[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 53, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171

[NRC-2019-0062]

RIN 3150-AK31

Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations by adding a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants in response to the Nuclear Energy Innovation and Modernization Act (NEIMA). The current application and licensing requirements were primarily developed to address license requests concerning light water-cooled reactors and operational requirements for those types of reactors. This final rule responds to NEIMA by creating an alternative, technology-inclusive regulatory framework to accommodate licensing of future commercial nuclear plants, including advanced reactor designs that may not employ light-water technology.

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Please refer to Docket ID NRC-2019-0062 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-2019-0062. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **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 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.

- **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.

FOR FURTHER INFORMATION CONTACT: Nicole Fields, Office of Nuclear Material Safety and Safeguards, telephone: 630-829-9570, email: Nicole.Fields@nrc.gov and Anders Gilbertson, Office of Nuclear Reactor Regulation, telephone: 301-415-1541,

email: Anders.Gilbertson@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

This rulemaking is separate from the NRC's comprehensive review and reform of its regulations, including those governing transportation, in accordance with Executive Order (E.O.) 14300, "Ordering the Reform of the Nuclear Regulatory Commission" (90 FR 22587; May 29, 2025). The rulemakings associated with that effort will comprehensively reexamine NRC requirements. While there could be additional revisions to part 53, "Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants," of title 10 of the *Code of Federal Regulations* (10 CFR) as a result of these future rulemakings, the NRC is moving forward with publication of this final rule at this time because it is a deregulatory action of high interest for stakeholders that was in progress before the issuance of E.O. 14300.

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

On January 14, 2019, the President signed the NEIMA into law (Pub. L. 115-439). NEIMA section 103(a)(4) directs the NRC to "complete a rulemaking to establish a technology-inclusive, regulatory framework for optional use by commercial advanced nuclear reactor applicants for new reactor license applications." NEIMA defines a "technology-inclusive regulatory framework" as one that is "developed using methods of evaluation that are flexible and practicable for application to a variety of reactor technologies, including, where appropriate, the use of risk-informed and performance-based techniques." NEIMA, as further amended by the Accelerating Deployment of

Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act), defines the term ‘‘advanced nuclear reactor” as “a nuclear fission reactor or fusion machine, including a prototype plant (as defined in sections 50.2 and 52.1 of title 10 of the *Code of Federal Regulations* (10 CFR) (as in effect on the date of enactment of [NEIMA])), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of [NEIMA].”

The NRC initially considered establishing the scope of 10 CFR part 53 as being for “advanced nuclear plants” consisting of one or more “advanced nuclear reactors” as defined in NEIMA. Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define “significant improvements” with enough specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor, “advanced,” implied enhanced safety, while the NEIMA definition includes “significant improvements” in areas other than safety enhancements. In response to this feedback, and to be technology-inclusive, the NRC determined that the broader term “commercial nuclear plant” is preferable.

The current application and licensing requirements in 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities,” and 10 CFR part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” were primarily developed to address license requests concerning light water-cooled reactors and operational requirements for those types of reactors. This final rule responds to NEIMA by creating an alternative, technology-inclusive regulatory framework to accommodate licensing of future commercial nuclear plants, including advanced reactor designs that may not employ light-water technology. The new alternative requirements and implementing guidance adopt technology-inclusive approaches and use risk-informed and performance-based techniques to ensure an equivalent level of safety to that of operating commercial nuclear plants while providing optionality and flexibility for

licensing and regulating a variety of technologies and designs for commercial nuclear reactors.

B. Major Provisions

Major provisions of this final rule, supported by accompanying guidance, include the following:

- A new alternative technology-inclusive, risk-informed, performance-based framework that includes requirements for licensing and regulating nuclear plants during the various stages of their life cycles.
- A new alternative technology-inclusive, risk-informed, and performance-based framework in 10 CFR part 26, “Fitness for Duty Programs,” developed from existing requirements in subpart K, “FFD Programs for Construction,” of part 26.
- A new alternative technology-inclusive and performance-based security framework in 10 CFR part 73, “Physical Protection of Plants and Materials,” that includes requirements for protection of licensed activities at commercial nuclear plants.

C. Costs and Benefits

The NRC prepared a final regulatory analysis to determine the expected quantitative costs and benefits of this final rule and associated guidance as well as qualitative factors to be considered in the NRC’s rulemaking decision. The conclusion from the analysis is that this final rule and associated guidance would result in net averted costs to the industry and the NRC of $152 million using a 7-percent discount rate and $203 million using a 3-percent discount rate. The annualized averted costs at a 7-percent discount rate are approximately $1.64 million per year to the NRC and $9.1 million per year to industry, or net annualized averted costs of approximately $10.7

million, over the 66-year analysis period. The number of future applicants was chosen conservatively, based on information known to the NRC; with each additional applicant beyond those included in the regulatory analysis, this final rule becomes even more cost-beneficial.

The final regulatory analysis also considers qualitative factors such as greater regulatory stability, predictability, and clarity to the licensing process. These benefits would result, for example, from incorporating advances in probabilistic risk assessment (PRA) and other risk-informed analyses into the regulatory framework. Another qualitative factor is promoting a performance-based regulatory framework that specifies requirements to be met and provides flexibility to an applicant or licensee regarding the information or approach needed to satisfy those requirements.

For more information, please see the final regulatory analysis (available in the NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML26042A230).

TABLE OF CONTENTS:

I. Background
NRC Advanced Reactor Readiness
II. Discussion
A. Objective and Applicability
B. Need for Changes to the Existing Regulatory Framework
C. 10 CFR Part 53 Framework
III. Part 53 Framework
Subpart A—General Provisions
A. Discussion of Definitions in Part 53
B. Other General Provisions
Subpart B—Technology-Inclusive Safety Requirements
Subpart C—Design and Analysis Requirements
Subpart D—Siting Requirements
Subpart E—Construction and Manufacturing Requirements
Subpart F—Requirements for Operation
Subpart G—Decommissioning Requirements
Subpart H—Licenses, Certifications, and Approvals
Subpart I—Maintaining and Revising Licensing-Basis Information

Subpart J—Reporting and Other Administrative Requirements
Subpart M—Enforcement
IV. Changes to Other Parts of 10 CFR Chapter I
10 CFR Part 26
A. Introduction
B. Changes to Part 26, Subparts A through E and I
C. Requirements for Part 26, Subpart M
D. Changes to Part 26, Subpart N
E. Changes to Part 26, Subpart O
10 CFR Part 50
A. Section 50.160: Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities
B. Appendix B to Part 50: Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
C. Appendix E to Part 50: Emergency Planning and Preparedness for Production and Utilization Facilities
10 CFR Part 73
A. Section 73.100: Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage
B. Section 73.110: Technology-inclusive requirements for protection of digital computer and communication systems and networks
C. Section 73.120: Access authorization program for commercial nuclear plants
V. Opportunities for Public Participation
VI. Public Comment Analysis
VII. Regulatory Flexibility Certification
VIII. Regulatory Analysis
IX. Backfitting and Issue Finality
X. Cumulative Effects of Regulation
XI. Plain Writing
XII. Environmental Assessment and Final Finding of No Significant Environmental Impact
XIII. Paperwork Reduction Act
XIV. Executive Orders
A. Executive Order 12866: Regulatory Planning and Review (as amended by Executive Order 14215: Ensuring Accountability for All Agencies)
B. Executive Order 14154: Unleashing American Energy
C. Executive Order 14192: Unleashing Prosperity Through Deregulation
D. Executive Order 14270: Zero-Based Regulatory Budgeting to Unleash American Energy
XV. Congressional Review Act
XVI. Criminal Penalties
XVII. Voluntary Consensus Standards
XVIII. Availability of Guidance
XIX. Availability of Documents

I. Background

The NRC is amending its regulations by adding an alternative risk-informed, performance-based, and technology-inclusive regulatory framework as an option for the

licensing and regulation of future commercial nuclear plants. This section discusses previous activities that have led to the development of this final rule.

NRC Advanced Reactor Readiness

In its “Policy Statement on the Regulation of Advanced Nuclear Power Plants,” dated July 8, 1986, the Commission stated that it considered the term “advanced” to apply to reactors that are significantly different from current (i.e., current in 1986) generation light-water reactors (LWRs) then under construction or in operation, and that “advanced” includes reactors that provide enhanced margins of safety or utilize simplified inherent or other innovative means to accomplish their safety functions. At the time, certain high temperature gas-cooled reactors, liquid metal reactors, and LWRs of innovative design were considered to be “advanced.” The 1986 policy statement provided the Commission’s policy regarding the review of, and desired characteristics associated with, advanced reactors. The NRC updated this statement in the “Policy Statement on the Regulation of Advanced Reactors,” dated October 14, 2008 (Advanced Reactor Policy Statement).

The agency has undertaken many activities related to advanced reactors, including issuing an advance notice of proposed rulemaking titled “Approaches to Risk-Informed and Performance-Based Requirements for Nuclear Power Reactors,” dated May 4, 2006 (71 FR 26267). These efforts were often done in parallel, and sometimes interwoven, with the NRC’s efforts to improve risk-informed and performance-based approaches within the agency (e.g., the Commission’s PRA policy statement, “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities,” dated August 16, 1995 (60 FR 42622)).

In 2016, the NRC issued “NRC Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Mission Readiness” (Advanced Reactor Vision and Strategy Document), in response to increasing interest in advanced reactor designs. The

NRC considered the Department of Energy's (DOE's) advanced reactor deployment goals in developing the Advanced Reactor Vision and Strategy Document. Since publication of the document, the NRC continues to manage its activities to support the DOE's deployment goals. The Advanced Reactor Vision and Strategy Document identified initiating and developing a new risk-informed and performance-based regulatory framework as a possible long-term goal. However, the NRC staff's initial efforts were focused on resolving policy issues and developing guidance for licensing non-LWR technologies under the existing regulatory frameworks (parts 50 and 52). The NRC staff issues annual Commission papers on the status and progress of the NRC staff's activities related to advanced reactors (e.g., SECY-24-0020, "Advanced Reactor Program Status," dated February 27, 2024). These Commission papers provide status updates for advanced reactor activities undertaken both prior to and after initiation of this rulemaking.

In 2017, the NRC staff prioritized activities to support the development of technology-inclusive, risk-informed, and performance-based licensing approaches that could be implemented under the existing regulatory framework in parts 50 and 52. These activities leveraged previous work described in NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," published in 2007. One key element of these efforts was the Licensing Modernization Project (LMP), a cost-shared initiative led by nuclear utilities and supported by DOE. The LMP methodology is a technology-inclusive, risk-informed, and performance-based methodology developed for non-LWR designs. The LMP methodology provides a systematic and reproducible process for licensing-basis event (LBE) selection and evaluation; classification of structures, systems, and components (SSCs); and assessment of defense in depth. The LMP methodology refined the DOE's Next Generation Nuclear Plant Program methodologies to reflect interactions with the NRC, to

address feedback from industry, and to broaden the scope of the approach to ensure applicability to various non-LWR technologies. The LMP methodology activities led to the publication and submittal of Nuclear Energy Institute (NEI) 18-04, Revision 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019. The document indicates that controlling the frequencies and potential consequences of a wide spectrum of events is the primary focus of the LMP methodology.

The NRC endorsed the principles and methodology in NEI 18-04, with clarifications, in 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." The NRC staff sought Commission approval of the use of the LMP methodology and NEI 18-04 in SECY-19-0117, "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 December 2, 2019. In that paper, the staff described the relationship between the LMP methodology and NEI 18-04 and previous relevant Commission decisions, including those described in SECY-93-092, "Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements," dated April 8, 1993. The Commission approved the use of the LMP methodology and NEI 18-04 as a reasonable approach for establishing key parts of the licensing basis and content of applications for licenses, certifications, and approvals for non-LWRs in Staff Requirements Memorandum (SRM) SRM-SECY-19-0117, dated May 26, 2020. Although the LMP methodology is technology-inclusive, the industry and NRC staff initially focused the LMP methodology's applicability on non-LWRs, both for efficiency and to support near-term non-LWR

applications under the existing regulatory framework, such as the Advanced Reactor Demonstration Projects supported by DOE.

As stated in the part 53 rulemaking plan, SECY-20-0032, dated April 13, 2020, the NRC staff developed part 53 by building upon recent and ongoing activities such as the LMP methodology described in SECY-19-0117. Such an approach supports implementing the NEIMA direction to establish a technology-inclusive framework as well as the requirement to use, where appropriate, risk-informed and performance-based techniques, and it also capitalizes on previous initiatives by the industry, DOE, and the NRC. The LMP methodology highlights the role of PRA in risk-informed and performance-based approaches to identifying enhanced safety margins that can be used to justify operational flexibilities. The part 53 framework is largely based on the methodology described in SECY-19-0117 and includes a prominent role for PRA, other systematic risk evaluations (SREs), or a combination thereof.

II. Discussion

A. Objective and Applicability

The NRC is adding a new, alternative part to its regulations that sets out a risk-informed, technology-inclusive framework for the licensing and regulation of commercial nuclear plants. This new approach achieves the following: (1) continue to provide reasonable assurance of adequate protection of public health and safety and the common defense and security; (2) promote regulatory stability, predictability, and clarity; (3) reduce requests for exemptions from the current requirements in parts 50 and 52; (4) establish new requirements to address non-LWR technologies; (5) recognize technological advancements in reactor design; and (6) credit the possible response of some designs of commercial nuclear plants to postulated accidents, including slower transient response times and relatively small and slow release of fission products. This final rule adds 10 CFR part 53; subpart M, “Fitness-for-Duty Programs for Facilities

Licensed Under 10 CFR Part 53," to part 26; § 73.100, "Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage," § 73.110, "Technology-inclusive requirements for protection of digital computer and communication systems and networks," and § 73.120, "Access authorization program for commercial nuclear plants," as well as makes conforming changes throughout 10 CFR chapter I, "Nuclear Regulatory Commission."

B. Need for Changes to the Existing Regulatory Framework

The NRC has long recognized that the licensing and regulation of a variety of nuclear reactor technologies presents challenges because the existing regulatory framework has evolved primarily to address the LWR designs that compose the current operating fleet. The NRC has had many interactions with designers of various reactor technologies under development, sometimes collectively referred to as advanced reactors. The interactions have informed the development of policies and guidance to support the potential licensing of new and different types of reactor facilities, some of which may not utilize LWR designs. The NRC issued its Advanced Reactor Policy Statement to provide all interested parties, including the public, with the Commission's views concerning the desired characteristics of advanced reactor designs. The NRC further described its early efforts to establish a technology-inclusive approach to the regulation of nuclear reactors in the advance notice of proposed rulemaking published in 2006. The NRC acknowledged in its "Report to Congress: Advanced Reactor Licensing," issued August 2012, that "while the safety philosophy inherent in the current regulations applies to all reactor technologies, the specific and prescriptive aspects of those regulations clearly focus on the current fleet of LWR facilities."

Congress similarly recognized the potential benefits of developing a regulatory infrastructure to support the development and commercialization of advanced nuclear

reactors. Consequently, Congress passed NEIMA in late 2018, and the President signed it into law in January 2019. NEIMA directed the NRC to undertake a rulemaking to establish a technology-inclusive regulatory framework for optional use by applicants for new commercial advanced nuclear reactor licenses. In addition, on July 9, 2024, the President signed into law the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024, also referred to as the ADVANCE Act. The NRC has evaluated the ADVANCE Act, including how NRC regulations, such as part 53 or future revisions to it, could be used to address provisions in the ADVANCE Act. The ADVANCE Act contains provisions on a variety of nuclear-related topics, such as microreactors, nuclear reactor license application reviews, and nuclear fuel. Finally, in 2025, the President signed E.O. 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” which builds on the provisions in the ADVANCE Act. E.O. 14300 will complement this rulemaking by providing additional mechanisms for streamlining the agency’s efforts to provide an efficient licensing pathway for advanced reactors.

The requirements in part 53 support a wide variety of potential commercial nuclear reactor technologies. The current regulatory framework in parts 50 and 52 evolved in the context of the current operating reactor fleet dominated by LWRs and as a result includes provisions specific to LWR technologies. While the NRC can license other reactor technologies under the current framework by using existing regulatory flexibilities and the exemption process, there is significant interest in developing a regulatory framework that is flexible enough to accommodate multiple technologies and robust enough to ensure a level of safety equivalent to parts 50 and 52, consistent with the Commission’s Advanced Reactor Policy Statements. The Commission reiterated its safety expectations for new reactors in the SRM for SECY-10-0121, “Modifying the Risk-Informed Regulatory Guidance for New Reactors,” dated March 2, 2011:

> Because new plant designs incorporate operating experience from current generation reactors, severe accident research, and risk insights from design probabilistic risk assessments, the Commission expects that the advanced technologies incorporated in new reactors will result in enhanced margins of safety. However, the Commission continues to expect (consistent with the 2008 Advanced Reactor Policy Statement), as a minimum, at least the same degree of protection of the public and the environment that is required for current-generation light-water reactors. New reactors with these enhanced margins and safety features should have greater operational flexibility than current reactors.

