departure from Tier 2 information required by § 52.47(a)(28) to address aircraft impacts shall consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by § 50.150(a) of this chapter. The applicant or licensee shall describe in the plant-specific DCD how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in § 50.150(a)(1) of this chapter.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6. a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and § 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter.

(1) Fuel mechanical and thermal-mechanical design evaluation reports, including fuel burnup limits.

(2) Control rod mechanical and nuclear design reports.

(3) Fuel nuclear design report.

(4) Critical power correlation.

(5) Fuel licensing acceptance criteria.

(6) Control rod licensing acceptance criteria.

(7) Mechanical and structural design of spent fuel storage racks.

(8) Steam dryer pressure load analysis methodology.

(9) ASME Boiler and Pressure Vessel Code, Section III, Subsections NE (Division 1) and CC (Division 2) for containment vessel design.

(10) American Concrete Institute 349 and American National Standards Institute/American Institute of Steel Construction—N690.

(11) Power-operated valves.

(12) Equipment seismic qualification methods.

(13) Piping design acceptance criteria.

(14) Instrument setpoint methodology.

(15) Safety-Related Distribution Control and Information System performance specification and architecture.

(16) Safety System Logic and Control hardware and software.

(17) Human factors engineering design and implementation.

(18) First of a kind testing for reactor stability (first plant only).

(19) Reactor precritical heatup with reactor water cleanup/shutdown cooling (first plant only).

(20) Isolation condenser system heatup and steady state operation (first plant only).

(21) Power maneuvering in the feedwater temperature operating domain (first plant only).

(22) Load maneuvering capability (first plant only).

(23) Defense-in-depth stability solution evaluation test (first plant only).

c. After the plant first achieves full power, all Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

*   *   *   *   *

■ 66. In appendix F to part 52, revise paragraphs II.D., VI.B.4., VI.B.6., VIII.A., VIII.B.5.a., and VIII.B.5.c.

Appendix F to Part 52—Design Certification Rule for the APR1400 Design

*   *   *   *   *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 1.0, ‘‘Introduction’’;

2. Design descriptions, which are located in the sections of the APR1400 Design Control Document Tier 1, Revision 3, identified in Table 1 to Paragraph D of this appendix, and any figures and non-ITAAC tables referenced in these sections:

Table 1 to Paragraph D

Section	Title
2.2	Structural and System Engineering
2.3	Piping Systems and Components
2.4	Reactor Systems
2.5	Instrumentation and Control
2.6	Electric Power
2.7	Plant Systems
2.8	Radiation Protection
2.9	Human Factors Engineering
2.10	Emergency Planning
2.11	Containment System
2.12	Physical Security Hardware
2.13	Design Reliability Assurance Program

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column, and the acceptance criteria column of the following tables of the APR1400 Design Control Document Tier 1, Revision 3: Tables 2.2.1–3, 2.2.2–2, 2.2.3–1, 2.2.4–1, 2.2.5–1, 2.2.6–2, 2.2.7–2, 2.2.8–1, 2.2.9–1, 2.3–3, 2.4.1–4, 2.4.2–4, 2.4.3.4, 2.4.4–4, 2.4.5–4, 2.4.6–4, 2.4.7–1, 2.5.1–5, 2.5.2–5, 2.5.3–3, 2.5.4–5, 2.5.5–2, 2.6.1–3, 2.6.2–3, 2.6.3–3, 2.6.4–3, 2.6.5–1, 2.6.6–1, 2.6.7–1, 2.6.8–1, 2.6.9–1, 2.7.1.1–1, 2.7.1.2–4, 2.7.1.4–4, 2.7.1.5–4, 2.7.1.8–3, 2.7.2.1–4, 2.7.2.2–4, 2.7.2.3–4, 2.7.2.4–1, 2.7.2.5–4, 2.7.2.6–4, 2.7.3.1–3, 2.7.3.2–3, 2.7.3.3–3, 2.7.3.5–3, 2.7.3.6–1, 2.7.4.1–1, 2.7.4.2–1, 2.7.4.3–4, 2.7.4.4–2, 2.7.4.5–1, 2.7.5.2–3, 2.7.6.1–2, 2.7.6.2–4, 2.7.6.3–2, 2.7.6.4–3, 2.7.6.5–3, 2.8–2, 2.9–1, 2.10–1, 2.11.1–2, 2.11.2–4, 2.11.3–2, 2.11.4–3, 2.12–1, and 2.13–1.

4. Significant site parameters, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 2.1, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 3.0, ''Interface Requirement.''

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. * * *

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

* * * * *

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously

reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

* * * * *

■ 67. In appendix G to part 52, revise paragraphs II.D., V.B.1., V.B.9., VI.B.4, V.B.6., VIII.A., VIII.B.5.a., and VIII.B.5.c. to read as follows:

Appendix G to Part 52—Design Certification Rule for NuScale

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Section 1.0, ''Introduction,'' Section 1.1, ''Definitions,'' and Section 1.2, ''General Provisions'';

2. Design descriptions, which are located in the following chapters of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5 and any figures and non-ITAAC tables referenced in these sections: Chapter 2, ''Unit Specific Structures, Systems, and Components Design Descriptions and Inspections, Tests, Analyses, and Acceptance Criteria,'' and Chapter 3, ''Shared Structures, Systems, and Components and Non-Structures, Systems, and Components Design Descriptions and Inspections, Tests, Analyses, and Acceptance Criteria'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Tables 2.1–4, 2.2–3, 2.3–1, 2.5–7, 2.6–1, 2.7–2, 2.8–2, 3.0–1, 3.1–2, 3.2–2, 3.3–1, 3.4–1, 3.5–1, 3.6–2, 3.7–1, 3.8–1, 3.9–2, 3.10–2, 3.11–2, 3.12–2, 3.13–1, 3.14–2, 3.15–1, 3.16–1, 3.17–2, and 3.18–2.

4. Significant site parameters, which are located in the following chapter of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Chapter 5, ''Site Parameters''; and

5. Significant interface requirements which are located in the following chapter of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Chapter 4, ''Interface Requirements.''

* * * * *

V. * * *

B. * * *

1. Paragraph (f)(2)(vi) of 10 CFR 50.34 and 10 CFR 50.46b—High point venting for the reactor coolant system and reactor pressure vessel head.

* * * * *

9. Appendix A of 10 CFR part 50—Electric Power Systems GDCs: * * *

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

* * * * *

B. * * *

5.

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

* * * * *

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

* * * * *

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

■ 68. The authority citation for part 53 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 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; Pub. L. 115–439, 132 Stat. 5571.

■ 69. In § 53.020, revise the definitions for ''*Construction*'' and ''*Quality Assurance (QA)*'' to read as follows:

§ 53.020 Definitions.

* * * * *

Construction means those activities which are conducted on-site to build the commercial nuclear plant, including the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for:

(1) Safety-related (SR) SSCs and those non-safety-related but safety-significant (NSRSS) SSCs of a facility for which special treatment includes requirements on design or installation, including associated quality assurance measures;

(2) SSCs necessary to comply with 10 CFR part 73.

* * * * *

Quality assurance (QA) means all those planned and systematic actions necessary to ensure that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to ensure the material, structure, component, or system meets predetermined requirements.

* * * * *

■ 70. In § 53.040, revise paragraph (b)(7)(ii) and add (b)(7)(iii) to read as follows:

§ 53.040 Written communications.

* * * * *

(b) * * *

(7) * * *

(ii) A change to an NRC-accepted QA topical report or quality management system topical report from non-licensees (*i.e.,* architect/engineers, nuclear steam supply system suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(iii) A change to the Safety Analysis report quality management system under § 53.1565, or a change to a licensee's NRC-accepted quality management system topical report under § 53.1565, must be submitted to the NRC's Document Control Desk, 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 this part. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

* * * * *

■ 71. In § 53.460, revise paragraphs (b)(1) and (b)(2) to read as follows:

§ 53.460 Safety categorization and special treatments.

* * * * *

(b) * * *

(1) The special treatments for SR SSCs must include meeting the applicable quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, applicable quality assurance requirements from appendix T of part 50 of this chapter.

(2) The special treatments for NSRSS SSCs and special treatments for SR SSCs beyond those required under paragraph (b)(1) of this section may include meeting selected quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, meeting selected quality assurance requirements from appendix T of part 50 of this chapter when such treatment is needed to address performance requirements, equipment reliability, or uncertainties.

* * * * *

■ 72. In § 53.500, revise paragraph (b) to read as follows:

§ 53.500 General siting and siting assessment.

* * * * *

(b) Activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of this part satisfy the applicable special treatment requirements of § 53.460, including, where applicable, the quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, meeting applicable quality assurance requirements from appendix T of part 50 of this chapter.

■ 73. In § 53.610, revise paragraph (b) introductory text to read as follows:

§ 53.610 Construction.

* * * * *

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under this part until that person has been issued either a CP or COL, an early site permit authorizing activities under § 53.1130, or a general license or LWA authorizing activities under § 53.1130.

* * * * *

■ 74. In § 53.855, add paragraphs (c) and (d) to read as follows:

§ 53.855 Emergency preparedness.

* * * * *

(c) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license amendment under § 53.1510 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State, local, and Tribal governmental authorities have agreed to the EPZ change.

(d) A licensee desiring to change its emergency plan to comply with either the requirements of § 50.160 of this chapter or appendix E to part 50 of this chapter and the planning standards of § 50.47(b) of this chapter, must submit an application for a license amendment under § 53.1510 and receive NRC approval before implementing the change.

■ 75. Revise § 53.865 to read as follows:

§ 53.865 Quality assurance.

Each holder of an OL or COL under this part must develop, implement, and maintain a quality assurance program in accordance with appendix B of part 50 of this chapter or, for eligible OL or COL holders, a quality management system in accordance with appendix T of part 50 of this chapter. A written quality assurance program manual must be developed and used to guide the conduct of the program.

■ 76. In § 53.1010, revise paragraph (b)(2) to read as follows:

§ 53.1010 Financial assurance for decommissioning.

* * * * *

(b) * * *

(2) The amount of financial assurance for decommissioning to be provided may be based on a design-specific or site-specific cost estimate for

decommissioning the facility under § 53.1020.

* * * * *

■ 77. Revise § 53.1020 to read as follows:

§ 53.1020 Cost estimates for decommissioning.