However, developing a regulatory framework that can accommodate a wide range of technologies while maintaining an acceptable level of safety presents significant regulatory challenges. The existing regulations have been developed over the course of decades and reflect changes to address events discovered through operating experience. As a result, the existing regulations have benefited from a focused and tailored treatment of safety issues as issues arose and evolved. In contrast, part 53 is being developed to accommodate technologies that, in some cases, lack significant operating experience. This lack of operating experience makes it challenging to develop technology-inclusive regulatory requirements when it is less well-known which issues may be more or less important to safety for any given set of technologies. To address these challenges, the NRC drew on well-developed approaches to licensing to produce a technology-neutral and robust regulatory framework. The regulatory framework uses PRAs, other SREs, or a combination thereof, to assess risks and focus on the issues most important to safety, help establish technical requirements, and manage operations. The framework builds on the LMP methodology, which is a technology-inclusive approach to licensing that leverages risk insights to provide applicants with significant design and operation flexibilities.

C. 10 CFR Part 53 Framework

This final rule consists of several major components, including a new part 53, to be added to 10 CFR chapter I, revisions for part 26, part 50, and part 73, and conforming changes throughout 10 CFR chapter I. The major features of this final rule include the following:

(1) *Technology-inclusiveness.* This rule provides a broad and flexible regulatory framework that can be used for any reactor technology, any size reactor, and any reactor end use.

(2) *Risk-informed framework to support safety-focused decision-making.* Part 53 provides a holistic, risk-informed framework that offers substantial flexibility in leveraging safety margins and focusing on design features and programmatic controls important to protecting public health and safety. The framework allows for explicit consideration of risk through the use of PRAs or other SRE techniques, or a combination thereof, to generate risk insights, and to assess and manage those risks. This approach departs from traditional deterministic methods, notably the use of the single-failure criterion, by enabling applicants to propose comprehensive risk metrics and associated risk performance objectives, appropriate systematic risk assessment techniques, and to demonstrate how their design and associated programmatic controls protect public health and safety.

(3) *Performance-based approach.* Part 53 is a performance-based framework that provides flexibility in establishing appropriate high-level safety objectives and demonstrating how a reactor design or specific commercial nuclear plant meets those objectives. Rather than prescribing specific methods or processes, the performance-based approach in part 53 promotes efficiency and innovation by allowing applicants to propose design features to meet safety objectives and achieve safety outcomes. This will support novel concepts such as leveraging functional containment concepts, alternative siting criteria for commercial nuclear reactors in relation to population centers,

reduced staffing levels, and remote operations, while eliminating traditional, prescriptive requirements, such as general design criteria and aircraft impact assessments.

(4) *Licensing pathways that accommodate a broad spectrum of design maturities and deployment models*. Part 53 provides several licensing options for applicants to choose from to meet their deployment model or business case needs, including the licenses, certifications, and approvals provided by parts 50 and 52. This final rule provides additional flexibility for manufacturing licenses (MLs), including the possible factory loading of fuel into manufactured reactors with appropriate features to prevent criticality for deployment to another location for operation.

(5) *Operator licensing.* Part 53 introduces the concept of self-reliant-mitigation facilities and the use of generally licensed reactor operators (GLROs) for those facilities. The allowance for GLROs provides flexibility for the types and locations of staffing needed under part 53.

(6) *Efficiency*. Part 53 provides opportunities to improve regulatory efficiency by including provisions for licensing first-of-a-kind proposals as well as provisions that benefit those proposing standardized and repetitious applications. Part 53 provides finality to designs for which an operating license has been issued to improve its incorporation into a standardized design approval or certification. Part 53 also provides for a risk-informed approach for managing plant equipment and programmatic controls that reduce the future need for regulatory approvals.

(7) *Codes and standards.* Part 53 does not incorporate by reference specific codes and standards as is done in § 50.55a, "Codes and standards." Instead, part 53 allows the use of generally accepted codes and standards to be tailored to the assessed safety significance of SSCs, such as the use of non-nuclear codes and standards for SSCs composed of commercial grade components.

Part 53 is comprised of subparts A through M. These provisions are organized to provide high-level performance criteria and to specify requirements to demonstrate compliance with those performance criteria throughout major stages of the life cycle of commercial nuclear plants. This organization reflects a systems-engineering style approach to the design, licensing, operation, and ultimately decommissioning of future commercial nuclear plants. Organizing requirements in this manner also supports performance-based approaches. Required programs (e.g., radiation protection) and monitoring (e.g., technical specification (TS) surveillance) during the operations phase that are similar to those required by part 50 complement the design and analysis requirements in subpart C. The performance-based approach adopted in part 53 also includes regulatory requirements that allow applicants to use a flexible and graded approach to the performance of safety functions based on the role of a particular SSC, human action, or program in limiting the overall risks to the public below accepted standards through balanced measures to prevent and mitigate possible events.

Subpart M of part 26 is new and is largely consistent with the objective-based fitness-for-duty (FFD) requirements in current subpart K, "FFD Programs for Construction," of part 26 supplemented by select requirements from subparts A through I, N, and O of part 26. Subpart M of part 26 is designed to ensure program effectiveness, maintain protections afforded to individuals subject to the FFD program, and align with FFD program implementation by parts 50 and 52 licensees. The requirements are not entirely equivalent because current subpart K of part 26 only applies during construction of the commercial nuclear plant, whereas subpart M of part 26 applies during construction, operation, and decommissioning. Furthermore, subpart M of part 26 allows the use of a variety of biological specimens for drug testing as well as innovative technologies for drug and alcohol screening and testing that are not described or

allowed by the requirements in subparts A through K, N, and O of part 26, except under limited conditions.

Revisions to part 73 establish a new technology-inclusive, consequence-based approach for a range of security areas, including physical security, cybersecurity, and access authorization (AA) for commercial nuclear reactors. The NRC used operating experience to include additional regulatory flexibility for a part 53 licensee's implementation of security requirements.

In addition, this final rule makes conforming changes throughout 10 CFR chapter I, by adding "and part 53" where appropriate to account for the addition of part 53.

III. Part 53 Framework

Subpart A—General Provisions

Subpart A provides the general provisions applicable to all applicants and licensees that are established in part 53 for the issuance, amendment, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under section 103 of the Atomic Energy Act of 1954, as amended (the AEA) and title II of the Energy Reorganization Act of 1974 (88 Stat. 1242). Subpart A includes purpose, scope, definitions, written communications, employee protections, completeness and accuracy of information, exemptions, standards for review, jurisdictional limits, consideration of attacks and destructive acts by enemies of the United States, and information collection requirements.

The requirements in subpart A are largely equivalent to the general requirements in part 50 that are applicable to all part 50 applicants and licensees (specifically, §§ 50.1 through 50.13) but reference the corresponding regulations in part 53 in place of references to part 50.

A. Discussion of Definitions in Part 53

This final rule includes a definition section in § 53.020. The definitions of most terms in § 53.020 are equivalent to the corresponding terms defined in: (1) §§ 50.2, 52.1, and other NRC regulations; (2) NEI 18-04, as endorsed by RG 1.233; or (3) American Society of Mechanical Engineers (ASME)/American Nuclear Society Risk Assessment Standard (RA-S)-1.4-2021, as endorsed for trial use by RG 1.247, "Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities." This is intended to provide clarity and consistency in terminology where possible and to utilize past and ongoing NRC initiatives to support the licensing of new reactors. Specific deviations from existing definitions are further explained in the following paragraphs.

Regarding the definition of "*Commercial nuclear plant*" and "*Commercial nuclear reactor*" in § 53.020, as noted previously, the NRC initially considered establishing the scope of part 53 as being for "advanced nuclear plants." The preliminary proposed rule language defined "advanced nuclear plant" as "a utilization facility consisting of one or more advanced nuclear reactors" as defined in NEIMA. NEIMA defines the term ''advanced nuclear reactor'' as "a nuclear fission reactor or fusion machine, including a prototype plant (as defined in sections 50.2 and 52.1 of 10 CFR (as in effect on the date of enactment of this Act)), with significant improvements compared to commercial nuclear reactors under construction as of the date of enactment of this Act, including improvements such as— (A) additional inherent safety features; (B) significantly lower levelized cost of electricity; (C) lower waste yields; (D) greater fuel utilization; (E) enhanced reliability; (F) increased proliferation resistance; (G) increased thermal efficiency; or (H) ability to integrate into electric and nonelectric applications."

Based on public discussions on the use of the term, the NRC determined that the NEIMA definition, although broad, did not define "significant improvements" with enough

specificity to implement in NRC regulations. Additionally, a number of stakeholders suggested that the descriptor “advanced” implied enhanced safety, while the NEIMA definition includes “significant improvements” in areas other than safety enhancements. In response to this feedback, and to be technology-inclusive, the NRC determined that the broader term “commercial nuclear plant” is preferable. The NEIMA definition of advanced nuclear reactor also includes fusion technologies. Fusion energy systems have not been included in the scope of part 53 but are the subject of a separate rulemaking activity, “Regulatory Framework for Fusion Systems.” See NRC docket ID NRC-2023-0017 on the Federal rulemaking website *https://www.regulations.gov*.

The NRC allows the use of part 53 by any “commercial nuclear plant.” The use of the term “plant” versus “reactor,” as used in existing regulations (i.e., § 50.2), recognizes that co-located support facilities and radionuclide sources need to be considered in the licensing of a facility. The phrase “commercial purposes,” as used in the definition of “commercial nuclear plant,” includes purposes such as providing process heat for a variety of industrial applications (e.g., desalination, oil refining, hydrogen production). The NRC has not compiled a complete list of such commercial purposes. The definition of “*Commercial nuclear plant*” refers to a “*Commercial nuclear reactor*,” which is defined based on the definition of “*Nuclear reactor*” in § 50.2. However, the phrase “in a self-supporting chain reaction” is not included in the definition of *Commercial nuclear plant* to enable applying part 53 to accelerator driven systems that use special nuclear material (SNM) but that do not involve self-sustaining chain reactions. Relatedly, “*Utilization facility*” is also defined in § 53.020 based on the definition of that term in § 50.2 and refers to a “*Commercial nuclear plant*” as defined in § 53.020.

The definition of “*Construction*” is different from the definition in § 50.10. Because the regulatory framework in part 53 uses risk-informed, less prescriptive, and performance-based requirements as compared to part 50, the part 53 definition takes a

different approach in determining what activities are prohibited without an NRC license. Under the part 53 approach, the definition of *"Construction"* specifies a variety of activities that are applicable to safety-related (SR) and non-safety-related but safety-significant (NSRSS) SSCs and are credited or relied upon for demonstrating compliance with safety criteria defined in subpart B of part 53 as well as SSCs necessary to comply with part 73 and onsite emergency facilities necessary to comply with § 53.855. By listing the activities for SR and NSRSS SSCs that are credited or relied upon for demonstrating compliance with safety criteria defined in subpart B, this definition describes activities related to SSCs subject to some sort of special treatment, as that term is defined in § 53.020. These special treatment requirements, which include quality assurance, design criteria, and programmatic controls, apply to safety-related SSCs and the set of non-safety-related SSCs for which a license is required to authorize construction activities. The latter category includes a facility's NSRSS SSCs. The non-safety-significant SSCs not subject to special treatment and NSRSS SSCs for which special treatments are limited to operational controls are, in general, identified as "commercial grade" and may be designed, procured, and installed in accordance with the usual practices employed for industrial plants. Importantly, under the part 53 definition, an SSC that falls outside the definition of construction may still be subject to the NRC's statutory authority during operations. In view of the foregoing, the definition of *"Construction"* in § 53.020 is consistent with the provisions of the AEA related to construction permits, while simultaneously allowing activities related to SSCs that are commercial grade but which could still be subject to the NRC's jurisdiction during operations. This definition also includes the listed activities which are for SSCs necessary to comply with part 73 or onsite emergency facilities necessary to comply with § 53.855. The inclusion of the listed activities which are for these SSCs is consistent with § 50.10(a)(1)(v) and (vii), which include activities for corresponding SSCs. Including

these activities in the definition of "*Construction*" is appropriate because, in both instances, part 53 points back to the relevant existing frameworks in part 73 and the relevant part 50 requirements, respectively, rather than creating an entirely new framework. Section 53.020 also adds definitions for terms related to event selection (LBEs, design-basis accidents (DBAs), anticipated event sequences, unlikely event sequences, and very unlikely event sequences); equipment classifications (SR, NSRSS, and non-safety-significant SSCs); performance metrics (e.g., safety criteria and functional design criteria); and special treatment.

The regulation defines "*Safety criteria*" in terms of the plant-level performance-based metrics that are provided in §§ 53.210 and 53.220. The term "*Functional design criteria*" is defined as metrics for the performance of specific SSCs that are determined from the role of the SSC in meeting the safety criteria. These are new terms that have not previously been defined or used in NRC regulation.

The term "*Safety-related SSCs*" refers to those SSCs needed to meet the safety criteria in § 53.210. The term "*Non-safety-related but safety-significant SSCs*" means those SSCs that are not SR because they are not relied upon to perform any function necessary to demonstrate compliance with § 53.210 but warrant special treatment because they are relied on to achieve adequate defense in depth or perform risk-significant functions. The term "*Non-safety-significant SSCs*" means those SSCs that are not SR or NSRSS.

The term "*Programmatic controls*" means administrative measures that govern human action in implementing programs and operating, monitoring, and maintaining SSCs and equipment of a commercial nuclear plant.

The terms "*Design-basis accidents*," "*Anticipated event sequences*," "*Unlikely event sequences*," and "*Very unlikely event sequences*" are defined to be different types of "*Licensing-basis events*" and are also largely equivalent to the LMP methodology's

definitions of DBAs, anticipated operational occurrences (AOOs), design-basis events (DBEs), and beyond-design-basis events, respectively. The term "*Design-basis accidents*" is defined as postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs through deterministic analyses. Design-basis accidents are derived from the unlikely event sequences from the PRA, a type of SRE, other SREs, or a combination thereof, and then analyzed in a conservative approach by prescriptively assuming that only SR SSCs are available to mitigate postulated accident scenarios. Within the LMP methodology, event sequences with mean frequencies of 1×10^{-2}/plant-year and greater are classified as anticipated event sequences. Within the LMP methodology, infrequent event sequences with mean frequencies of 1×10^{-4}/plant-year to 1×10^{-2}/plant-year are classified as unlikely event sequences. "*Very unlikely event sequences*" are less likely to occur than unlikely event sequences. Within the LMP methodology, rare event sequences with frequencies of 5×10^{-7}/plant-year to 1×10^{-4}/plant-year are classified as very unlikely event sequences. While the terminology for these event sequences creates some differences between part 53 and the LMP methodology, part 53 uses new terms for these event sequences specifically to avoid conflicts with terms already used within part 50 and part 52 to represent different concepts. Further, because some stakeholder comments demonstrated confusion related to the history of beyond-design-basis accidents terminology, these definitions seek to clarify the event categories in part 53. Finally, although the term "event sequence" is often used in the context of a PRA, that term is used generically in part 53 and does not imply the use of a specific type of SRE, such as a PRA. The sections of this preamble related to subparts B and C provide additional discussion of LBEs.

Section 53.020 includes a definition of "*Special treatment*" to explain that it means those requirements, such as quality assurance (QA), design criteria, and

programmatic controls, that are taken beyond the procurement, installation, and maintenance of commercial grade products. Routine commercial practices may include the use of selected consensus codes and standards that are cited in applications to support the identification of special treatments that may go beyond what would otherwise be required by those selected commercial codes and standards. The special treatments increase confidence that SR and NSRSS SSCs will provide defense in depth, or perform risk-significant functions, under service conditions and with SSC reliabilities that are consistent with the analysis required in subpart C. Structures, systems, and components designated as SR also contribute to defense in depth and risk-significant functions and may warrant special treatments beyond those defined for the SR functions needed for compliance with § 53.210.

To maintain alignment with definitions in part 52, the NRC has added a definition of early site permit (ESP). The NRC proposed definitions for “Consensus code or standard” and “probabilistic risk assessment” but is not including a definition for these terms in this final rule because these terms were determined not to be essential for the framework and including the definitions could introduce issues with consistency given alternative definitions developed by other organizations.

B. Other General Provisions

Section 53.040 governs written communications and how applications and other required information must be submitted to the NRC. These requirements are equivalent to those in § 50.4.

Section 53.050 establishes requirements for enforcement action to which a licensee, an applicant, or a licensee’s or applicant’s contractor or subcontractor, or an employee of any of them may be subject for engaging in deliberate misconduct. These requirements are equivalent to those in § 50.5.

Section 53.060 prohibits discrimination against an employee of a holder or applicant for an NRC license, permit, design certification (DC), or design approval, or a contractor or subcontractor of a holder or applicant for an NRC license, permit, DC, or design approval for engaging in certain protected activities. Section 53.060 also prescribes a procedure for seeking a remedy for employees who believe they have been discriminated against for engaging in such protected activities. These requirements are equivalent to those in §§ 50.7 and 52.5.

Section 53.070 governs the completeness and accuracy of information provided to the NRC. These requirements are equivalent to those in §§ 50.9 and 52.6.

Section 53.080 governs exemptions from the requirements of the regulations in part 53. These requirements are equivalent to those in §§ 50.12 and 52.7.

Paragraphs (a) through (d) of § 53.090 establish requirements for standards that the NRC will consider in determining whether a construction permit (CP), operating license (OL), ESP, combined license, or ML under part 53 will be issued to an applicant. These requirements are equivalent to those in §§ 50.40, 50.42, 50.43 and 50.22, respectively. Requirements equivalent to those in §§ 50.41 and 50.21 are not included in part 53 because they apply to Class 104 licenses, and part 53 does not apply to those licenses.