(a) A certification relying on a design-specific decommissioning cost estimate must demonstrate that there is reasonable assurance that sufficient funds necessary for safely decommissioning the facility will be available, when needed, and provide the factors used to develop the design-specific decommissioning cost estimate, including reactor technology, power level (in MWt), and costs related to labor, energy, and waste burial. The amount to be provided must also address the approach to annual adjustments required by § 53.1030. Finally, design-specific decommissioning cost estimates must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

(b) Site-specific decommissioning cost estimates (DCEs) must be in an amount that may be more, but not less, than the amount stated in paragraph (a) of this section. Site-specific DCEs must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination of the license. They must include the costs for decontaminating structures, systems, and components and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal of removed components and materials in appropriate facilities; and any other activities supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.1030. Finally, site-specific DCEs must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

■ 78. Revise § 53.1040 to read as follows:

§ 53.1040 Methods for providing financial assurance for decommissioning.

Financial assurance for decommissioning is to be provided by the following methods.

(a) *Prepayment.* Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.1570 into an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds based on a design-specific or site-specific decommissioning cost estimate under § 53.1020 may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund.* An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has collected funds based on a design-specific or site-specific decommissioning cost estimate under § 53.1020 may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph (b). This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by ''cost of service'' or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to satisfy this condition.

(2) By an applicant or licensee whose source of revenues for its external sinking fund is a ''non-bypassable charge,'' the total amount of which will provide funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575.

(c) *A surety method, insurance, or other guarantee method.*

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) *Funding method for Federal licensees.* For a Federal licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) *Contractual funding method.* Contractual obligation(s) on the part of an applicant's or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant's or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) must include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) *Other funding mechanisms.* Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each application or licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Applicants or licensees who do not have sources of funding described in paragraph (b) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

■ 79. Revise § 53.1050 to read as follows:

§ 53.1050 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure an applicant's or licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds and, either independently or in cooperation with FERC and the applicant's or licensee's State Public Utility Commission, take additional actions as appropriate on a case-by-case basis, including modification of an applicant's or licensee's schedule for the accumulation of decommissioning funds.

■ 80. In § 53.1109, revise paragraph (g) to read as follows:

§ 53.1109 Contents of applications; general information.

* * * * *

(g)(1) If the application is for an OL or COL for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.1146(b)(2)(ii), the applicant must coordinate radiological emergency preparedness activities with offsite organizations with responsibilities for coping with emergencies including State, local, and Tribal governmental agencies, as applicable. Specifically, the applicant must ensure that these response organizations are aware of the potential radiological consequences of the facility and have been consulted on appropriate protective measures including the extent of any emergency planning zone (EPZ) for implementing predetermined, prompt protective measures. The application must include information that describes the extent of the applicant's interaction with these response organizations. If the application is for an early site permit that, under § 53.1146(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph (g)(1). Generally, the plume exposure pathway EPZ for a commercial nuclear plant must consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 53.1109(g)(2). The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant must be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

(2) For a case-by-case EPZ determination, the applicant or licensee must submit an analysis used to determine whether the criteria in § 53.1109(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Dose to an individual is projected to exceed 1 rem (10 millisieverts) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) [Reserved]

* * * * *

■ 81. In 53.1130, revise the section heading and paragraphs (a)(3)(ii), (b)(1)(i), and (c) and add paragraph (e) to read as follows:

§ 53.1130 Limited work authorizations, general licenses.

(a) * * *

(3) * * *

(ii) Information to demonstrate the applicability of a categorical exclusion, or if a categorical exclusion is not applicable, an environmental report in accordance with part 51 of this chapter; and

* * * * *

(b) * * *

(1) * * *

(i) The NRC staff issues the final documentation required under NEPA and all applicable Federal environmental consultations have been complete, in accordance with part 51 of this chapter;

* * * * *

(c) *Effect of limited work authorization.*

(1) Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (b)(1) of this section, the issuance of the LWA has no bearing on the issuance of a CP or COL with respect to the requirements of the Act and rules, regulations, or orders issued under the Act. The environmental impact statement for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer in a contested hearing will not consider, the sunk costs of the holder of the LWA in determining the proposed action (*i.e.,* issuance of the CP or COL).

(2) Any activities that are determined to be outside the scope of those defined in the definition of construction in § 53.020 and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

* * * * *

(e) *Issuance of general license.* A general license is hereby issued to an applicant for a construction permit or combined license for a utilization facility under this part for construction activities on a site that is specified in the application, subject to the following conditions:

(1) The applicant has submitted and the Commission has docketed a CP or COL application for a commercial nuclear plant under this part that meets the following criteria;

(i) The application references a reactor design for which the Commission issued an operating license under this part or issued a combined license under this part and made the finding under § 53.1452(g) and for which the Commission afforded generic finality under § 53.1387(e) or § 53.1440(d); and

(ii) The operating license or combined license described in paragraph (e)(1)(i) of this section met the criteria for a categorical exclusion or resulted in a finding of no significant impact from an environmental assessment in accordance with part 51 of this chapter;

(iii) The application utilizing the general license includes a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary; and

(iv) The application must contain information demonstrating that the site characteristics are bounded by the site parameters postulated for the approval of generic finality.

(2) The applicant may perform construction only upon notification to the NRC Director of NRR using instructions in § 53.040 before the start of construction. The notice must state that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action have been obtained. The notice may be in the form of a letter, but must contain the applicant's name, address, and the name and means of contacting a person responsible for providing additional information concerning construction under this general license;

(3) All applicable Federal environmental consultations have been completed;

(4) The general license only authorizes construction of those generic aspects of the design of the commercial nuclear plant for which the Commission afforded generic finality and does not authorize installation of the reactor vessel, the reactor coolant system, or associated reactivity control and heat removal systems;

(5) The applicant must allow for NRC inspections that the Commission deems necessary related to activities performed under the general license; and

(6) Any activities undertaken by the applicant or on its behalf under the general license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

■ 82. Revise § 53.1161 to read as follows:

§ 53.1161 Extent of activities permitted.