Section 53.100 requires that no license issued under part 53 may cover activities that are not under or within the jurisdiction of the United States. These requirements are equivalent to those in § 50.53.

Section 53.110 states that licensees and applicants are not required to provide design features or other measures for the specific purpose of protection against the effects of attacks and destructive acts by enemies of the United States directed against the facility or deployment of weapons incident to U.S. defense activities. These requirements are equivalent to those in § 50.13.

Section 53.115 establishes requirements for rights related to SNM. These requirements are equivalent to those in § 50.54(b) and (c).

Section 53.117 establishes requirements for license suspension and rights of recapture of the material or control of the facility in a state of war or national emergency declared by Congress. These requirements are equivalent to those in § 50.54(d).

Section 53.120 establishes requirements for information collection requirements that have received Office of Management and Budget (OMB) approval. These requirements are equivalent to those in § 50.8.

Subpart B—Technology-Inclusive Safety Requirements

Subpart B, “Technology-Inclusive Safety Requirements,” provides technology-inclusive safety criteria that serve as performance standards for the subsequent performance-based requirements used throughout part 53. Subsequent subparts define how specific activities during various stages of the life cycle of a commercial nuclear plant contribute to satisfying these high-level performance standards. The performance standards in subpart B also establish a means to determine appropriate regulatory controls for SSCs, human actions, and programs in the following subparts. For example, the classification of SR SSCs is built upon the safety criteria in § 53.210, “Safety criteria for design-basis accidents.” The more detailed requirements for those SSCs are then further defined in the design and analysis requirements in subpart C, “Design and Analysis Requirements.” The activities for manufacturing, constructing, and maintaining the SR SSCs are governed by subpart E, “Construction and Manufacturing Requirements,” and subpart F, “Requirements for Operation.”

Requirements for NSRSS SSCs warranting special treatment are likewise determined under § 53.220, “Safety criteria for licensing-basis events other than design-basis accidents,” in subpart B and § 53.460, “Safety categorization and special

treatment," in subpart C. Regulatory requirements related to the NSRSS SSCs are distinguished from the regulatory requirements for SR SSCs throughout part 53. Part 53 affords more flexibility to applicants and licensees regarding how NSRSS SSCs are used in the design and maintained during plant operations, as compared to SR SSCs.

The collective set of performance-based requirements in part 53 are sufficient, if met, for the NRC to make the findings required to grant an application for a utilization facility under section 182 of the AEA that the utilization of SNM will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. This construct is similar to existing NRC regulations, which the Commission has said on many occasions do not specifically define "adequate protection." However, compliance with NRC regulations may be presumed to assure adequate protection at a minimum. The requirements throughout part 53 that support demonstrating compliance with § 53.220 are similar to current regulations that both contribute to assuring adequate protection of public health and safety and are desirable to promote the common defense and security or to protect health or to minimize danger to life or property under section 161 of the AEA.

Consistent with historical practice, sections 182 and 161 of the AEA are cited as authorizing legislation within this final rule. However, specific language from the AEA is not incorporated into the safety objectives or safety criteria in part 53. This is because, again consistent with historical practice, the NRC is not defining "adequate protection" through the individual safety requirements in part 53. Rather, part 53 enables the NRC to make its required findings under the AEA by providing sufficient performance standards, safety criteria, and related requirements on how applicants must demonstrate compliance with subpart B and other subparts.

Section 53.210 provides safety criteria for DBAs that are required to be identified under § 53.240 and analyzed under § 53.450(f) in subpart C of part 53. Subsequent

sections in part 53 require that the SSCs relied upon to demonstrate compliance with the criteria in § 53.210 be classified as SR. The use of SR SSCs and the 25 rem reference values for potential radiological consequences aligns with traditional deterministic approaches for LWRs from §§ 50.34, 52.79, and 100.11 for evaluating the effectiveness of plant design features with respect to postulated reactor accidents. A footnote similar to that included in § 50.34(a)(1)(ii)(D)(*1*) and § 52.79(a)(1)(vi)(A) is included in § 53.210 to explain that the use of the 25 rem value 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 that is used in the evaluation of plant design features with respect to DBAs to verify that the proposed designs would provide assurance of low risk of public exposure to radiation in the event of an accident. The inclusion of the safety criteria for DBAs in subpart B provides a logical structure supporting the identification and treatment of SR SSCs and establishing the corresponding functional design criteria for those SSCs.

Section 53.220 provides safety criteria for LBEs other than DBAs that are required to be identified under § 53.240 and analyzed under § 53.450(e) in subpart C. Whereas § 53.210 and the related requirements for SR SSCs provide that a defined success path exists for DBAs, the safety criteria for LBEs other than DBAs establish the connections between SSC design, human actions, and programmatic controls and a broader set of potential internal and external hazards. These safety criteria also address defense-in-depth matters such as a balanced consideration of prevention and mitigation.

The safety criterion in § 53.220(b) includes a requirement to use a comprehensive risk metric or set of metrics and associated risk performance objectives against which calculated values of the risk metrics are compared. The comprehensive risk metrics or set of metrics and associated risk performance objectives support a performance-based approach to developing an appropriate combination of design

features and programmatic controls to prevent or mitigate LBEs other than DBAs. The applicant must propose the comprehensive risk metric or set of metrics and associated risk performance objectives, and the comprehensive risk metric or set of metrics and associated risk performance objectives must provide an appropriate level of safety. Comprehensive risk metrics should consist of a proposed plant risk metric or set of proposed risk metrics that approximate the total, overall risk from the facility and that address the range of possible plant configurations and associated internal and external hazards to the extent practicable. The associated risk performance objectives are pre-established, indicative values of the comprehensive risk metrics that are used as part of risk-informed decision-making. The methodology for developing and using proposed comprehensive risk metrics and associated risk performance objectives is defined by the requirements for analyses in § 53.450. Therefore, the application must include a description of that methodology and, among other things, should explain the initial conditions, boundary conditions, and key assumptions used to develop and calculate the risk metrics. Screening tools and bounding or simplified methods may be used for any mode or hazard, provided that the applicant provides an acceptable technical basis. As with all risk-informed methodologies, treatment of uncertainties must be addressed.

The risk performance objectives established under this methodology are likely to involve assessing and averaging the risks over a period of time (e.g., plant year) and do not constitute a real-time requirement that must be continuously demonstrated by the licensee. The use of a comprehensive risk metric or set of risk metrics and risk performance objectives that reflect an average risk to establish performance goals for SR and NSRSS SSCs is consistent with current practices that use other risk assessment techniques to address short-term plant configurations during plant maintenance activities.

It is worth noting that the evaluation of plant risks, as represented by a comparison of analysis results to acceptable risk performance objectives for comprehensive risk metrics, is one of several performance standards used in subpart B. The use of multiple performance standards, including deterministic criteria and defense-in-depth measures, reflects an integrated decision-making process similar to that described in RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3. The NRC’s approval of using a comprehensive risk metric or set of metrics with associated risk performance objectives is not, by itself, an indicator of adequate protection. Rather, the comparison of comprehensive risk metrics to associated risk performance objectives that are acceptable to the NRC is part of a suite of regulatory requirements that, when considered holistically, form the basis for the NRC’s decision-making. This is analogous to the approach used for plants licensed under part 50 and part 52, where no single regulatory requirement governs whether a plant is “safe enough.”

The 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,” describes an example of an acceptable approach for identifying and analyzing LBEs under part 50 and part 52, including the use of the quantitative health objectives (QHOs) stated in the NRC’s policy statement, “Safety Goals for Nuclear Power Plant Operation,” dated August 4, 1986 (51 FR 28044), as corrected and republished August 21, 1986 (51 FR 30028) (Safety Goals Policy Statement), as acceptable performance objectives for comprehensive risk metrics. The use of comprehensive risk metrics, such as the individual early fatality risk (IEFR) and the individual latent cancer fatality risk (ILCFR), and associated risk performance objectives, such as the QHOs, from the Safety Goals

Policy Statement, could form the basis for one approach to meet § 53.220(b). The requirement for comprehensive risk metrics, in combination with the other requirements in subparts B and C, brings the approach endorsed in RG 1.233 for parts 50 and 52 into part 53. Additionally, the use of comprehensive risk metrics and associated risk performance objectives provides a logical performance objective to support the risk management approaches in the various subparts comprising part 53.

The Commission stated in the introduction of the Safety Goals Policy Statement that improvements to then-current regulatory practices could lead to a more coherent and consistent regulation of nuclear power plants, a more predictable regulatory process, a better public understanding of the regulatory criteria that the NRC applies, and public confidence in the safety of operating plants. Accordingly, the Commission announced the safety goals with a focus on the risks to the public from nuclear power plant operation. Following the issuance of the Safety Goals Policy Statement, the NRC has used the comprehensive risk metrics and performance objectives provided in the safety goals within the criteria for many decisions involving safety judgments during the licensing and regulation of operating reactors and proposed nuclear reactor designs. Consistent with NUREG-0880, the proposed comprehensive risk metrics and associated risk performance objectives required under § 53.220(b) can be expressed in terms of a biologically average individual in terms of age and other risk factors. Although some comprehensive risk objectives such as the IEFR and ILCFR are defined in terms of fatality risks, the Commission continues to make clear that no death attributable to nuclear power plant operation will ever be “acceptable” in the sense that the Commission would regard it as a routine or permissible event. Comprehensive risk metrics and associated risk performance objectives as used in this final rule establish acceptable risks, not acceptable deaths.

Applicants under part 53 may choose to develop and seek NRC approval of comprehensive risk metrics or sets of risk metrics and associated risk performance objectives beyond those previously discussed, including the use of surrogate measures for use in specific analyses to satisfy the requirements in § 53.220(b). Such surrogate measures for comprehensive risk metrics and associated risk performance objectives could be used in a manner similar to the use of core damage frequency and conditional containment failure probability for LWRs within the safety goal evaluation process in NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” and other assessments of LWRs using the NRC’s safety goals. The NRC will, as appropriate, review novel approaches for comprehensive risk metrics and associated risk performance objectives proposed by applicants, industry organizations, or standard development organizations and will engage stakeholders during the development of the related regulatory guidance or specific licensing actions.

Section 53.230 requires safety functions needed to ensure that the safety criteria under §§ 53.210 and 53.220 can be met if an assumed LBE were to occur at a commercial nuclear plant. Section 53.230 specifies that limiting the release of radioactive materials from the facility is the primary safety function, and therefore, limiting potential offsite consequences (i.e., dose to a hypothetical individual) can be used as the primary performance metric throughout part 53. The additional or subsidiary safety functions needed to limit the release of radionuclides may include, without limitation, controlling processes related to reactivity, heat generation, heat removal, and chemical interactions. This final rule provides flexibility to applicants and licensees in identifying, implementing, and maintaining the safety functions supporting retention of radionuclides for commercial nuclear plants of varying sizes and technologies.

Section 53.240 requires applicants to identify and address LBEs. LBEs are unplanned events, resulting from both internal and external hazards, that are used in the

design and analyses required under part 53 for licensing commercial nuclear plants. This ensures estimates of offsite consequences from analyses performed under § 53.450 are below the safety criteria identified under §§ 53.210 and 53.220 and that SSCs, personnel, and programs address the safety functions from § 53.230. Including a high-level performance requirement related to the identification of LBEs to address appropriate risk-informed combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards and analysis thereof in subpart B reflects the historical and continuing importance of evaluating unplanned events as part of the licensing of commercial nuclear plants. Section 53.240 requires identification and analysis of LBEs under § 53.450 using a PRA, other SREs, or a combination thereof. An example of acceptable methods of using PRAs to identify and assess LBEs is the methodology in RG 1.233, as discussed in RG 1.254, “Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants.”

Section 53.250 establishes defense-in-depth requirements based on the longstanding philosophy of providing defense in depth to address uncertainties about the design, operation, and performance of commercial nuclear plants. For example, parts 50 and 52 address defense in depth through layered prescriptive technical requirements (e.g., fuel performance, cladding integrity, reactor coolant system integrity, containment performance) for LWRs. In contrast, the flexibility afforded to applicants in how they propose to demonstrate compliance with the high-level safety criteria within part 53 necessitates this specific requirement to ensure defense in depth is provided. The requirements in this section state that no single engineered design feature, human action, or programmatic control, no matter how robust, should be exclusively relied upon to address the range of LBEs other than DBAs. The requirement under § 53.250(c) is different from the single failure criterion described in appendix A to part 50. The § 53.250(c) requirement does not allow the safety analysis to exclusively rely upon a

single engineered design feature, human action, or programmatic control to address the range of LBEs other than DBAs (i.e., ranging from very unlikely event sequences to anticipated event sequences). In contrast, the single failure criterion under appendix A to part 50 relates, in part, to the failure of a component to perform its intended safety function, regardless of whether that component was exclusively relied upon to address the range of LBEs. This means the requirement under § 53.250(c) does not strictly disallow single failures, as defined in appendix A to part 50, because a component could experience such a single failure and, if it is not otherwise exclusively relied upon to address the range of LBEs other than DBAs, its failure alone does not preclude being able to satisfy § 53.250(c). In that regard, § 53.250 allows for greater flexibility such that other measures could be taken to ensure appropriate defense in depth without needing to accommodate single failures, as defined in appendix A to part 50. The phrase "engineered design feature" does not preclude the possible crediting of inherent characteristics within the design and analysis for commercial nuclear reactors. While defense in depth is only assessed for LBEs other than DBAs, the need to ensure dedicated success paths for DBAs contributes to the overall defense in depth for each commercial nuclear plant under part 53.

Section 53.260 governs normal operations and establishes a level of safety based on requirements in 10 CFR part 20, "Standards for Protection Against Radiation," which limit doses to members of the public and dose rates in unrestricted areas.

Section 53.270 provides for the protection of plant workers and establishes a level of safety based on requirements in 10 CFR part 20, which limit occupational dose.

Subpart C—Design and Analysis Requirements

This subpart provides requirements for the design of commercial nuclear plants and the supporting analyses, including the analyses of LBEs, to demonstrate that the

performance standards in subpart B can be satisfied. The sections within subpart C reflect the overall hierarchy throughout part 53, which covers: (1) plant-level safety criteria (§§ 53.210 and 53.220); (2) safety functions (§ 53.230) needed to demonstrate compliance with the safety criteria; (3) design features (§ 53.400), human actions, and programmatic controls needed to fulfill the safety functions; and (4) functional design criteria (§§ 53.410 and 53.420) that must be defined for each design feature relied upon to demonstrate the safety criteria (§§ 53.210 and 53.220) are met. Subpart C also contributes to the logic and structure of part 53 by distinguishing between SR SSCs and NSRSS SSCs and licensee-controlled programs that address LBEs other than DBAs. Specifically, SR SSCs, human actions, and programmatic controls needed to protect against DBAs are used to satisfy the safety criteria in § 53.210. NSRSS SSCs, human actions, and licensee-controlled programs that address LBEs other than DBAs generally contribute to the appropriate measures considering potential risks to public health and safety.

Section 53.400 establishes a requirement that design features be provided for each commercial nuclear plant to satisfy the safety criteria and fulfill safety functions from subpart B during LBEs. Other sections in subpart C, in turn, further address the necessary capabilities and reliabilities for SSCs by establishing functional design criteria, fulfilling design requirements, performing analyses of LBEs, performing other supporting analyses, and categorizing SSCs based on their roles in preventing or mitigating LBEs.

Section 53.410 requires that functional design criteria be defined for safety-related design features relied upon to demonstrate that the consequences from DBAs would be below the criteria in § 53.210 through analyses performed under § 53.450(f), which includes insights from both PRAs and deterministic analyses. Other sections within part 53 establish appropriate controls on these design features (e.g., safety classification, protection from external hazards, quality assurance, and TS) to

ensure the functional design criteria are satisfied. The performance requirements for the SSCs needed to address DBAs and the consideration of human actions and programmatic controls in the identification of special treatments associated with the design of SR SSCs will contribute to ensuring that a commercial nuclear plant licensed under part 53 would meet the safety criteria in § 53.210.

Section 53.415 requires that SR SSCs be protected against or designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and constructed hazards (e.g., from dams, transportation routes, and military or industrial facilities). Specifically, § 53.415 requires that SR SSCs remain capable of performing the safety functions stated in § 53.230 for which they are credited up to the design-basis external hazard levels as determined under § 53.510. As used in § 53.415 and subpart D of part 53, a hazard level refers to such things as the magnitude and recurrence rate of an earthquake and the resultant ground motions, the height of a flood, the force of hurricane winds, or the concentrations of chemicals resulting from a release from a nearby facility. These requirements will support either traditional deterministic approaches for determining and protecting against external hazards or probabilistic approaches that are being developed for seismic and some other external hazards.

Section 53.420 requires that functional design criteria be defined for design features that play a significant role in demonstrating that the safety criteria for LBEs other than DBAs are satisfied. The analyses required for this demonstration are described in § 53.450(e), which requires that those events be identified and assessed using a PRA, other SREs, or a combination thereof, together with other generally accepted approaches for systematically evaluating engineered systems. The SSCs determined to be safety significant (i.e., either SR or NSRSS) will have associated special treatment requirements as specified in § 53.460. Special treatment is defined in

subpart A of part 53 and generally refers to measures (e.g., quality assurance, testing, monitoring) taken beyond normal commercial practices related to the procurement, installation, and maintenance of commercial grade products to provide confidence that SR and NSRSS SSCs will perform under the service conditions and with the reliability assumed in the analysis under § 53.450(e) and will comply with the applicable functional design criteria. Such normal commercial practices include the use of consensus codes and standards, as identified in an application, to support the identification of special treatments that include measures that may go beyond the use of commercial codes and standards. The inclusion of a systematic approach to identifying the functional design criteria for SSCs and tailoring the special treatments to specific LBEs and safety functions is an important contributor to satisfy the safety criteria in subpart B. Therefore, designers and licensees for commercial nuclear plants are provided flexibility on how LBEs other than DBAs are either prevented or mitigated and how the calculated comprehensive plant risks satisfy the safety criterion established under § 53.220(b).

Section 53.425 establishes requirements for design features and related functional design criteria limiting doses to members of the public during normal operations to satisfy the criteria in part 20. Section 53.430 provides similar requirements for design features and related functional design criteria for protection of plant workers to meet the safety criteria in part 20. Section 53.425 provides applicants and licensees flexibility to define design objectives for design features related to controlling liquid, gaseous, and solid wastes as required under part 20. The design objective will assist designers, applicants, and licensees in performing the evaluations of possible reductions in public dose from routine effluents when considering costs and other factors.

The requirements in §§ 53.425 and 53.430 for design features and functional design criteria to support radiation protection activities have parallels in existing regulations such as § 50.34(a) and (b)(3), which require in part that the means be

provided for meeting the requirements of part 20 and General Design Criterion 60, 61, 63, and 64 in appendix A to part 50, which provide radiation protection related design criteria.

Section 53.440 addresses various design requirements that warrant specific mention to ensure that the design features required by § 53.400 comply with the functional design criteria required by §§ 53.410 and 53.420. These requirements will be met through design practices, consideration of testing and operating experience, and various assessments of LBEs and other potential challenges to commercial nuclear plants. Discussion of some of the key design requirements included in section 53.440 follow.

(1) § 53.440(a): An essential element to ensuring a proposed design can comply with the performance criteria in part 53 is that the ability of design features to fulfill their safety functions is demonstrated by a combination of analyses, test programs, prototype testing, and operating experience. This requirement closely aligns with the language in § 50.43(e) and is included in part 53 as the same foundational requirement. In addition, § 53.440(a) requires the design processes for SSCs under this section to include administrative procedures for evaluating operating, design, and construction experience for considering applicable important industry experiences in the design of those SSCs. This requirement corresponds to the existing requirement under § 50.34(f)(3)(i) that was developed in response to the 1979 accident at Three Mile Island Nuclear Generating Station.

(2) § 53.440(b): The design and licensing of commercial nuclear plants should use generally accepted consensus codes and standards for design features classified as safety-related. Such codes and standards ensure sufficient testing and qualification of materials and equipment and provide defined processes, specifications, and acceptance criteria for use by designers and suppliers. The NRC will indicate acceptance of

consensus codes and standards used in the design and licensing of a specific commercial nuclear plant either through the NRC's generic endorsement of a code or standard (i.e., through regulatory guidance), including any limitations or conditions, that can be referenced within an application, or through the review of a referenced code or standard as part of the review of a specific application.

(3) § 53.440(c): The design requirements in subpart C require the materials used for SR and NSRSS SSCs to be qualified for their service conditions over the design life of the SSC as appropriate to satisfy the special treatments established for the SSC under § 53.460.

(4) § 53.440(d): The requirements in § 53.440 include the need to consider possible degradation mechanisms for materials and equipment to inform both the design process and the development of integrity assessment programs to be executed during plant operations in accordance with subpart F of part 53. The inclusion of requirements related to designing and monitoring for possible degradation mechanisms reflects important lessons learned from the history of LWRs as well as operating experience with structures and systems in countless other engineering endeavors.

(5) § 53.440(e) and (f): The design requirements in subpart C state specific design requirements similar to existing requirements in parts 50, 52, and 73 for protections against fires and explosions and consideration of safety and security together in the design process. Under § 53.440(f), safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features. This approach ensures considerations are given for safety and security together throughout the plant's lifetime, including the design process and prior to implementing changes to plant configurations, to ensure risks are effectively managed. The implementation of a security strategy and design features early in the design process has the potential to be more

efficient and cost-effective rather than implementing these features after the plant has been designed and constructed.

(6) § 53.440(g) and (h): Specific design requirements will ensure that commercial nuclear reactors under part 53 have the capability to achieve and maintain subcriticality and long-term cooling. The requirements are included to address the potential that some reactor designs may be able to achieve a stable end state for the purpose of event analyses but might need further actions to completely shut down and service the facility.

(7) § 53.440(i): The design, analysis, and development of programmatic controls under part 53 will consider the number of reactor units and other significant inventories of radioactive materials contributing to the risks to public health and safety. This reflects the definition of "*Commercial nuclear plant*" in subpart A and reinforces that the evaluation of LBEs is performed on a plant-wide basis. This aspect of part 53 is different from parts 50 and 52, which generally define safety requirements on the assumption of events involving only individual reactor units.

(8) § 53.440(k): The inclusion of a specific requirement for design features and related functional design criteria, including associated programmatic controls or a combination thereof, to address the risks to public health from potential chemical hazards of licensed material is appropriate given the diversity of reactor technologies and designs that might be licensed under part 53. The requirement in part 53 is similar to the existing requirements in 10 CFR part 70, "Domestic Licensing of Special Nuclear Material," that address both potential radiological and chemical hazards for licensed materials at fuel cycle facilities.

(9) § 53.440(l): These provisions require that measures be taken during the design of commercial nuclear plants to minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste in accordance with § 20.1406.

(10) § 53.440(m): This design requirement provides a technology-inclusive equivalent to the requirements in § 50.68 by including options for commercial nuclear plants to either have a monitoring system capable of detecting a criticality as described in § 70.24 or to have restrictions on SNM handling and storage that would prevent inadvertent criticality events.

(11) § 53.440(n): The design needs to reflect state-of-the-art human factors principles for safe and reliable performance in all settings that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

One notable exclusion from the design requirements in the part 53 proposed rule is an explicit requirement to consider and address the potential impact of a large, commercial aircraft, as is currently required of parts 50 and 52 applicants under § 50.150, “Aircraft impact assessment.” When the Commission promulgated the aircraft impact final rule on June 12, 2009 (74 FR 28112), it noted that “the impact of a large aircraft on the nuclear power plant is regarded as a beyond-design-basis event” and it was “the NRC’s view that effective mitigation of the effects of events causing large fires and explosions (including the impact of a large, commercial aircraft) can be provided through operational actions,” which were covered by other requirements. In light of this view, the Commission stated that “the mitigation of the effects of aircraft impacts through design should be regarded as a safety enhancement which is not necessary for adequate protection.” In the Regulatory Analysis that accompanied the aircraft impact rule, the NRC quantified the costs of the rule, but did not quantify the benefits of the rule, stating that the “benefits of the final rule can be evaluated only on a qualitative basis.” The NRC concluded that the key benefit of the rule was “improvement in knowledge.” The Commission acknowledged that “it is difficult to quantify the safety enhancement gained through implementation of the aircraft impact rule,” but stated that “the NRC

nevertheless believes that the cost of performing the assessment and incorporating the results into the design…is justified in view of the increased safety provided by implementation of the aircraft impact rule."

It has been over 15 years since the promulgation of the aircraft impact rule in 2009. Events like the terrorist attacks of September 11, 2001, are now much less likely due to significant increases in security at commercial aviation facilities as well as hardened access to aircraft cockpits. In addition, it is not clear that the Commission's previous belief that the cost of implementation of the aircraft impact rule was justified by the increase in safety provided by the rule would hold true for future reactors licensed under part 53. As stated previously, the NRC concluded that the key benefit of the rule was "improvement in knowledge" achieved by performing the aircraft impact assessment. It's worth noting that licenses issued under parts 50 and 52 were largely based on deterministic analyses of the safety of the facility relying on the General Design Criteria. The technical requirements in part 50 were supplemented over the years to address specific beyond-design-basis events, such as the loss of large areas of the plant due to fires and explosions. In contrast, under part 53, applicants will be required to perform a comprehensive assessment of their reactor design to identify potential failures, susceptibility to internal and external hazards, and other contributing factors that could pose a risk to public health and safety. The spectrum of events and hazards considered will include those that have traditionally been considered design-basis events and those that have been considered beyond-design-basis events. Although part 53 does not include prescriptive requirements to assess a licensing-basis event comprising an intentional act that could cause large fires or explosions, it does require applicants to assess a full spectrum of unplanned events, to include anticipated events, unlikely events, and very unlikely events. The NRC believes that the systematic evaluations of internal hazards, external hazards, and security threats under part 53 and

part 73 sufficiently address the potential loss of large areas of the plant due to explosions or fire currently addressed under § 50.155(b)(2).

Therefore, part 53 applicants will have considered how to mitigate the broader potential plant impacts that may result from an event such as the impact of a large aircraft. As a result, applicants and licensees under part 53 will have substantially more information about the design of their facilities than applicants and licensees did before the promulgation of the aircraft impact rule. Accordingly, the “improvement in knowledge” to be gained by requiring a separate assessment of the impact of a large commercial aircraft under part 53 is expected to be significantly less than the improvements in knowledge for part 50 or 52 applicants the Commission estimated when it promulgated the aircraft impact rule. Because the potential impact of beyond-design-basis events are considered in other ways under part 53, the NRC concludes that the cost of performing a separate aircraft impact assessment and incorporating the results into the design of a commercial nuclear plant licensed under part 53 would not be justified. For these reasons, this final rule does not contain requirements for applicants to assess the impact of a large, commercial aircraft on the design of the facility.

Section 53.450 establishes analysis requirements and centers upon the use of a PRA, other SREs, or a combination thereof with other generally accepted approaches for systematically evaluating engineered systems. The use of PRA, other SREs, or a combination thereof as a key component in the analysis requirements for part 53 reflects the decades of improvements in the use of such methodologies and their increasing use in the design, licensing, and oversight of both operating and future nuclear reactors. Part of the Commission’s PRA Policy Statement is that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC’s deterministic approach and supports the NRC’s traditional defense-in-depth philosophy. This policy statement

also acknowledges the variability in the characteristics of events considered and the associated complexity of engineered systems related to different regulatory activities and that risk-informed analysis techniques of varying complexity may be employed to yield meaningful insights and results. In that regard, the use of PRA, other SREs, or a combination thereof under part 53 needs to be commensurate with the complexity of the analyzed systems and their behaviors, with consideration of all aspects of operations. The need to supplement PRA insights with other engineering approaches and judgments reflects the NRC's longstanding policy described in the SRM to SECY-98-144, "Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations," dated February 24, 1999, for regulatory decision-making to be risk-informed but not solely based on numerical results of a risk assessment (i.e., not a risk-based approach). Part 53 maintains a role for NRC's traditional deterministic approaches (particularly for DBAs) and defense-in-depth philosophy by including specific requirements utilizing these regulatory tools in subparts B and C.

PRA, other SREs, or a combination thereof will be used together with other techniques in part 53 to identify and categorize LBEs, classify SSCs, evaluate defense in depth, and inform the appropriate special treatments for SSCs. This increased role for PRA and SREs necessitates that they be developed, performed, and maintained in accordance with NRC approved standards and practices (see § 53.450(c) and (d)). The computer codes used to model the plant response and the behavior of the barriers to the release of radionuclides must be qualified for the range of conditions being simulated across a wide range of unplanned events. These analyses must use realistic approaches and address uncertainties associated with states of knowledge, modeling, and performance of SSCs.

While industry consensus PRA standards and PRA peer review processes endorsed in RGs 1.200 and 1.247 remain acceptable for developing a PRA, they are not

regulatory requirements and an application under part 53 need not follow every aspect of the applicable consensus PRA standard. Existing processes for defining the scope and capability of a PRA supporting an application offer flexibility in determining the degree to which the PRA needs to be developed and may be informed by other factors such as design complexity and the needed degree of realism and level of detail, consistent with the use of the PRA with SREs and the substance of the application. Such processes are currently available for appropriately defining the scope of the PRA and determining applicability of supporting requirements in consensus PRA standards needed to satisfy the regulatory requirements for the specific uses of analyses under § 53.450(b). The specific uses of analyses in § 53.450(b) are to inform LBE selection; inform classification of SSCs according to safety significance; evaluate adequacy of defense in depth; identify and assess all plant operating states with a potential for uncontrolled release of radioactivity to the environment; identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment; and inform the establishment and updating of appropriate measures for plant operations, including availability controls, to ensure configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and reliability consistent with satisfying the high-level safety criteria in § 53.220.

Likewise, NRC determinations of the acceptability of such PRAs would include consideration of the appropriateness of the applicant-defined scope as part of determining the applicability of and conformance to consensus PRA standard supporting requirements consistent with the current state of practice. In addition, these determinations would include consideration of other aspects of the development of the PRA, such as PRA peer reviews. An NRC determination of the acceptability of a PRA includes but is not limited to assessing the initial and boundary conditions and key

assumptions used in the analysis, treatment of uncertainties, and the use of screening tools and bounding or simplified methods for any mode or hazard, provided the use of those tools and methods is justified by an acceptable technical basis. In that regard, the consensus PRA standards would not be applied by the NRC as a strict checklist of requirements for part 53 PRA acceptability determinations.

For risk contributors that are excluded from PRA logic models or PRA screening processes and are otherwise analyzed by an SRE—also referred to as supplementary analyses—the NRC plans to develop guidance for determining the acceptability of such SREs.

Section 53.450(c) requires periodic maintenance and upgrading of the PRA, other SREs, or a combination thereof to maintain an alignment between the supporting analyses and the design and performance of plant equipment, programs and procedures, and other factors associated with meeting the safety criteria of § 53.220 and the evaluation criteria of § 53.450(e)(2). The periodic maintenance of the PRA, other SREs, or a combination thereof is also a means to consider new or revised information related to external hazards, industry operating experience, performance issues with or degradation of SSCs, and other contributors to the frequency and potential consequences of various event sequences. The periodic assessments performed by licensees to support the maintenance of the PRA, other SREs, or a combination thereof and other requirements in part 53 will be complemented by NRC inspections and programs to assess new or revised information related to topics such as natural hazards, operating experience, and potential generic safety issues.

Section 53.450(d) provides requirements for the qualification of the analytical codes used in modeling the physical behavior of plant systems and that those codes must be qualified for the range of conditions for which they are to be used.

The categories of LBEs used in part 53 include anticipated event sequences, unlikely event sequences, and very unlikely event sequences. The unlikely event sequences include those events with estimated frequencies well below the frequency of events expected to occur during the lifetime of a commercial nuclear plant. An important aspect of the analysis requirements is that, under § 53.450(e), the analyses of LBEs other than DBAs will be used not only to show the performance criteria of § 53.220 are satisfied but also to show that evaluation criteria defined for each LBE or category of LBEs are satisfied. Such evaluation criteria for specific LBEs or categories of LBEs are defined in terms of limits on the release of radionuclides or maintaining the integrity of one or more barriers used to limit the release of radionuclides and reflect a graded approach of allowing lesser potential consequences from more frequent events. An example of such evaluation criteria for a range of LBEs that could likely be expanded for part 53 is provided in RG 1.233. An applicant's or licensee's defining of evaluation criteria under § 53.450(e) and the risk performance objectives under § 53.220(b) are also part of the integrated approach within part 53 where the analyses from subpart C are used for decisions on design, siting, and operations. As an example, an applicant or licensee could propose to justify siting proposals by defining their evaluation criteria such that the calculated consequences for an individual at the exclusion area boundary are less than the total effective dose equivalent (TEDE) values used in graded approaches to assessing population densities under subpart D. Another requirement for the § 53.450(e) analyses is that the methodology must include a means to identify event sequences deemed risk-significant such that those event sequences can be given special attention within other sections of part 53.

Part 53 maintains an important role for a deterministic analysis of DBAs in the performance criteria of § 53.210 and the related analytical requirements in § 53.450(f). The analysis of DBAs will be required to address event sequences drawn from those

with estimated frequencies below the expected lifetime of a generation of reactors (e.g., event sequences with frequencies as low as one in ten thousand years). As set forth in this section, DBAs must be analyzed using deterministic methods and ensure a safe, stable end state with reliance upon only SR SSCs and human actions, if needed, to be performed by operators licensed under the provisions of §§ 53.760 through 53.795.

While the DBAs analyzed under part 53 are similar to the traditional DBAs analyzed under parts 50 and 52, there are important distinctions between the overall role of DBA analyses in part 50 and part 53. In part 53, the role of the DBA analysis is more narrowly focused on selecting SR SSCs and determining functional design criteria for those SSCs to ensure the commercial nuclear plant meets the safety criteria in § 53.210. The overall control of risks posed by commercial nuclear plants under part 53 is provided by the analyses of and measures taken for both DBAs and other LBEs, including very unlikely event sequences. This contrasts with the traditional deterministic approach in part 50 wherein the analyses of DBEs such as DBAs were used to provide bounding assessments, to incorporate standard design rules such as assumptions related to single failures, and to define conservative performance requirements for SR SSCs. Limitations related to the traditional deterministic approach were addressed in part 50 through case-by-case assessments and specific actions for beyond-design-basis events such as anticipated transients without scram and station blackout.