If the activities authorized by § 53.1158(c) are performed and the early site permit holder has applied for termination, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site under the terms of the site redress plan required by § 53.1146(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit must carry out the redress plan to the greatest extent possible consistent with the alternate use.

■ 83. In § 53.1164, revise paragraph (a) and remove and reserve paragraph (b) to read as follows:

§ 53.1164 Duration of permit.

(a) An early site permit issued under this subpart will be issued with no fixed term.

(b) [Reserved]

* * * * *

■ 84. Revise § 53.1173 to read as follows:

§ 53.1173 Application for amendment to update an early site permit.

(a) An early site permit holder may choose to submit an application to amend an early site permit to update the data and information on which the permit is based at any time after issuance of the early site permit. The early site permit holder may provide updated information on as many issues as the early site permit holder chooses and may request to extend the period for which the agency will afford those issues finality up to 20 additional years from the date of the amendment's issuance. The early site permit holder may request such an extension for an already extended permit. The application must meet the requirements of §§ 53.1510 and 53.1520.

(b) An application submitted under paragraph (a) of this section must contain all information necessary to bring up to date the information and data contained in the previous application for those issues the early site permit holder has chosen to update.

(c) Each application must include a complete environmental report as required by part 51 of this chapter, or a request and justification for a categorical exclusion under part 51 of this chapter.

(d) Any person whose interest may be affected by the update of the permit may request a hearing on the application for the update. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.309 of this chapter.

■ 85. Revise § 53.1176 to read as follows:

§ 53.1176 Issuance of amendment to update an early site permit.

The Commission shall grant amendment of an early site permit only if it determines that:

(a) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(b) Any new requirements the Commission may wish to impose are necessary for adequate protection to public health and safety or common defense and security.

§ 53.1179 [Removed and Reserved]

■ 86. Remove and reserve § 53.1179.

■ 87. Revise § 53.1182 to read as follows:

§ 53.1182 Use of site for other purposes.

(a) A site for which an early site permit has been issued under this part may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, under the provisions of § 53.1188.

(b) If the permit holder no longer intends to use the site for a nuclear power plant or for other reasons no longer wishes to hold the permit, as described in the request, the permit holder may at any time request the Director to terminate the early site permit. The request to terminate the permit must comply with the filing requirements of §§ 53.040 and 53.1100 and identify the applicable requirements for site redress of § 53.1161. Upon request, the Director may terminate the permit.

(c) Termination of the early site permit does not bar the permit holder or another applicant from filing a new application for the site.

■ 88. In § 53.1188,

■ a. In paragraph (a)(1), remove the phrase ''or § 53.1179'';

■ b. In paragraph (a)(2), wherever it appears remove the word ''renewal'' and add in its place the word ''amendment'';

■ c. Revise and republish paragraph (c)(1);

■ d. In paragraph (d), remove the word ''renewed'' and in its place the word ''amended'';

■ e. In paragraph (e), in the last sentence add in sequential order the reference ''53.1173''.

The revision is to read as follows:

§ 53.1188 Finality of early site permit determinations.

* * * * *

(c) * * *

(1) In any proceeding for the issuance of a CP, OL, or COL referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness;

(v) The information as required in the site safety analysis report in accordance with § 53.1146(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later, or

(vi)(A) Any significant environmental issue that was not resolved in the early site permit proceeding;

(B) For an application that references an early site permit issued or updated by amendment, whichever is later, no more than 20 years before the submission of the application, any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified; and

(C) For an application that references an early site permit, issued or updated by amendment, whichever is later, more than 20 years before submission of the application, any issue involving the impacts of construction and operation of the facility regardless of whether the early site permit proceeding resolved the issue.

* * * * *

■ 89. In § 53.1263,

■ a. Revise paragraphs (a)(1)(v) and (vi), and remove paragraph (a)(1)(vii);

■ b. In paragraph (a)(4)(ii), remove the last sentence; and

■ c. Revise paragraph (b).

The revisions are to read as follows:

§ 53.1263 Finality of standard design certifications.

(a)(1) * * *

(v) Is necessary to correct material errors in the certification information; or

(vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security.

* * * * *

(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information, if one is required per § 53.1525. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the OL or COL hearing.

* * * * *

■ 90. In § 53.1282, add paragraph (e) to read as follows:

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

* * * * *

(e) *Optional operational programs.* An applicant may include in its application descriptions of essentially complete programmatic controls, operational programs, or operational requirements beyond those required by § 53.1279 in order to satisfy requirements for license applications that may reference a manufacturing license. If approved by the NRC as part of the manufacturing license, such programmatic controls, operational programs, and operational requirements would have finality under § 53.1288.

■ 91. In § 53.1288, revise paragraphs (a)(1) and (b) to read as follows:

§ 53.1288 Finality of manufacturing licenses.

(a)(1) During the term of an ML issued under this part, the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor; the requirements for the manufacture of the manufactured reactor; or the programmatic controls, operational programs, or operational requirements, 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 ML was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

* * * * *

(b) An applicant who references or uses a manufactured reactor manufactured under an ML under this part may include in the application a request for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the COL or CP hearing.