Section 53.450(g) includes provisions to ensure that analyses are performed to support the design requirements of § 53.440(e) on fire protection and § 53.425 on using design features and plant programs to control doses to members of the public from routine effluents and direct radiation from contained sources. The analysis requirements related to fire protection support either a traditional, deterministic approach or a more risk-informed approach where the risks from fires are addressed within the identification and analyses of LBEs.

Section 53.460 establishes criteria for the safety classification of SSCs and determination of appropriate special treatments. As noted in subpart A, the term "*Special treatments*" is defined to mean those items, such as measures taken to satisfy functional design criteria, quality assurance, and programmatic controls, that provide assurance that certain SSCs will provide defense in depth or perform risk-significant functions. These requirements also provide confidence that the SSCs will perform under the service conditions and with the reliability credited in the analysis performed in accordance with § 53.450 to satisfy the safety criteria in §§ 53.210 and 53.220. The terminology used in part 53 includes the following categories for SSC classification: (1) SR; (2) NSRSS; and (3) non-safety significant. Requirements for SR SSCs are defined in other sections of part 53 and include using TSs for controls during operation and the application of quality assurance requirements from appendix B to part 50.

Requirements for NSRSS SSCs include the need to identify necessary special treatments such as performance measures on reliability. Licensees will generally be afforded flexibility in maintaining and changing special treatments for SSCs categorized as NSRSS. Non-safety-significant SSCs will be addressed under normal licensee programs for commercial grade equipment and typical industry practices for general plant design and maintenance. Safety-related SSCs also contribute to defense in depth and risk-significant functions and may warrant special treatments beyond those defined for their SR functions to reflect their role in meeting the safety criteria in § 53.220 and the evaluation criteria in § 53.450(e).

Section 53.480 establishes seismic design considerations. This section relates to the safety criteria in subpart B, the analytical requirements related to external hazards in § 53.450, and subpart D, "Siting Requirements." For licenses issued under part 53, this section in subpart C will support a variety of approaches to seismic design. For example, a design for a commercial nuclear plant could show that SSCs are able to withstand the

effects of earthquakes by adopting an approach similar to that in appendix S to part 50. Alternatively, an applicant could follow the more recent risk-informed alternatives afforded by standards development organizations (e.g., American Society of Civil Engineers (ASCE)/Structural Engineering Institute (SEI) 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities”). Because the agency has not endorsed ASCE/SEI-43-19, an applicant can propose to use ASCE/SEI 43-19 on an application-specific basis to meet § 53.480 and the NRC would evaluate the adequacy of the standard as applied in that application. The design could also be done with the full integration of seismic PRAs into the design and licensing of a particular commercial nuclear plant. This section has been developed to accommodate a variety of potential risk-informed, performance-based seismic design approaches. The analyses required by § 53.450 must address seismic hazards as well as other external hazards. The expected responses of SSCs to a range of seismic events must be included in the analyses when ensuring that the safety criteria defined under § 53.220 will be met. The potential SSC responses to seismic hazards could be addressed in the analyses using a fragility model (conditional probability of its failure at a given hazard input level), a high confidence of low probability of failure value, or other method endorsed or otherwise found acceptable by the NRC.

Subpart D—Siting Requirements

Subpart D in part 53 states requirements for the siting of commercial nuclear plants and serves the role provided by 10 CFR part 100, “Reactor Site Criteria,” for nuclear reactors licensed under parts 50 and 52. As reflected in § 53.500, the reason for establishing siting requirements remains the same as it has been historically, which is to ensure that licensees and applicants assess what impact the site environs may have on a commercial nuclear plant (e.g., external hazards) and, conversely, what potential

adverse health and safety impacts a commercial nuclear plant may have on nearby populations in view of the site characteristics.

Section 53.510 requires that design-basis external hazard levels be identified and characterized based on site-specific assessments of natural and constructed hazards with the potential to adversely affect plant functions. The site-specific assessments are used in § 53.415, which requires that SR SSCs be designed to withstand the effects of natural phenomena and constructed hazards of levels or severities up to design-basis external hazard levels. The design-basis levels for external hazards relevant to a site need to account for uncertainties and variabilities in data, models, and methods used to characterize those hazards. Existing approaches can be used to demonstrate compliance with this requirement. The historical importance of assessing seismic events as risks to commercial nuclear plants and the associated development of risk-informed approaches to address seismic events are reflected in § 53.480, “Earthquake engineering,” and specific requirements in subpart C. The NRC is developing a graded approach for seismic design by grouping SSCs into different seismic design categories (SDCs) based on their risk significance. While the agency has not endorsed ASCE/SEI-43-19, an applicant can propose to use ASCE/SEI 43-19 on an application-specific basis to meet § 53.480 and the NRC will evaluate the adequacy of the standard as applied in that application. The NRC staff will continue to review ASCE/SEI-43-19 as part of its efforts to further develop guidance in this area. The approach described in RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” is an acceptable way to develop site-specific ground motion response spectra for SSCs under appendix S to part 50, which corresponds to SSCs that are categorized as the highest SDC (SDC-5) in ASCE/SEI 43-19.

The evaluation of seismic hazards under subpart D needs to be sufficient to inform a site-specific design (e.g., a CP or custom combined license (COL)) or confirm the use of a standard design for a commercial nuclear plant under § 53.480 and other sections of subpart C. A risk-informed approach can use several design-basis ground motions (DBGMs) to assess SSCs in various SDCs (i.e., one DBGM per SDC). Section 53.510(d) states that geologic and seismic siting factors must also include related hazards such as seismically induced flooding and volcanic activity that may affect the design and operation of a proposed commercial nuclear plant for the proposed site.

Section 53.520 requires applicants to identify and assess site characteristics related to topics that include meteorology, geology, hydrology, or other areas in the design and analyses required under subpart C.

Section 53.530 sets requirements for population-related considerations and largely maintains requirements and definitions similar to those currently in part 100 for an exclusion area, low population zone, and population center distance. The NRC recognizes that some applicants may propose to essentially collapse the exclusion area and low population zone to the site boundary. This approach would rest on a demonstration that the calculated consequences of DBAs remain below the dose guidelines used in § 53.210, which are the same as those in the existing regulations in parts 50, 52, and 100. The definitions in § 53.020 allow such configurations, assuming they were justified by the design and analyses from subpart C. This approach should provide flexibility to justify alternative exclusion areas and low population zones without foreclosing the option for an applicant to define more conventional exclusion areas and low population zones outside of a defined site boundary. The NRC’s long-standing preference for siting reactors in areas of low population density is maintained in part 53 by using the current language from part 100 as one option under § 53.530(c). The NRC

revised guidance related to population densities surrounding a commercial nuclear plant in Revision 4 to RG 4.7, “General Site Suitability Criteria for Nuclear Power Stations” to reflect Commission direction in SRM-SECY-20-0045, “Population Related Siting Considerations for Advanced Reactors.” The NRC recognizes that safety, environmental, economic, or other factors may justify siting commercial nuclear plants in areas with higher population densities or within a densely populated center containing more than about 25,000 residents. Therefore, an option is included within § 53.530 for such sites to be proposed using 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) in comparison to the societal benefits of a specific site (e.g., ability to use existing infrastructure for a retired fossil fuel power plant). Site-related requirements in part 20 (restricted area) and part 73 (protected and owner-controlled areas) remain applicable to commercial nuclear plants licensed under part 53.

Section 53.540 requires that site characteristics be appropriately considered in other activities such as the design and analysis performed under subpart D of part 53 and the emergency planning and security programs under subpart F of part 53.

Subpart E—Construction and Manufacturing Requirements

The part 53 language establishes construction and manufacturing requirements in subpart E. The language for construction-related activities largely reflects current requirements in part 50 without any fundamental changes. Limited changes were made in several places, as described in the following paragraphs, to be technology-neutral and for consistency with the organization and language of part 53. The language for requirements for manufacturing activities largely mirrors those for construction-related activities. However, the manufacturing requirements have been updated from the current

requirements in subpart F of part 52 to better accommodate the possible factory fabrication of manufactured reactors. The manufacturing of specific components outside the scope of an ML is not addressed by these subparts.

Section 53.600 establishes the overall construction and manufacturing requirements for CPs, OLs, COLs, MLs, and limited work authorizations (LWAs). This section connects the construction and manufacturing requirements to the safety criteria, quality assurance requirements, and other requirements located in other subparts. These requirements require that construction and manufacturing activities be managed and conducted such that when combined with associated design features and programmatic controls, the constructed plant will satisfy the relevant requirements in subpart B.

Section 53.605 establishes requirements for the reporting of defects and instances of noncompliance during construction. This section provides equivalent requirements to those in § 50.55(e).

Section 53.610(a) establishes the requirement to have in place a well-defined command and control structure to manage construction activities. The requirements generally reflect current requirements, with an emphasis on the quality assurance programs for complying with the requirements in appendix B to part 50.
Section 53.610(a)(6) requires programmatic controls for implementing special treatment for NSRSS SSCs to align with requirements in other subparts in part 53. The section also refers to other NRC regulations to address matters such as requirements to have an FFD program, a radiation protection program if radioactive materials are brought onto the site, and security programs to protect sensitive information and protect against cyber threats.

Section 53.610(b) provides requirements governing construction activities, including the equivalent of the requirement in § 50.10(e) that prohibits starting

construction until the NRC has authorized the activities by issuing a CP, COL, ESP, or LWA. Section 53.610(b)(1)(iii) requires procedures to be in place prior to beginning construction to ensure that construction-related activities do not undermine important features such as slope stability and that construction-related activities such as backfilling of excavated portions of the site appropriately address potential pre-construction activities such as the emplacement of retaining walls or drainage systems. Other requirements in these paragraphs are equivalent to requirements in parts 50 and 52 with appropriate references to other parts for items such as possession of byproduct material or SNM, protecting operating units from construction activities for commercial nuclear plants with multiple reactor units, and having a redress plan in case LWA activities are terminated.

Section 53.610(c) addresses inspection and acceptance activities by including requirements in part 53 equivalent to specific quality assurance criteria in appendix B to part 50 and inspections, tests, analyses, and acceptance criteria (ITAAC) in part 52 for COLs.

Section 53.620(a) includes requirements covering the activities performed under an ML issued under part 53. Provisions related to MLs were first adopted by the NRC in 1973 through the addition of appendix M to part 50. The regulation supported the manufacture of a nuclear power reactor to be incorporated into a commercial nuclear plant under a CP and operated under an OL at a different location from the place of manufacture.[1] The regulations and processes for MLs were changed substantially in the part 52 rulemaking in 2007 (72 FR 49352). The most important shift in the ML concept in that rulemaking was that a final reactor design, which would be equivalent to that

[1] On December 17, 1982, the NRC issued "Manufacturing License ML-1 to Offshore Power Systems for the manufacture of a maximum of eight floating nuclear plants," dated September 30, 1982, but the project was subsequently canceled.

required for a standard DC under part 52 or an OL under part 50, must be submitted and approved before issuance of an ML. The rationale for that change was that approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which greatly enhances regulatory stability and predictability.

The part 53 sections in subpart E for manufacturing and in subpart H for licensing matters maintain requirements largely equivalent to those in part 52 for MLs. The NRC approval of a standard design and related manufacturing processes, coupled with a stable workforce and established procedures, has the potential for maintaining and even improving the quality and consistency of manufacturing, as compared to the traditional method of constructing reactors onsite by a variety of contractors and subcontractors.

Subpart E includes requirements that apply to portions of a manufactured reactor in recognition that some activities covered by an ML may occur at different fabrication facilities. As with the preceding sections on construction, § 53.620 establishes the requirements to have in place programs, procedures, and a well-defined command and control structure to manage manufacturing-related activities.

Section 53.620(b) in subpart E includes requirements for executing the manufacturing activities following receipt of an ML under part 53. Information about the design and manufacturing processes should be provided by the applicant. The importance of the ML is reflected in several of the requirements in § 53.620(b) that refer to complying with the ML, including conducting manufacturing processes within facilities for which the license holder can control activities. The essential role of post-manufacturing inspections is also incorporated into this section by requiring the holder of the ML to perform inspections and have acceptance processes for manufactured reactors or portions of a manufactured reactor.

Section 53.620(c) provides requirements for the control of radioactive materials if the holder of an ML plans to possess and use source, byproduct, or SNM as part of the manufacturing process. By and large, subpart E refers to NRC regulations in 10 CFR part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” 10 CFR part 40, “Domestic Licensing of Source Material,” and part 70 for the requirements on controlling radioactive materials. Several specific requirements to address the potential hazards of radioactive materials are included in areas such as having a fire protection program, an emergency plan, training programs, and procedures to minimize contamination.

The most significant change for MLs in part 53 as compared to MLs under part 52 relates to § 53.620(d) in subpart E and the associated licensing provisions in subpart H. These provisions allow and establish requirements for the loading of fuel into a manufactured reactor at the manufacturing site for subsequent transport to a commercial nuclear facility that will operate pursuant to a COL or OL. The first requirement in § 53.620(d) establishes limitations on when a license under part 70 would authorize the loading of fuel into a reactor manufactured under an ML. The regulation requires the manufactured reactor to be configured during its loading, storage, and transport with features to prevent criticality and that those features be specified in the ML. The requirement provides flexibility because of the potential variety of reactor designs, the variety of possible measures to prevent criticality, and the range of possible conditions associated with the loading, storage, and transport of manufactured reactors. For example, the features to prevent criticality that could be considered individually and collectively to address possible adverse conditions include the reactivity control systems in place to support operations, inherent features of the fuel and materials within a manufactured reactor, and temporary measures or physical mechanisms (e.g., neutron poisons) for specific circumstances and conditions, such as during transport. This

requirement contributes to the NRC's longstanding practice of requiring defense in depth for preventing accidents in any facility dealing with SNM, including requirements in § 70.64 for certain part 70 licensees to adhere to the "double contingency principle."

The requirements to have in place features to prevent criticality could likewise support meeting other provisions in subpart H to part 70, such as those related to having a safety program and integrated safety assessment. The features to prevent criticality in the part 53 requirements will reasonably ensure that a manufactured reactor does not become critical over a range of possible conditions. With the requirements for features to prevent criticality under part 53 and all criticality safety controls required by 10 CFR part 70 in place, the presence of fuel in the manufactured reactor would not create a nuclear hazard different than the hazard from the presence of the same fuel in a storage location or container licensed under 10 CFR part 70. Collectively, these measures will reasonably ensure that the manufactured reactor is not capable of operations, thereby obviating the need for a COL under §§ 53.1416 and 53.1440 to authorize fuel loading. Additionally, this approach focuses the ML application and its review on the design, manufacture, and deployment of the manufactured reactor.

The activities involving SNM within the manufacturing facility, including the loading of fuel, will be regulated primarily under the part 70 license. The reference to the requirements in subpart H of part 70 in § 53.620(d) assures that the activities involving the receipt, storage, and loading of a variety of possible fuel forms and enrichments at the manufacturing facility will be analyzed in a systematic manner and appropriate protection will be provided against equipment malfunctions, human errors, external hazards, and other adverse conditions. The regulations in 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," provide a flexible approach for environmental review to address the range of regulated activities under part 70. The flexibility in part 51 will enable the NRC to

determine the appropriate type of environmental review based on the circumstances associated with the loading of fuel into a specific manufactured reactor.

Section 53.620(d) cites the requirements in parts 70, 71, and 73 to ensure important features and programs are in place prior to the receipt of SNM. The features and programs required to be in place prior to receipt of SNM include (1) radiation monitoring instrumentation and alarms; (2) measures to detect potential criticality accidents; (3) appropriate procedures, equipment, and personnel qualified for the fuel loading; (4) programs for physical security and cybersecurity; and (5) material control and accounting (MC&A) programs. Section 53.620(d)(2)(i) includes requirements to address security programs for any ML authorizing possession of a manufactured reactor into which fuel has been loaded at the manufacturing facility. Currently, for category II SNM, security measures may be required in addition to requirements included in § 73.67, “Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance,” on a case-by-case basis. Including appropriate security measures in the part 53 regulations will provide additional openness and transparency for applicants applying for an ML who seek to load fuel into manufactured reactors at a manufacturing site.

Currently, § 73.67 only requires a security plan for licensees who possess, use, transport, or deliver to a carrier for transport SNM of moderate strategic significance, or 10 kg or more of SNM of low strategic significance. However, the physical security program for fueled manufactured reactors requires a security plan for any ML authorizing possession of a manufactured reactor into which fuel has been loaded at the manufacturing facility, regardless of fuel type, enrichment, and quantity. This is consistent with other controls for MLs, including reactivity and criticality controls.

The requirements also require a holder of an ML and part 70 license to address cybersecurity to ensure a cyberattack would not adversely impact the functions

performed by digital assets necessary for physical security, radiation monitoring, or criticality prevention.

The regulations in part 53 covering the activities related to the storage, movement, and loading of fresh fuel into a manufactured reactor in the manufacturing facility likewise refer to the applicable regulations in part 70. Section 53.620(d) also requires the loading or unloading of unirradiated fuel into or from a manufactured reactor and any changes to the configuration of reactivity-related systems to be performed by a certified fuel handler meeting the requirements in subpart F. The NRC is aware of proposals to introduce reprocessing of existing or future spent nuclear fuel into the fuel cycle for some potential commercial nuclear plants. This final rule does not address the loading of spent nuclear fuel or fuel resulting from reprocessing of spent nuclear fuel into a manufactured reactor.

Section 53.620(e) only allows the transport or removal of a manufactured reactor or portions of a manufactured reactor for either (1) delivery to a domestic site for which the Commission has issued a COL or CP authorizing the construction of a commercial nuclear plant using a manufactured reactor under the specific ML, or (2) export in accordance with 10 CFR part 110, “Export and Import of Nuclear Equipment and Material.” This requirement is similar to the limitations in § 52.153. An additional paragraph in § 53.620(e) provides requirements for protecting fueled manufactured reactors during transport to the site of the commercial nuclear plant by referencing the transportation and security requirements in 10 CFR part 71, “Packaging and Transportation of Radioactive Material,” and part 73. As noted previously, § 53.620(e) includes an additional provision that allows a manufactured reactor or portions of a manufactured reactor to be removed from the place of manufacture for export in accordance with part 110, which represents another difference from the similar provision in § 52.153.

Section 53.620(f) includes requirements for the acceptance and installation of a manufactured reactor at the site of a commercial nuclear plant. The requirements reference the construction requirements in § 53.610 to govern the integration of the manufactured reactor into the construction of a commercial nuclear plant. Other requirements in the section address required receipt inspections and verification that interface requirements between the manufactured reactor and the balance of the commercial nuclear plant have been met.

Subpart F—Requirements for Operation

Subpart F provides the requirements for the operations phase of a commercial nuclear plant to ensure that the safety criteria in subpart B are satisfied throughout the plant's lifetime and during all modes of normal operation and unplanned events. Section 53.700 provides the general organization and overall objectives of subpart F, which are to establish requirements during operations for (1) plant SSCs; (2) personnel; and (3) plant programs.

Section 53.710 provides the requirements for maintaining capabilities, availability, and reliability of SSCs to demonstrate compliance with the safety criteria and design requirements for unplanned events that are described in subparts B and C. The basic structure of this section is that measures for SR SSCs are provided by TS and measures for NSRSS SSCs are required to be addressed with licensee-controlled documents and procedures.

The general content and control of TS under part 53 are similar to the requirements in part 50. The requirements for TS include limits on the inventories of radioactive materials, plant operating limits, and specific requirements for each SR SSC, including limiting conditions for operation (LCO) and required surveillances. The requirements for TS also include a section on important design elements, which is

similar to design features in § 50.36, and a section for administrative controls. A provision addressing the development and submittal of TS to address decommissioning activities is also included in subpart G.

The requirements for TS under part 53 do not carry over safety limits or associated limiting safety system settings from § 50.36, which contains TS requirements for operating reactors under parts 50 and 52. As discussed in SECY-18-0096, systematic assessments and more mechanistic approaches to evaluating source terms support an alternative approach to establishing barrier-based safety limits. An example provided in that paper is a comparison of: (1) the traditional specified acceptable fuel design limits (SAFDL) that support protecting a specific barrier from potential failure mechanisms (e.g., departure from nucleate boiling to protect fuel cladding); and (2) the specified acceptable system radionuclide release design limit (SARRDL) concept, which limits the possible increase in circulating radionuclide inventory during normal operations or an AOO as part of an integrated or “functional containment” approach. Additional discussion of the use of SARRDL in the design and licensing of advanced reactors is provided in RG 1.232. The SARRDL could be addressed as an operating limit within this construct of requirements for TS. In cases, such as LWRs, where a SAFDL approach might be used as part of a mechanistic approach to meeting the design and analysis requirements in subpart C, the associated functional design criteria in § 53.410 and TS under § 53.710(a) define similar requirements as those provided by the safety limit and limiting safety system setting requirements in § 50.36.

The requirements for TS under part 53 do not include specific criteria for identifying when LCOs must be established (i.e., do not include an equivalent to § 50.36(c)(2)(ii)). Instead, consistent with subparts B and C, the TS requirements in subpart F of part 53 define TS LCOs as providing limits on SR SSCs. The SR SSCs protect against DBAs to demonstrate compliance with the safety criteria in § 53.210. In

the construct for part 53, risk-significant SSCs are addressed through a combination of TS for SR SSCs and establishment and monitoring of performance standards for NSRSS SSCs.

In addition to addressing TS for SR SSCs, § 53.710 requires appropriate control measures be developed and implemented for NSRSS SSCs. Examples include appropriate surveillances and controls established through reliability assurance programs. Configuration management and other special treatments provide that the capabilities, availabilities, and reliabilities of NSRSS SSCs are maintained consistent with the underlying risk assessments while providing flexibility to licensees through maintaining the management functions within licensee-controlled programs. Controls on NSRSS SSCs are appropriate as part of the overall performance-based approach within part 53. Special treatments beyond those defined for their SR functions may also be warranted for SR SSCs to reflect their role in meeting the safety criteria in § 53.220 and the evaluation criteria in § 53.450(e). The performance objectives for NSRSS SSCs reflect that the comprehensive risk metrics and related risk performance objectives established under § 53.220 may involve assessing and averaging the risks over a defined period (e.g., plant year) and do not constitute a real-time requirement that must be continuously demonstrated by the licensee. The controls under § 53.710(b) justify changes in part 53 from the traditional or deterministic approaches in parts 50 and 52 in areas such as replacing the single-failure criterion with a probabilistic reliability criterion (see SRM-SECY-03-0047, “Policy Issues Related to Licensing Non-Light-Water Reactor Designs,” dated June 26, 2003). This approach can also support the incorporation of risk insights and analytical margins to gain operational flexibilities in areas such as siting and staffing requirements described in subsequent sections of subpart F.

Section 53.715 provides the requirements for developing and implementing a program to do the following: (1) control maintenance activities; (2) take appropriate

corrective action when performance issues are identified; (3) conduct routine evaluations of effectiveness; and (4) assess and manage risks resulting from maintenance activities. These requirements are similar to those included in § 50.65 (maintenance rule), including the need to assess and manage the increase in risk that may result from the maintenance activities. While, for the maintenance rule, specific criteria must be developed to capture both SR and non-SR but otherwise important SSCs, § 53.715 covers SR SSCs and NSRSS consistent with other subparts in part 53.

Section 53.720 provides the requirements for responding to a seismic event during the operating phase of the life cycle of a commercial nuclear plant and is equivalent to the requirements in paragraph IV(a)(3) of appendix S, “Earthquake Engineering Criteria for Nuclear Power Plants,” to part 50.

Part 53 includes provisions to address staffing, training, personnel qualifications, and human factors engineering (HFE) in a manner that is risk-informed, technology-inclusive, performance-based, and flexible in nature. During the development of part 53, the staff prepared a draft white paper on “Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors,” to support interactions with stakeholders and the Advisory Committee on Reactor Safeguards (ACRS). Key considerations include the recognition that staffing, operator qualifications, and HFE are interconnected areas that must be approached in an integrated manner and, furthermore, that safety functions, including the means by which they are fulfilled, provide an effective method for informing technology-inclusive requirements.

The requirements associated with this approach are in §§ 53.725 through 53.830. Section 53.725 discusses applicability and defines specific terms. Some definitions draw from those in § 55.4. Several new definitions are introduced for use within the context of subpart F. These new definitions are the following: “*Automation*,” “*Auxiliary operator*,” “*Generally licensed reactor operator*,”

"*Interaction-dependent-mitigation facility,"* "*Load following*," and "*Self-reliant-mitigation facility*."

Sections 53.725 through 53.830 are divided into four portions that cover general operational requirements, operator and senior operator licensing requirements, GLRO requirements, and general training requirements for plant staff. The NRC intends to provide guidance addressing the review of operator staffing plans; the review of operator, senior operator, and GLRO examination programs; and the implementation of scalable HFE reviews. Licensees will be required to use GLROs upon demonstrating compliance with the criteria in § 53.800.

Certain routine communications are necessary to facilitate the operator licensing process. The NRC adapts the requirements of §§ 55.5 and 50.74 to § 53.726 to accomplish this.

Specific information must be collected in order to facilitate the initial issuance of operator licenses, as well as to allow for license renewals and required updates thereafter. Such information collection activities must also be approved by the OMB. The NRC adapts the requirements of § 55.8, to include any needed updates in OMB approval information, to § 53.120 to accomplish this.

The information used within the regulatory processes of the NRC must be free from omissions and inaccuracies to facilitate effective regulation. Consistent with this, the NRC adapts the requirements of § 55.9 to § 53.728 to require the completeness and accuracy of material information provided by individual applicants and license holders.

Section 53.730 provides performance-based and technology-inclusive requirements for assessing the role of personnel in facility safety, applying human system considerations within facility design, and incorporating operational approaches that are consistent with design-specific safety considerations. Most of these requirements are adapted from portions of §§ 50.34(f) and 50.54 and 10 CFR part 55,

“Operators' Licenses,” with considerable modification in order to reflect the introduction of new technologies and possible changes in the roles of personnel in preventing and mitigating events. The NRC intends that these technical requirements will, together, serve as a component of the required content of applications for OLs and COLs under part 53. Additionally, the NRC intends that the specific technical requirements associated with HFE, human-system interface design, concept of operations, functional requirements analysis, and function allocation will serve as a component of the required content of applications for standard DCs, standard design approvals, MLs, and CPs, as well.

Human factors engineering is essential to facilitate the role of personnel in facility safety in a manner that is both effective and reliable. The NRC adapts § 53.730(a) from the HFE design requirements of § 50.34(f)(2)(iii). A key difference is that the requirement is now focused on settings where personnel fulfill their safety or emergency response roles wherever they may occur. The NRC additionally includes within the scope of this requirement activities for assuring the continued availability of plant equipment that is needed for safety, and the NRC envisions that these activities may encompass relevant maintenance, inspections, and testing as well. This requirement is associated with the staff guidance for conducting scalable reviews of HFE in DRO-ISG-2023-03, “Development of Scalable HFE Review Plans” that accompanies part 53.

Human-system interfaces provide vital information to operators across a spectrum of operating conditions that can range from normal operations through severe accident conditions. The specific types of information that must be available to support operations staff during such conditions include, in part, those associated with safety function parameters, safety system status, possible core damage states, barrier integrity, and radioactive leakage. Due to the importance of such information, the NRC requires under § 53.730(b) such human-system interface design features for all facilities,

irrespective of other flexibilities under part 53. Therefore, the NRC adapts specific post-Three Mile Island requirements of § 50.34(f) in a technology-inclusive manner as detailed in the following:

- Paragraph (b)(1) is adapted from § 50.34(f)(2)(iv).
- Paragraph (b)(2) is adapted from § 50.34(f)(2)(v).
- Paragraph (b)(3) is adapted from § 50.34(f)(2)(xi), 50.34(f)(2)(xii), and 50.34(f)(2)(xxi).
- Paragraph (b)(4) is adapted from § 50.34(f)(2)(xvii), 50.34(f)(2)(xviii), 50.34(f)(2)(xix), and 50.34(f)(2)(xxiv).
- Paragraph (b)(5) is adapted from § 50.34(f)(2)(xxvi).
- Paragraph (b)(6) is adapted from § 50.34(f)(2)(xxvii).

In addition to the requirements of § 53.730(b)(1) through (6), a further set of human-system interface design requirements applicable only to those facilities that will be staffed by GLROs is provided under § 53.730(b)(7). This prescriptive set of design requirements for those facilities that demonstrate compliance with the criteria of § 53.800 recognizes that the application of HFE under § 53.730(a) is anticipated to be significantly streamlined at such facilities in the absence of an expected operator role for the fulfillment of safety functions. However, it should be noted that the capability for an immediately initiated, manual reactor shutdown is conservatively mandated irrespective of any other design considerations for both interaction-dependent and self-reliant mitigation facilities, as required under § 53.730(b)(8).

The NRC requires under § 53.730(c) the submittal of a concept of operations that is of sufficient scope and detail to appropriately inform the staff. The development of a concept of operations can facilitate a clear understanding on the part of the NRC for potential novel operating concepts. Additionally, such information is likely to reduce the

degree of resources and interactions needed for the NRC to obtain the understanding necessary to enable flexible requirements in areas such as staffing, operator qualifications, and HFE.

The NRC requires under § 53.730(d) the submittal of both a Functional Requirements Analysis and a Function Allocation. The identification of design-specific safety functions and how they are fulfilled serves as a primary means for achieving technology-inclusive requirements within areas such as staffing, operator qualifications, and HFE. The Functional Requirements Analysis and Function Allocation processes (which are both HFE methods derived from systems engineering principles), provide an effective means to identify both how safety functions will be satisfied and how to characterize any associated operator role in doing so. A Functional Requirements Analysis shows what features, systems, and human actions are relied upon to demonstrate safety (i.e., fulfill safety functions). A Function Allocation then describes how safety functions are assigned to both personnel and automatic systems. However, an important adaptation of the Function Allocation for use under this final rule is the further need not only to describe allocations of safety functions to human action and automation, but also to identify allocations made to active safety features, passive safety features, or inherent safety characteristics as well.

Operating experience provides an important source of information by which to inform various aspects of facility design and operations. Accordingly, the NRC adapts in § 53.730(e) the requirements of § 50.34(f)(3)(i) for requiring an operating experience program.

New technologies may involve concepts of operations that are more conducive to customizable licensed operator staffing requirements than the prescriptive requirements of § 50.54(m). Analyses and assessments that are based on HFE principles provide a performance-based means of determining licensed operator and senior operator staffing

needed to support safe operations. In contrast, for those facilities required to be staffed by GLROs, the NRC anticipates that the operator staffing plans will reflect a simpler approach of showing that a continuity of responsibility will be maintained for facility operations throughout the operating phase, with at least one GLRO providing continuous oversight and remaining immediately available when any units are fueled. Additionally, a revised approach to the traditional position of the shift technical advisor that focuses on the availability of engineering expertise as a means of addressing uncertainties and abnormal circumstances is more suitable within the context of part 53 and is intended to be applicable to all facilities, irrespective of other design and staffing considerations.

Consistent with this approach, the NRC requires under § 53.730(f) the submittal of a staffing plan that details operations staffing, how engineering expertise will be provided, and what staffing will be available to provide other needed support functions. The staffing plan description of how engineering expertise will be provided should include details of the position, such as location, expected response time, access to plant status information, and methods of communication. The staffing plan description should contain information on how the described response time has been or will be determined to be adequate based on the facility design. This requirement is associated with the staff guidance for reviewing operations staffing plans in DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53” that accompanies part 53.Following NRC approval of the OL or COL, the staffing plan will become a condition of the facility license.

The NRC intends that, at a minimum, the approved licensed operator and senior operator (or, if applicable, GLRO) staffing, positions, and personnel locations will be

incorporated into corresponding requirements within the facility TS and that a license amendment would therefore be required for any subsequent changes.

Operator training and qualification programs provide an essential component of supporting human performance in implementing tasks with safety implications. Such programs must include components that cover the stages of initial training, examination, and continuing training. Additionally, recognizing the potential for varying concepts of operations to affect traditional, prescriptive approaches to operator proficiency, under part 53 the NRC allows facilities to develop operator proficiency programs based on facility-specific considerations.

Therefore, the NRC requires in § 53.730(g)(1), as part of its approval of the OL or COL, approval of the programs that will be used for the initial training, initial examination, requalification training and examination, and proficiency of both licensed operators and senior operators. In a corresponding manner, the NRC requires in § 53.730(g)(2) approval of the programs that will be used for the GLRO equivalents of each of these programs for facilities with such staffing. The NRC intends that examination program requirements will be associated with staff guidance for the review of tailored examination processes that are planned to accompany part 53. Following the completion of an initial training program, continuing training programs provide an important means of sustaining the knowledge and abilities of individuals. The NRC adapts the requirements of § 50.54(i-1) in § 53.730(g)(3) to require that operator continuing training programs be in effect to support operator performance. Under part 53, the NRC requires these programs to be in effect concurrent with when the initial operator examinations first commence, in effect putting the programs in place only when they are needed. This represents a modification of the comparable requirement of § 50.54(i-1), which links the commencement of these programs to a timeline driven by the licensing of the facility.

The authorization to manipulate controls of the facility that directly affect reactivity or power level is restricted to individuals who are either licensed operators, licensed senior operators, or GLROs. However, for practical purposes, situations in which an individual is participating in an approved training program or reestablishing proficiency may also call for them to operate the controls of the facility under the cognizance of a licensed individual. The NRC adapts the requirements of § 55.13 in § 53.735 to accomplish this, with a notable difference being the incorporation of GLROs.

Section 53.740 provides requirements for OL and COL holders under part 53. Portions of § 53.740 are adapted from the conditions of § 50.54. In general, the conditions for operations staffing under part 53 reflect considerations for potential technological differences and varying concepts of operation that are expected among part 53 facility licensees. Additionally, certain requirements are specific to the operating phase while others remain in effect following the permanent cessation of facility operations during the decommissioning phase.

All commercial nuclear plants licensed under part 53 require some form of licensed operator staffing, whether it be by specifically or generally licensed operators. Consistent with this, the NRC requires under § 53.740(a) that facility licensees demonstrate compliance with the programmatic requirements for either specifically licensed operators and senior operators or for GLROs, as applicable to the facility.

The NRC recognizes that technology-inclusive facility staffing will need to account for a potentially wide range of concepts of operations; for this reason, flexible and performance-based approaches for establishing required facility staffing are appropriate. However, once the appropriate facility staffing has been determined and approved by the NRC, such staffing must be maintained to ensure that the appropriately qualified individuals will be available when needed to support the safe operation of the facility. Therefore, the NRC requires under § 53.740(b) that the staffing described within

the approved facility staffing plan be maintained as a condition of the facility license as opposed to prescriptive staffing requirements like those of § 50.54(k) and (m).