■ 92. In § 53.1309, revise paragraph (a)(2)(i) and remove and reserve paragraph (a)(4) to read as follows:

§ 53.1309 Contents of applications for construction permits; technical information.

* * * * *

(a) * * *

(2) * * *

(i) *Quality assurance program.* A description of the QAP or, for eligible applicants, the quality management system to be applied to the design, fabrication, construction, and testing of the SSCs of the facility under § 53.610(a)(6), including a discussion of how the requirements of appendix B of part 50 of this chapter or, for eligible applicants, how the requirements of appendix T of part 50 of this chapter will be satisfied.

* * * * *

(4) [Reserved]

* * * * *

■ 93. In § 53.1369, revise paragraph (l) and add paragraph (bb) to read as follows:

§ 53.1369 Contents of applications for operating licenses; technical information.

* * * * *

(l) *Quality assurance.* A description of the QAP or, for eligible applicants, the quality management system that demonstrates compliance with the requirements under § 53.865.

* * * * *

(bb) *Requests for generic finality.* An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for an operating license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

■ 94. In § 53.1375, revise paragraph (b) to read as follows:

§ 53.1375 Review of applications.

* * * * *

(b) *Administrative review of applications; hearings.*

(1) A proceeding on an OL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on OLs are governed by the procedures contained in 10 CFR part 2.

(2) If an applicant requests generic finality under § 53.1369(bb) for an OL under this part, the Commission will include a request for generic finality as a proposed action in the notice of proposed action required by § 2.105 of this chapter.

■ 95. In § 53.1387, add paragraph (e) to read as follows:

§ 53.1387 Issuance of operating licenses.

* * * * *

(e) The Commission may afford generic finality to generic aspects of the design of a commercial nuclear plant under this part, including postulated site parameters, and requirements submitted pursuant to § 53.1369(bb), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 96. Revise § 53.1390 to read as follows:

§ 53.1390 Finality of operating licenses.

(a) After issuance of an OL, the Commission may not modify, add, or delete any term or condition of the OL, except in accordance with the provisions of § 53.1590.

(b) In a proceeding for the issuance of a CP, OL, or COL, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which an OL issued under § 53.1387 is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced OL including, if applicable, the adequacy of a reactor design, where the referenced OL was afforded finality pursuant to § 53.1387(e).

■ 97. In § 53.1416, revise paragraphs (a)(12) and (d) and add paragraph (i) to read as follows:

§ 53.1416 Contents of applications for combined licenses; technical information.

* * * * *

(a) * * *

(12) *Quality assurance.* A description of the QAP or, for eligible applicants, the quality management system under § 53.865.

* * * * *

(d) If the COL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1437.

(3) If the early site permit site safety analysis report information required by § 53.1146(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later; the combined license application shall include updated information and revised analyses, as necessary, in the final safety analysis report.

(4) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the COL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the COL must be set forth as terms or conditions of the COL.

(5) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or

would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(6) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(9)(i) of this section are not required.

* * * * *

(i) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for a combined license that requests generic finality must include applicable site parameters postulated for the design under this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

■ 98. In § 53.1422, revise paragraph (b) to read as follows:

§ 53.1422 Review of applications.

* * * * *

(b) *Administrative review of applications; hearings.*

(1) A proceeding on a COL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the COL, then those ITAAC will be identified in the notice of hearing. All contested hearings on COLs are governed by the procedures contained in 10 CFR part 2.

(2) If an applicant requests generic finality under § 53.1416(i) for a COL under this part, the Commission will include a request for generic finality as a proposed action in the notice of hearing required by § 2.104 of this chapter.

§ 53.1437 [Amended]

■ 99. In § 53.1437, in paragraph (c), remove the last sentence.

■ 100. In § 53.1440, add paragraph (d) to read as follows:

§ 53.1440 Issuance of combined licenses.

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a commercial nuclear plant under this part, including postulated site parameters, and requirements submitted pursuant to § 53.1416(i), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 101. In § 53.1443, add paragraph (g) to read as follows:

§ 53.1443 Finality of combined licenses.

* * * * *

(g) In a proceeding for the issuance of a CP, OL, or COL, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which a COL issued under § 53.1440 is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced COL including, if applicable, the adequacy of a reactor design, where the referenced COL was afforded finality pursuant to § 53.1440(d).

■ 102. In § 53.1525, revise paragraphs (a) and (b) to read as follows:

§ 53.1525 Revising certification information within a design certification rule.

(a) A holder of a license who references a design certification rule issued under this part must request a license amendment in accordance with §§ 53.1510, 53.1515, and 53.1520 if proposing to change certification information that has been incorporated into the license.

(b) For certification information that has not been incorporated into the license, a holder of a license who references a design certification rule issued under this part may make changes to the certification information without requesting an exemption, if the changes meet the criteria in § 53.1550(a)(1) and (2) using the specifications in § 53.1550(b)(2) and (3). If an exemption is requested, the Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080.

* * * * *

■ 103. In § 53.1530, in paragraph (a) revise the last sentence to read as follows:

§ 53.1530 Revising information within a Final Safety Analysis Report associated with a manufacturing license.

* * * In those cases where an ML references a design certification rule, the provisions of § 53.1525 apply.

* * * * *

■ 104. Revise § 53.1535 to read as follows:

§ 53.1535 Amendments and exemptions during construction.