Because operation of facility controls directly affects reactivity or power level, only those individuals who possess appropriate levels of qualification and authorization are permitted to operate those controls. The NRC adapts the requirements of § 50.54(i) in § 53.740(c) to require that only specifically licensed operators and senior operators or, alternatively, GLROs, may operate facility controls, with allowance for specified exceptions for the purposes of operator training or proficiency.

Senior operators, by virtue of their license level, are qualified and authorized both to perform certain important responsibilities and to direct the licensed activities of licensed operators. Therefore, facilities that are required to be staffed by specifically licensed operators must also include senior operators within their staffing. In contrast, facilities staffed with GLROs only have a single license level available and, therefore, there is no equivalent provision for such facilities. The NRC adapts the requirements of § 50.54(l) in § 53.740(d) to require the licensing and designation of senior operators at facilities staffed by specifically licensed operators.

In contrast with control manipulations that directly affect reactor power and reactivity (e.g., control rod movement, control drum rotation, recirculation pump speed adjustment, reactor coolant system boration or dilution, etc.) and are therefore restricted to performance only by licensed operators, other types of plant operations that may result in reactor power and reactivity changes via means that are indirect in nature (e.g., electrical generation changes, turbine bypass valve operation, steam usage by process heat applications, etc.) may be implemented by non-licensed personnel. However, due to the potential influence of such operations on reactor power and reactivity, the continuous oversight of reactor parameters by a licensed operator is necessary during these operations. The NRC therefore adapts the requirements of

§ 50.54(j) in § 53.740(e) to require appropriate oversight of operations, other than those associated with the controls themselves, that may affect reactivity or power level.

Load following where plant output automatically changes in response to externally originated instructions or signals is not permitted under the existing regulations of § 50.54. However, new technological considerations and concepts of operation may justify such an operational approach under appropriate circumstances. The NRC recognizes that, beyond electrical power generation, load following may also affect other applications of plant output, such as hydrogen production, desalination, or district heating. For load following to be permissible, measures must be in place to provide assurance that plant output considerations are not permitted to lead to challenges to safe reactor operations. These measures may consist of automated control systems, automatic protective features, or the continuous oversight and immediate intervention capability of an appropriately qualified and authorized individual. Section 53.740(f) allows for load following, provided that appropriate measures are in place. In considering the acceptability of the measures associated with load following, the NRC expects that any automatic protection relied upon would be separate from that credited for reactor protection purposes and would employ setpoints that are set so as to prevent actuation of the reactor protection system while accomplishing its functions to the extent practical.

Core alterations such as refueling are associated with specific considerations that warrant limiting the oversight of such operations to appropriately qualified and authorized individuals. Unlike other types of fuel handling operations, core alterations occur within the confines of a reactor vessel that is specifically designed to support and sustain nuclear criticality, thereby justifying the imposition of higher qualification levels within such contexts. The NRC adapts the requirements of § 50.54(m)(2)(iv) in § 53.740(g) to require the supervision of core alterations by either a specifically licensed

senior operator, a specifically licensed senior operator whose license is limited to fuel handling, or by a GLRO, as applicable to the facility. Because certain commercial reactor designs may be capable of refueling while at power and, in any event, overall facility oversight will already be required by either a specifically licensed senior operator or by a GLRO, the NRC omits this requirement as redundant during periods where core alterations occur while the plant is operating.

It is impossible to predict every possible scenario that a commercial nuclear plant might potentially encounter. Therefore, it is prudent to grant the authority for appropriately qualified individuals to depart from facility license conditions when emergency circumstances dictate that doing so is in the interest of public health and safety. The NRC adapts the requirements of § 50.54(x) and (y) in § 53.740(h) to permit specific individuals to authorize departures from facility license conditions or TSs when emergency conditions warrant doing so for the protection of the public health and safety. Recognizing that certain facilities licensed under part 53 may be staffed by GLROs in lieu of specifically licensed senior operators, the NRC extends this authority to GLROs. While it is not anticipated that GLROs will have a role in the fulfillment of safety functions at self-reliant-mitigation facilities, nor is it anticipated that operators at such facilities would be in a position by which to significantly influence radiological safety outcomes, the very nature of the § 50.54(x) and (y) and § 53.740(h) provisions concern situations that are unanticipated and, therefore, unforeseeable. Thus, it is appropriate to grant GLROs a comparable authority to that of senior licensed operators and certified fuel handlers as it relates to invoking this provision under emergency conditions as a means of accounting for such possibilities.

Due to the unique authorities and responsibilities of both specifically and generally licensed reactor operators, it is essential that any individual fulfilling such a role demonstrate compliance with the regulatory requirements for operator licensing.

Section 107 of the AEA authorizes the Commission to prescribe conditions for the licensing of operators and to issue licenses consistent with those conditions. The NRC adapts the requirements of § 55.3 in § 53.745 to require that any person performing the function of an operator, senior operator, or GLRO must be authorized by a license issued by the Commission.

The NRC will license individuals as operators under both specific and general licensing frameworks. Specific licenses will be for licensed operators (i.e., reactor operators) and senior operators (i.e., senior reactor operators) and will be issued to a named person upon approval by the Commission of an application for that named person. In contrast, GLROs will perform duties under the provisions of a general license that is effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC sets forth requirements for the use of a specific licensing process for licensed operators and senior operators under §§ 53.760 through 53.795, with § 53.760 addressing applicability.

Medical fitness is an important component of the overall process of specifically licensing operators because it provides assurance that operators will be able to carry out important duties without being precluded from doing so by health-related issues. Medical fitness also provides assurance that such issues will not adversely affect the performance of assigned job duties or cause operational errors that endanger public health and safety. In addition to a requirement for medical fitness, a medical examination by a physician to confirm compliance with this requirement is necessary. The NRC adapts the requirements of §§ 55.21, 55.23, and 55.27 under § 53.765 to require medical fitness, examinations by physicians, and medical certification for specifically licensed operators and senior operators. In recognition of the fact that GLROs are not expected to have a role in the fulfillment of safety functions at the facilities at which they are licensed, the NRC does not extend a comparable medical requirement to GLROs.

The NRC also adapts the requirements of §§ 55.25 and 50.74(c) in § 53.770 to require that timely notifications be made to the NRC if a specifically licensed operator or senior operator develops a permanent physical or mental condition that adversely affects the performance of assigned operator job duties or could cause operational errors endangering public health and safety. Notwithstanding this requirement related to permanent medical conditions, the NRC continues to recognize that it is appropriate for facility licenses to impose administrative restrictions and conditions upon specifically licensed operators and senior operators in response to temporary medical conditions.

The process of specifically licensing individuals as licensed operators or senior operators requires the submittal of applications to the NRC for review. These applications must detail certain elements associated with licensing, including the demonstration of compliance with examination, experience, and medical requirements. The NRC adapts the requirements of §§ 55.31 through 55.35 in § 53.775 to include requirements for the applications associated with the specific licensing of licensed operators and senior operators at commercial nuclear plants licensed under part 53. In contrast with the part 55 requirements, the NRC provides additional flexibility by locating certain details associated with the preparation and submittal of these applications within guidance in lieu of placement within this final rule itself.

The NRC includes overall programmatic requirements for specifically licensed operator and senior operator training, examination, and proficiency in § 53.780. In general, the requirements are adapted from those in part 55, with several additional flexibilities being incorporated to better account for potential variations in reactor technologies and concepts of operations. The requirements in § 53.780 cover, in part, the initial training, initial examination, requalification training, requalification examination, and proficiency of specifically licensed operators and senior operators.

The initial training process provides individuals with the knowledge and abilities needed to subsequently fulfill assigned duties as licensed operators or senior operators in a safe and reliable manner. The use of a systems approach to training (SAT) ensures that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology, concepts of operations, and operator roles in the fulfillment of design-specific safety functions. The NRC requires under § 53.780(a) that facility licensees implement a SAT-based training program for the initial training of licensed operator and senior operator applicants. The program must be adequate to ensure that applicants will be capable of performing the duties necessary both to protect public health and safety and to maintain plant safety functions. The NRC further requires that such programs be subject to NRC approval and subsequent change control processes of an appropriate nature.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that is sufficient to carry out assigned duties as licensed operators or senior operators in a manner that is safe and reliable. The NRC adapts the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.780(b) to require that facilities establish and implement an initial examination program. However, a key difference from the comparable requirements of part 55 is that facilities have the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory applicant performance. Such examination programs (including those used within the scope of requalification training) must provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance will be available to facilitate the review of licensing examination programs that are proposed by facility licensees and that, following NRC approval, initial examination programs will be subject to an appropriate change control process. Furthermore, the NRC provides holders of licenses to operate commercial nuclear plants

under part 53 the alternative of administering their own approved licensing examinations. The NRC will continue to exercise appropriate oversight of the program, make operator licensing decisions based upon the examination results, and reserve the right to administer the examinations in lieu of permitting the facility to do so. However, irrespective of the provided flexibilities in examination format and structure, at a minimum, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions
- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Requalification training programs provide for the continuing training and examination of specifically licensed operators and senior operators to ensure that they maintain the knowledge and abilities needed to support the safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC adapts the requirements of § 55.59 in § 53.780(c) to require that facilities implement both a SAT-based requalification training program and a biennial requalification examination program. However, a notable difference from the biennial requalification examinations required under part 55 is that distinct annual operating test and biennial written examination components are not mandated, with the facility licensee instead proposing the examination methods and criteria to be used in assessing satisfactory performance. The NRC intends that guidance will be available to facilitate the review of the requalification examination programs that are proposed by facility

licensees and that, following NRC approval, requalification examination programs will be subject to an appropriate change control process.

For examinations to provide valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect their underlying integrity. The NRC adapts the requirements of § 55.49 in § 53.780(d) to require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators, and the NRC is specifically authorized under the Nuclear Waste Policy Act of 1982, as amended (NWPA), section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC adapts the requirements of § 55.46 in § 53.780(e) to address the use of simulation facilities for training, examinations, and applicant experience requirements, as well as to address the maintenance of simulator fidelity. However, the requirements of part 53 do not mandate that full scope, plant-referenced simulators be used and will allow the use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, provided that all associated requirements can be demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training, examination, or experience requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these purposes. Rather, the NRC perspective is that the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job performance measures, simulated tasks, use of augmented reality technology, and similar approaches that

provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which applicants for operator or senior operator licenses have previous training and experience that justifies waiving some, or all, of the initial examination requirements. The NRC adapts the requirements of § 55.47 in § 53.780(f) to allow for consideration of requests for waivers of examinations requirements. In contrast with the part 55 requirements, the NRC locates certain details associated with such waiver requests within guidance documentation in lieu of placement within this final rule itself.

For licensed operators and senior operators to perform their assigned duties safely and reliably, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. The NRC adapts the requirements of § 55.53(e) and (f) in § 53.780(g) to require that specifically licensed operators and senior operators maintain proficiency and, if proficiency is not maintained, regain proficiency prior to resuming licensed duties. However, in recognition of the fact that varying concepts of operations are possible for advanced reactor facilities, the NRC, in contrast with the requirements of part 55, is allowing facility licensees to establish their own programs for operator proficiency, subject to NRC approval.

As the holders of specific licenses, licensed operators and senior operators must be subject to license conditions on an individual basis to ensure that the basis upon which the licenses were issued remains valid. The NRC adapts the requirements of § 55.53 in § 53.785 to require appropriate conditions of licenses for specifically licensed operators and senior operators. However, in contrast with the requirements of § 55.53(e) and (f), the NRC is allowing certain aspects of operator proficiency to be addressed by an NRC-approved facility proficiency program.

Licenses for specifically licensed operators and senior operators are issued by the NRC and must remain subject to modification or revocation. The NRC adapts the requirements of §§ 55.51 and 55.61 in § 53.790 to address the issuance, modification, and revocation of licenses issued to specifically licensed operators and senior operators.

The licenses issued to specifically licensed operators and senior operators are valid for a period of 6 years, after which they expire, unless otherwise renewed. The NRC adapts the requirements of §§ 55.55 and 55.57 in § 53.795 to address the expiration and renewal of licenses issued to specifically licensed operators and senior operators.

In developing this final rule, the NRC has discussed with stakeholders the considerations that might justify the omission of the specifically licensed operators and senior operators. However, even for an inherently safe reactor with autonomous operation features, certain important administrative functions (e.g., compliance with TS, operability determinations, NRC notifications, emergency declarations, risk assessment, maintenance oversight, and radiological release limit compliance) would still need to be accomplished by appropriately qualified and authorized individuals. Additionally, the NRC recognized that manual manipulations of facility reactivity controls must only be performed by individuals who have been appropriately licensed by the Commission. The NRC therefore establishes under § 53.800 a new class of facility (defined as a self-reliant-mitigation facility), according to the criteria contained in § 53.800 for part 53. These facilities will employ GLROs rather than specifically licensed operators and senior operators. The GLRO regulations offer enhanced flexibilities and targeted relaxations in a manner that is commensurate with the modified role of such operators to ensure the safe operation of the associated facilities. In contrast, those facilities not meeting the criteria of § 53.800 will instead be considered interaction-dependent-mitigation facilities and will require staffing by specifically licensed operators and senior operators. The

terminology used to designate these facility types reflects differences in how operators are anticipated to need to interact with their plant systems in mitigating events and achieving safe outcomes; such systems may either need operators to interact with them in some manner (i.e., be interaction-dependent) or may instead be able to rely fully upon their own capabilities independent of operator interaction (i.e., be self-reliant).

Generally licensed reactor operators differ from specifically licensed operators because the latter will be directly and independently evaluated by the NRC as part of their licensing process. This direct and independent evaluation remains appropriate when operators may reasonably be expected to exert a significant influence on public health and safety outcomes. Therefore, a key determinant as to whether generally licensed reactor operators can be utilized in facility staffing is the assessment of the operator's role in maintaining and fulfilling safety functions at the facility, such as through the performance of credited actions for the mitigation of plant events.

The criteria in § 53.800 designate self-reliant-mitigation facilities. These criteria are derived from the following set of considerations:

- no human action needed to satisfy radiological consequence criteria;
- no human action needed to address LBEs;
- safety functions not allocated to human action;
- reliance upon robust and highly reliable safety features; and
- appropriate defense in depth achieved without reliance on important human action.

It should be noted that those facilities not meeting the criteria in § 53.800 will instead be classified as interaction-dependent-mitigation facilities and will require staffing by specifically licensed operators and senior operators instead.

Generally licensed reactor operators will perform duties under the provisions of a general license that is effective without the filing of an application with the Commission or the issuance of licensing documents to a particular person. The NRC sets forth requirements for the general licensing process for GLROs under §§ 53.805 through 53.820. The requirements for GLROs parallel those for senior operators in regard to their comparable administrative responsibilities. Nonetheless, the requirements for GLROs are relaxed and incorporate greater flexibilities compared to the requirements for specifically licensed operators in a manner that is consistent with the GLRO's role in safety at self-reliant-mitigation facilities.

In order to use GLROs in lieu of specifically licensed operators and senior operators, a OL/COL applicant must demonstrate that its proposed facility is a self-reliant-mitigation facility, i.e., that it will comply with the following requirements on an ongoing basis: maintaining GLRO qualifications for the performance of important functions and tasks; incorporating relevant programmatic controls into TS; administering the related programs for training, examination, and proficiency; and ensuring that the relevant provisions of parts 26 and 73 are met. Additionally, to provide for an accurate accounting of what individuals are licensed under the general license, facility licensees are required to report the identities of all generally licensed reactor operators to the NRC on an annual basis. Furthermore, a facility licensee must ensure that the facility design and performance continue to meet the technological criteria to be classified as a self-reliant-mitigation facility (i.e., the criteria of § 53.800) on a continual basis during the operating phase, as the relaxations afforded to such facilities in the areas of operator licensing, staffing, and HFE are predicated on this assumption. The NRC therefore establishes under § 53.805 requirements for facility licensees that address issues such as these. Finally, the failure of a self-reliant-mitigation facility to subsequently meet the criteria of § 53.800 after the issuance of an OL or COL will constitute a reportable event

(i.e., an unanalyzed condition that significantly degrades plant safety) under the provisions of § 53.1630.

The NRC sets forth the general license for GLROs under § 53.810. GLROs will be licensed as a class of individuals under the provision of § 53.810(a) and will be subject to the conditions specified in § 53.810(b) through (g). Portions of these conditions are adapted from § 55.53 and from those conditions currently included in the licenses issued to specifically licensed operators and senior operators. The NRC retains the ability to suspend or prohibit individuals from operating under the general license should such action be warranted.

The NRC includes overall programmatic requirements for GLRO training, examination, and proficiency under § 53.815. In general, these requirements are adapted from those of part 55 and parallel those also included for specifically licensed senior operators in § 53.780. These requirements include increased flexibilities and several targeted relaxations that reflect the limited role of GLROs in facility safety. The requirements under § 53.815 cover, in part, the initial training, initial examination, continuing training, requalification examination, and proficiency of GLROs.
Section 53.805 requires the facility licensee to develop, implement, and maintain these programs. Section 53.810, in turn, prescribes that the requirements of § 53.805 must be met as a requirement of the general license. The implication of this structure is that the facility licensee must implement these programs for training, examination, and proficiency, and GLROs must participate in these programs to demonstrate compliance with the requirements of the general license.