(a) The holder of a CP or limited work authorization (LWA) under this part may request an amendment to the CP or LWA in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or ML. Amendments to CPs or LWAs under this part must be requested and processed under §§ 53.1510 and 53.1520. The holder of a CP or LWA under this part may also request an exemption, if required by § 53.1525, to depart from a design certification rule.

(b) The holder of a COL under this part for which the NRC has not yet made a finding in accordance with § 53.1452(g) must request exemptions required by § 53.1525 and amendments required by § 53.1525 or 53.1550 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the exemption or amendment will not be granted.

■ 105. Revise § 53.1550 to read as follows:

§ 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.

(a) The holder of an OL or COL may make changes in the facility as described in the FSAR (as updated) and make changes in the procedures as described in the FSAR (as updated) without obtaining an exemption pursuant to § 53.1525 or license amendment pursuant to § 53.1510 only if—

(1) A change to the technical specifications or other certification information incorporated in the license is not required; and

(2) The change meets all of the following criteria:

(i) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence not previously identified as risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).

(ii) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence exceeds the licensing-basis event evaluation criteria required to be established in accordance with § 53.450(e).

(iii) Does not involve either of the following:

(A) A change to the NRC-approved comprehensive risk metric(s) or associated risk performance objective under § 53.220(b), or

(B) An increase to the frequency or consequences of one or more event sequences such that any calculated comprehensive risk metric exceeds the associated risk performance objective established in accordance with § 53.220.

(iv) Does not involve a departure from a method of evaluation described in the FSAR (as updated) used in assessing design basis accidents in accordance with § 53.450(f) unless the results of the analysis under § 53.450(f) are conservative or essentially the same; the revised method of evaluation has been previously approved by the NRC for the intended application; the revised method of evaluation can be used under an NRC-endorsed consensus code or standard; or the licensee has demonstrated through a documented verification, validation, and uncertainty quantification (VVUQ) process, conducted under a VVUQ program that meets the requirements of § 50.221 of this chapter and has been approved by the NRC for the intended application, that the departure from a method of evaluation described in the FSAR (as updated) meets the criteria established for credibility in the VVUQ program.

(v) Does not result in a change to the safety classification of an SSC from non-safety-related to safety-related, from non-safety-related but safety-significant to safety-related, or from safety-related to either non-safety-related but safety-significant or non-safety-related.

(vi) Does not result in more than a minimal decrease in defense in depth.

(vii) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are adopted in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the alternate evaluation criteria are exceeded.

(viii) Does not result in the identification of a new design-basis accident in accordance with § 53.450(f).

(ix) Does not result in more than a minimal increase in the consequences of any design-basis accident.

(3) In implementing this paragraph (a), the FSAR (as updated) is considered to include FSAR changes since submittal of the last update of the FSAR under § 53.1545.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.1525 are applicable.

(2) The licensee must maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the termination of the license. The licensee must identify the location and nature of departures from licensing-basis information within supporting documents for a certified design within the updates to the Safety Analysis Report required by § 53.1545.

(3) Licensees for which the NRC has docketed the certifications required under § 53.1070 need not retain records of departures from the design of the facility associated with SSCs that have been permanently removed from service using an NRC-approved change process.

(c) The holder of an OL or COL that authorizes operation of a manufactured reactor may make changes in the facility as described in the FSAR (as updated) and make changes in the procedures as described in the FSAR (as updated) without obtaining a license amendment pursuant to § 53.1510 if the changes are identical to changes approved by the Commission by amendment to the manufacturing license for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the manufacturing license and not involve any additional changes that would require an amendment to the OL or COL.

(d)(1) The licensee must maintain records of changes in the facility and procedures made under paragraphs (a) and (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment under paragraph (a)(2) or (c) of this section.

(2) The licensee must submit, as specified in § 53.040, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For COLs, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a COL to the date the Commission makes its findings under § 53.1452(g).

(3) The records of changes in the facility must be maintained until the termination of an OL or COL issued under this part, or the termination of a renewed license issued under § 53.1595—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

■ 106. In § 53.1565, in paragraph (d), revise (1)(i) introductory text, add (1)(iii), revise (2), add (3)(i)(E), and revise (3)(ii), (iii), and (vii) to read as follows:

§ 53.1565 Evaluating changes to programs included in licensing-basis information.

* * * * *

(d) * * *

(1) * * *

(i) Each holder under this part of an OL or COL, after the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix B of part 50 of this chapter, may make a change to a previously accepted quality assurance program (QAP) description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.1545. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

* * * * *

(iii) Each holder of an OL or COL after the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix T of part 50 of this chapter, must submit changes to the quality management system to the NRC and receive NRC approval prior to implementation as follows:

(A) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of part 50 of this chapter and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(D) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

(2) *Quality assurance program—siting, construction, and manufacturing.*

(i) Each holder of an LWA, early site permit, CP, ML, or COL, before the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix B to part 50 of this chapter, may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the QAP description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(A) Changes to the Safety Analysis Report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted QA topical report descriptions must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of part 50 of this chapter and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(D) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(ii) Each holder of a CP or COL, before the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix T of part 50 of this chapter, must submit changes to the quality management system to the NRC and receive NRC approval prior to implementation as follows:

(A) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of part 50 of this chapter and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(D) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

(3) * * *

(i) * * *

(E) *Risk significant planning standard* means the most essential functions of emergency preparedness to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency. For the purposes of this section, the risk significant planning standards are classification, notification, assessment, protective actions, staffing, and facilities.

(ii) A holder of an OL under this part, or a COL under this part after the Commission makes the finding under § 53.1452(g), must follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to part 50 of this chapter and the planning standards of § 50.47(b) of this chapter, or an emergency plan that meets the requirements in § 50.160 of this chapter.

(iii) A licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that:

(A) For planning standards that are risk significant, the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the risk-significant requirements of § 50.160 of this chapter or the applicable requirements in appendix E to part 50 of this chapter and the risk significant planning standards of § 50.47(b) of this chapter; and

(B) For planning standards that are not risk-significant, the plan, as changed, continues to meet the applicable requirements.

* * * * *

(vii) The licensee must provide for annual evaluation of the adequacy of the interfaces between the licensee and the applicable State, local, and Tribal governments, including licensee drills, exercises, capabilities, and procedures. The results of the evaluation, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, retained for a period of 5 years, and must be made available to the appropriate State, local, and Tribal governments.

* * * * *

PART 54—REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS

■ 107. The authority citation for part 54 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 102, 103, 104, 161, 181, 182, 183, 186, 189, 223, 234 (42 U.S.C. 2132, 2133, 2134, 2136, 2137, 2201, 2231, 2232, 2233, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); 44 U.S.C. 3504 note.

Section 54.17 also issued under E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; ADVANCE Act of 2024, sec. 301 (42 U.S.C. 2133 note).

§ 54.9 [Amended]

■ 108. In § 54.9, in paragraph (b), remove the reference ''54.22''.

■ 109. In § 54.17, revise paragraph (c) to read as follows:

§ 54.17 Filing of application.

* * * * *

(c) An application for a renewed license may not be submitted to the Commission earlier than the start of the period of operation that directly precedes the requested renewal period.

* * * * *

■ 110. In § 54.21, add paragraph (a)(4) and remove and reserve paragraph (c)(2) to read as follows:

§ 54.21 Contents of application—technical information.

* * * * *

(a) * * *

(4) An applicant may voluntarily use risk-informed and performance-based alternatives to the requirements in paragraphs (a)(1), (a)(2), and (a)(3) of this section. The application must describe the alternatives, justify their basis, and include a description of the underlying systematic analysis.

* * * * *

(c) * * *

(2) [Reserved]

* * * * *

§ 54.22 [Removed and Reserved]

■ 111. Remove and reserve § 54.22.

■ 112. In § 54.29, revise paragraphs (a) introductory text and (a)(1) to read as follows:

§ 54.29 Standards for issuance of a renewed license.

(a) Appropriate actions have been identified and have been or will be taken with respect to the matters identified in paragraphs (a)(1) and (a)(2) of this section, such that there is reasonable assurance that the activities authorized by the renewed license will continue to be conducted in accordance with the CLB, and that any changes made to the plant's CLB in order to comply with this paragraph are in accord with the Act and the Commission's regulations. These matters are:

(1) managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified to require review under § 54.21(a)(1) and alternatives authorized by § 54.21(a)(4); and

* * * * *

■ 113. In § 54.31, revise paragraphs (b) and (c) to read as follows:

§ 54.31 Issuance of renewed license.

* * * * *

(b) A renewed license will be issued for a fixed period of time, not to exceed 40 years.

(c) A renewed license will become effective upon expiration of the operating license or combined license previously in effect. Prior to the renewed license becoming effective, the licensee shall take all necessary steps to ensure the renewed license remains up to date, consistent with the CLB.

* * * * *

■ 114. In § 54.37, revise paragraph (b) to read as follows:

§ 54.37 Additional records and recordkeeping requirements.

* * * * *

(b) After the renewed license is in effect, FSAR updates required by 10 CFR 50.71(e) must contain any changes to summary descriptions of how the effects of aging will be managed for any newly identified systems, structures, and components that require aging management or an evaluation of time-limited aging analyses in accordance with § 54.21. Documentation of the related aging management review or evaluation of time-limited aging analyses shall be retained in accordance with § 54.37(a).

§ 54.43 [Amended]

■ 115. In § 54.43, in paragraph (b), remove the reference ''54.22''.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

■ 116. The authority citation for part 71 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 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, sec. 180 (42 U.S.C. 10175); 44 U.S.C. 3504 note.

Section 71.97 also issued under Sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

■ 117. In § 71.55, revise and republish paragraph (g) to read as follows:

§ 71.55 General requirements for fissile material packages.

* * * * *

(g) Packages containing uranium hexafluoride only are excepted from the requirements of paragraph (b) of this section provided that:

(1) Following the tests specified in § 71.73, there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight;

(2) There is an adequate quality control in the manufacture, maintenance, and repair of packagings;

(3) Each package is tested to demonstrate closure before each shipment;

(4) The uranium is enriched to not more than 10 weight percent uranium-235; and

(5) A design feature is incorporated to protect the valve or other fill device from impact for contents with uranium-235 enriched above 5 weight percent and up to 10 weight percent.

PART 100—REACTOR SITE CRITERIA

■ 118. The authority citation for part 100 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 103, 104, 161, 182 (42 U.S.C. 2133, 2134, 2201, 2232); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

§ 100.1 [Amended]

■ 119. In § 100.1, in paragraphs (a) and (d), remove the word ''stationary''.

§ 100.2 [Amended]

■ 120. In § 100.2, remove the word ''stationary''.

■ 121. In § 100.3, add in alphabetical order the definitions ''*Tier 1 reactor*'' and ''*Tier 2 reactor*'' to read as follows:

§ 100.3 Definitions.

* * * * *

Tier 1 reactor means a *power reactor* having an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site EAB.

Tier 2 reactor means a *power reactor* having an unmitigated consequence of greater than 25 rem (0.25 Sv) TEDE at the site EAB or where the unmitigated consequence is undetermined.

* * * * *

■ 122. In § 100.8, revise paragraph (b) to read as follows:

§ 100.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 100.10, 100.11, 100.20, 100.21, and 100.23.

■ 123. Revise subpart A section heading consisting of § 100.10 through § 100.11 to read as follows:

Subpart A—Evaluation Factors for Tier 1 Power and Testing Reactors

* * * * *

■ 124. Revise § 100.10 to read as follows:

§ 100.10 Factors to be considered when evaluating sites.

This approach to evaluating sites applies to Tier 1 power reactors and testing reactors. The Commission will take the following factors into consideration in determining the acceptability of a site for a Tier 1 power or testing reactor:

(a) Characteristics of reactor design and proposed operation.

(b) Population density and use characteristics of the site environs, including the exclusion area, low population zone, and population center distance (or alternate area assessed by consideration of societal risks and benefits).

(c) Physical characteristics of the site, including seismology, meteorology, geology, and hydrology. Applications to earthquake engineering criteria are contained in appendix S to part 50 of this chapter.

(d) Where unfavorable physical characteristics of the site exist, the proposed site may nevertheless be found to be acceptable if the design of the facility includes appropriate and adequate compensating engineering safeguards.

(e) For siting criteria described in § 100.11(a)(3)(i)(B), a comparison of societal risks and societal benefits.

■ 125. Revise § 100.11 to read as follows:

§ 100.11 Determination of exclusion area, low population zone, and population considerations.

(a) As an aid in evaluating a proposed site, an applicant should assume a fission product release,[1] the expected demonstrable leak rates from potential flow paths, and the meteorological conditions pertinent to the site to derive an exclusion area, a low population zone, and population center distance. For the purpose of this analysis the applicant should determine the following:

(1) An exclusion area of such size that an individual located at any point on its boundary for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem [2] TEDE.

(2) A low population zone of such size that an individual located at any point on its outer boundary who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a total radiation dose in excess of 25 rem (0.25 Sv) TEDE.

(3)(i) The reactor site must either:

(A) Provide a population center distance of at least one and one-third times the distance from the reactor to the outer boundary of the low population zone; or

(B) Be found acceptable to the NRC based on assessments of societal risks in comparison to societal benefits for the specific site.

(ii) The boundary of the population center or the alternate area assessed considering societal risks and benefits must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance or the alternate area assessed considering societal risks and benefits.

(b) [Reserved]

[1] 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 to bound a broad range of design basis accidents.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of reactor sites with respect to potential reactor accidents of exceedingly low probability of occurrence, and low risk of public exposure to radiation in the event of an accident.

■ 126. Revise subpart B section heading to read as follows:

Subpart B—Evaluation Factors for Tier 2 Power Reactor Site Applications

* * * * *

■ 127. In § 100.20, revise the introductory paragraph to read as follows:

§ 100.20 Factors to be considered when evaluating sites.

This approach to evaluating sites applies to Tier 2 power reactors. The Commission will take the following factors into consideration in determining the acceptability of a site for a Tier 2 power reactor:

* * * * *

■ 128. In § 100.21, redesignate footnote 3 as footnote 1 and revise footnote 1 and paragraphs (b), (g), and (h) to read as follows:

§ 100.21 Non-seismic siting criteria.

* * * * *

(b) (1) The reactor site must either:

(i) Provide a population center distance, as defined in § 100.3, of at least one and one-third times the distance from the reactor to the outer boundary of the low population zone; or

(ii) Be found acceptable to the NRC based on assessments of societal risks in comparison to societal benefits for the specific site;

(2) The boundary of the population center or the alternate area assessed considering societal risks and benefits must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance or the alternate area assessed considering societal risks and benefits;

* * * * *

(g) Physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans must be identified; and

(h) Reactor sites should be located away from very densely populated centers or otherwise be shown to be acceptable by assessments of societal risks in comparison to societal benefits for the specific site. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low density or when assessing a site considering societal risks and benefits, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable [1].

[1] Examples of these factors include, but are not limited to, such factors as the higher population density site having superior seismic characteristics, better access to skilled labor for construction, better rail and highway access, shorter transmission line requirements, the ability to use existing infrastructure for a retired fossil fuel power plant, or less environmental impact on undeveloped areas, wetlands or endangered species, etc. Some of these factors are included in, or impact, the other criteria included in this section.

■ 129. In § 100.23, revise paragraph (a) to read as follows:

§ 100.23 Geologic and seismic siting criteria.

* * * * *

(a) *Applicability.* The requirements in paragraphs (c) and (d) of this section apply to applicants for an early site permit or combined license pursuant to part 52 of this chapter, or a construction permit or operating license for a nuclear power plant pursuant to part 50 of this chapter that do not meet the entry criteria for subpart A of this part.

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Appendix A to Part 100 [Removed]

■ 130. Remove appendix A to part 100.

Dated: July 14, 2026.

For the Nuclear Regulatory Commission.

Jody Martin,

Secretary of the Commission.

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