The initial training process provides GLROs with the knowledge and abilities needed to fulfill assigned duties as GLROs. The use of an SAT serves to ensure that the training program is based upon job requirements in a manner that can be adapted to account for differences in plant technology and concepts of operations. The NRC

requires under § 53.815(b) that facility licensees implement a SAT-based training program for the initial training of GLROs that is adequate to ensure that they have the necessary knowledge, skills, and abilities to perform their duties. The NRC further requires that such programs be subject to NRC approval, oversight, and appropriate change control processes. The training program must ensure that GLROs maintain the necessary knowledge, skills, and abilities.

Examinations provide a means of assessing that individuals have achieved a degree of knowledge and ability that will be sufficient to enable them to carry out assigned duties as GLROs in a manner that is both safe and reliable. The NRC adapts the requirements of §§ 55.40, 55.41, 55.43, and 55.45 in § 53.815(b) to require that facility licensees establish and implement an initial examination program. A key difference from the comparable requirements of part 55 is that facility licensees are afforded the flexibility to propose, subject to NRC approval, the examination methods and criteria to be used in assessing satisfactory individual performance. Such examination programs (including those used within the scope of continuing training) must provide for acceptable levels of both test validity and test reliability in order to be considered acceptable. The NRC intends that staff guidance will be available to facilitate the review of initial examination programs that are proposed by facility licensees and that approved initial examination programs will be subject to an appropriate change control process. In contrast with both the requirements of part 55 and the requirements of § 53.780, the NRC does not intend to administer or evaluate these initial examinations. However, the examination processes themselves will continue to be subject to ongoing NRC oversight. Irrespective of the provided flexibilities in examination format and structure, topics from the following general categories of knowledge and abilities should be sampled in such examinations:

- Reactor Theory, Thermodynamics, and Chemical Interactions

- Plant Systems and Components
- Reactivity Management and Manipulations
- Radiation Control and Safety
- Emergency, Abnormal, and Normal Operations
- Administrative Requirements and Conditions of the Facility License

Continuing training programs provide the ongoing training and examination of GLROs to ensure that they maintain the knowledge and abilities needed to support the safe and reliable performance of job duties following the completion of an initial training and examination program. The NRC adapts the requirements of § 55.59 in § 53.815(b) to require that facility licensees implement both an SAT-based continuing training program and a requalification examination program. However, a notable difference from the examinations required under part 55 is that distinct annual operating test and biennial written examination components are not mandated. The facility licensee will instead propose examination methods and criteria to be used in assessing satisfactory performance. Furthermore, unlike the comparable requirements of part 55 and those for specifically licensed operators and senior operators, a biennial periodicity for requalification examinations is not prescribed. However, adequate justification for the proposed periodicity of requalification examinations is required. The NRC intends that staff guidance will be available to facilitate the review of the requalification examination programs that are proposed by facility licensees. Approved requalification examination programs will be subject to an appropriate change control process.

For examinations to provide for valid assessments of the knowledge and abilities of individuals, the examinations must remain free from compromises that could affect their underlying integrity. The NRC adapts the requirements of § 55.49 in § 53.815(d) to

require that examinations and related activities remain free from any compromise that might affect the integrity of the examination process.

Simulators provide a valuable means of training and evaluating plant operators and the NRC is specifically authorized under the NWPA, section 306 (42 U.S.C. 10226) to establish regulations for the use of simulators within such context. The NRC adapts the requirements of § 55.46 in § 53.815(e) to address the use of simulation facilities for training and examinations, and experience requirements, as well as to address the maintenance of simulator fidelity. The use of full scope, plant-referenced simulators is not mandated. The potential use of alternative simulation facilities consisting of, for example, partial scope simulators or the plant itself, is allowed provided that all associated requirements are demonstrated to be met using alternative approaches and methods. Additionally, in allowing for the possibility that an applicant or licensee might demonstrate compliance with training and examination requirements using the plant itself, the NRC is not allowing the initiation of transients on the actual plant. Consistent with this, aside from controlled reactivity manipulations that are conducted for the purposes of demonstrating compliance with experience requirements, actual plant components may not be operated for these purposes. Rather, the use of the plant for training and examination purposes should be restricted to techniques such as walkthroughs, job performance measures, simulated tasks, use of augmented reality technology, and similar approaches that provide training and examination value while avoiding the operation of actual plant components.

There may be situations in which GLROs have previous training and experience that justifies waiving some, or all, of the initial examination. Therefore, under § 53.815(f) the NRC allows facility licensees to waive some, or all, portions of initial examinations provided that such waivers are consistent with a program that has been approved by the NRC.

For GLROs to safely and reliably perform their assigned duties, it is essential that they perform those duties frequently enough so as to maintain a sufficient degree of proficiency. However, the NRC recognizes that facilities that utilize GLROs may have concepts of operation that warrant unique proficiency considerations. Therefore, the NRC requires in § 53.815(g) that facility licensees develop, implement, and maintain programs to maintain and reestablish, if needed, the proficiency of GLROs. This could occur, for example, if an individual's extended absence from watch standing has rendered proficiency requirements unmet.

The general license should remain in effect for an individual only while that individual remains employed in a position that may call for the individual to manipulate the reactivity controls of the facility. The NRC requires under § 53.820 that the general license ceases to be applicable on an individual basis when an individual's employment status becomes such that this is no longer the case. However, the NRC recognizes that for some types of self-reliant-mitigation facilities, very long periods may elapse between circumstances that necessitate manual manipulation of reactivity controls. Therefore, the general license remains in effect for an individual as long as the individual's current position could potentially require that individual to manipulate reactivity controls at some point within the course of the individual's assigned job duties.

The NWPA, section 306 (42 U.S.C. 10226) authorizes and directs the NRC to, in part, issue regulations and guidance that address the training and qualifications of civilian nuclear power plant operators, supervisors, technicians, and other appropriate operating personnel. The NRC implements this in part 50 through the requirements of § 50.120, "Training and qualification of nuclear power plant personnel." The NRC adapts under § 53.830, with modifications, the requirements of § 50.120 for use in part 53 to provide more flexible personnel training and qualification requirements than those in § 50.120 and better reflect diverse concepts of operations.

The NRC recognizes that the categories of nuclear power plant personnel in § 50.120 may not be needed for the diverse concepts of operations, staffing models, and non-traditional personnel roles and responsibilities anticipated under part 53; conversely, and for the same reasons, additional categories of personnel may need to be covered by part 53. The NRC also recognizes that the timeframe prescribed in § 50.120 for the establishment of training programs may not be aligned with the schedules associated with the startup of certain types of commercial nuclear plant facilities. However, the NRC also recognizes that the SAT-based training required under § 50.120 remains an appropriate means by which training programs should continue to be developed and implemented. Therefore, the approach taken by the NRC in addressing the training of certain plant staff under part 53 reflects greater flexibilities in personnel categories and programmatic timeframes, while still retaining the requirement that such training programs be based on SAT.

The NRC requires under § 53.830 SAT-based training programs with the timeframe for when such programs are required being based upon when the associated personnel are needed to support facility-specific needs. The training programs will cover the training and qualification of personnel in the general categories of supervisors, technicians, and other appropriate operating personnel. Regarding the category of supervisors, this is intended to reflect on-shift supervisors for the licensed operators, similar to the current classification in § 50.120(b)(2)(iii), but § 53.830 uses language that is less specific to account for different conduct of operations and organizational structures for commercial nuclear plants which may require greater regulatory flexibility. The licensee is not required to seek NRC approval of a training program prior to usage. However, the licensee is required to accommodate NRC inspection of the training program. The NRC intends to develop guidance to facilitate the inspection of these

training programs but does not intend for such guidance to preclude the potential for the training programs to be maintained by a separate, NRC-approved accreditation process.

Section 53.845 requires programs to be developed, implemented, and maintained to help ensure that design features and human actions have the capabilities and reliabilities necessary to demonstrate compliance with the safety criteria in subpart B throughout the operating life of each commercial nuclear plant. The programmatic requirements in subpart F also address areas such as radiation protection needed to control routine effluents during normal operations. Sections 53.850 through 53.910 require programs to support specific activities needed to ensure the prevention or mitigation of unplanned events or to support normal operations for any reactor design. However, each holder of an OL or COL is required to assess whether additional programs are needed for the specific reactor design and location of the commercial nuclear plant. Licensees are able to combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

Section 53.850 requires a radiation protection program associated with the requirements in subparts B and C for public doses resulting from normal operations and the protection of plant workers. The requirements related to doses from normal operations, including routine effluents, are similar to those specified in § 50.36a, “Technical specifications on effluents from nuclear power reactors,” and related requirements in standard TS for offsite dose calculation manuals. While the section includes requirements that are technically and programmatically similar to part 50, § 53.850 does not include a requirement for effluent-related TS as is required in § 50.36a. A requirement similar to that found in the administrative controls section of TS for operating reactors licensed under parts 50 and 52 is included for programmatic controls of solid wastes to complement the design requirements in § 53.425.

Section 53.855 requires an emergency response plan that demonstrates compliance with the requirements in appendix E to part 50 and § 50.47(b) or § 50.160. The regulations in § 50.47 stating that the NRC will not issue certain licenses unless it finds that there is reasonable assurance that adequate protective measures can and will be taken to protect public health and safety in the event of a radiological emergency apply equally to applications under part 53 complying with the applicable standards set forth in either § 50.160 or the requirements in appendix E to part 50 and § 50.47(b).

In its 2008 Advanced Reactor Policy Statement, the Commission stated their expectation that “the safety features of advanced reactor designs will be complemented by the operational program for Emergency Planning (EP). This EP operational program, in turn, must be demonstrated by inspections, tests, analyses, and acceptance criteria to ensure effective implementation of established measures.” Consistent with this policy statement, emergency plans and emergency planning zones are not safety features in the design. In SECY-97-020, “Results of Evaluation of Emergency Planning for Evolutionary and Advanced Reactors,” dated January 27, 1997, the staff indicated that the rationale upon which EP for current reactor designs is based, that is, potential consequences from a spectrum of accidents, is appropriate for use as the basis for EP for evolutionary and passive advanced LWR designs and is consistent with the Commission's defense-in-depth safety philosophy. Also, in its Safety Goals Policy Statement the Commission stated that: “A defense-in-depth approach has been mandated in order to prevent accidents from happening and to mitigate their consequences. Siting in less populated areas is emphasized. Furthermore, emergency response capabilities are mandated to provide additional defense-in-depth protection to the surrounding population.” Consistent with this policy statement, § 53.855 contributes an additional independent layer of defense in depth for commercial nuclear plants. Therefore, the emergency plans and emergency planning zones under § 53.855 are not

used to demonstrate compliance with subpart B and subpart C of part 53. Rather, compliance with the requirements in § 53.855 provides reasonable assurance that adequate protective measures can and will be taken to protect public health and safety in the event of a radiological emergency.

Section 53.860 identifies the applicable regulations for part 53 applicants related to the programs for physical security, cybersecurity, FFD, AA, and information security. These programs are discussed in more detail in section IV, “Changes to Other Parts of 10 CFR,” of this document.

Section 53.860(a) requires licensees to develop, implement, and maintain a physical protection program that meets either § 73.55 or § 73.100, and includes physical protection of SNM and Category 1 and Category 2 radioactive material, if applicable.

Section 53.860(b) requires licensees to establish, implement, and maintain an FFD program under part 26. Section 53.860(c) requires licensees to establish, implement, and maintain an AA program in accordance with either § 73.56 or § 73.120, as appropriate. Section 53.860(d) requires licensees to establish, implement, and maintain a cybersecurity program in accordance with either § 73.54 or § 73.110. Section 53.860(e) requires licensees to establish, implement, and maintain an information protection system that complies with the requirements of §§ 73.21, 73.22, and 73.23, as applicable.

Section 53.865 establishes requirements for quality assurance and refers to appendix B to part 50 for the part 53 requirements for SR design features. Requirements related to evaluating and reporting changes to the quality assurance program are included in subpart I and are equivalent to those found in § 50.54.

Section 53.870 requires licensees to actively assess possible degradation of SSCs from the effects of aging, fatigue, and environmental conditions. The inclusion of requirements related to designing and monitoring for possible degradation mechanisms

reflects important lessons learned from the history of LWRs and the likely introduction of new design features and materials in future commercial nuclear plants. The allowable combinations of design features, operating experience, testing, and monitoring during operations support performance-based approaches to the initial licensing of new technologies. The performance-based approach to integrity assessment programs also allows for the subsequent consideration of operating experience and appropriate corrective actions or allowable relaxations for ensuring that design features comply with the functional design criteria of §§ 53.410 and 53.420. The program is based upon a comprehensive and integrated evaluation of the aging and other degradation mechanisms applicable to the design; identification of the affected SSCs; the allowances provided in the design of the SSCs for degradation; and schedules and procedures for determining if and at what rate degradation is occurring, as well as its cause. Risk insights can be used to prioritize the monitoring, evaluation, and management of degradation based upon the importance of the SSC to safety and the time frame for when the effects of degradation could be of concern.

Section 53.875 establishes requirements for a fire protection program supporting operations similar to § 50.48. The fire protection program during operations will work in concert with specific fire protection requirements in subpart C for design and analyses and in subpart E for construction and manufacturing.

Section 53.880 establishes requirements for an inservice inspection (ISI) and inservice testing (IST) program, which are historically important activities conducted in accordance with ASME codes and regulations in § 50.55a. While part 53 does not incorporate specific consensus codes and standards into the regulations, § 53.880 allows for the use of generally accepted codes and standards. The requirement for an ISI and IST program reinforces the need to develop monitoring programs to be conducted during a plant’s operations phase to complement the design process and

address inherent uncertainties. The NRC encourages the continued use of consensus codes and standards supporting design, testing, and inspections to support integrated and performance-based approaches in demonstrating compliance with the requirements in part 53.

Section 53.910 establishes requirements for developing, implementing, and maintaining procedures (e.g., operations and emergency operating procedures) and guidelines (e.g., accident management guidelines). The programmatic requirements for many of the procedures listed in this section are similar to the requirements found in the administrative controls section of TS for plants licensed under parts 50 and 52. The inclusion, where appropriate, of accident management guidelines in these requirements is intended to ensure that an integrated set of procedures and guidelines is established by licensees to ensure command and control across the spectrum of possible event sequences. The required procedures also include those needed to complement the design requirements in § 53.440(m) related to criticality alarms and the equivalent of the procedures required in § 50.54(hh) to address notifications of potential aircraft threats.

Subpart G—Decommissioning Requirements

Subpart G provides the regulatory requirements for the decommissioning phase of the life cycle of a commercial nuclear plant. The requirements in subpart G for the decommissioning of a commercial nuclear plant are adapted from the current regulations in § 50.75, “Reporting and recordkeeping for decommissioning planning,” § 50.82, “Termination of license,” and § 50.83, “Release of part of a power reactor facility or site for unrestricted use.” Although the requirements from those sections of part 50 have been copied into subpart G with relatively few changes, the requirements are reorganized to fit within the part 53 structure. The few changes made were primarily to

make the requirements more technology-inclusive by adding alternatives within sections, whereas some requirements in part 50 were developed specifically for LWRs.

As an example, § 50.75 provides minimum amounts of decommissioning funds required to demonstrate reasonable assurance of funds for decommissioning LWRs. Such generic amounts have not been developed for all reactor technologies that may be licensed under part 53. Therefore, a requirement is included in § 53.1020, "Cost estimates for decommissioning," for site-specific cost estimates for decommissioning to be developed considering costs in such areas as engineering, labor, and waste disposal. The derivation of the generic cost estimates for LWRs in § 50.75 is provided in NUREG/CR-5884, "Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station," and NUREG/CR-6187, "Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station." Similar to part 50, a provision for an annual adjustment of decommissioning cost estimates is included in § 53.1030.

The NRC is currently pursuing another rulemaking, "Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning," which was published as a proposed rule for public comment on March 3, 2022 (87 FR 12254). As these rulemakings progress, the NRC will consider revisions to part 53 to align the two rulemaking efforts. For example, § 53.1075 could be expanded to include or reference requirements for decommissioning in areas such as EP and security in addition to the decommissioning fire protection plans that provide an equivalent to § 50.48(f).

Subpart H—Licenses, Certifications, and Approvals

Subpart H provides requirements related to applications under part 53 for NRC licenses, certifications, or approvals for commercial nuclear plants.

Subpart H specifies requirements applicable to all part 53 applications as well as requirements specific to part 53 applications for LWAs, ESPs, standard design approvals, standard DCs, MLs, CPs, OLs, and COLs. Subpart H is equivalent to and includes all existing licensing, certification, and approval processes currently covered under parts 50 and 52, with the exception of the process for early review of site suitability issues. Interactions with external stakeholders during the development of the proposed rule did not identify significant interest in or need for including the process for early review of site suitability issues in part 53.

Much of the subpart H regulatory text is identical to the corresponding language in parts 50 and 52, with minor changes to account for cross-references in part 53, to make language technology neutral, or to reflect the unique analytical approach in part 53. In these instances, this preamble discussion will describe the language as "equivalent" to the existing corresponding requirement in part 50 or part 52 and will describe any deviations, where applicable.

Because part 53 carries over the majority of the licensing options from parts 50 and 52, there are several sections in subpart H that are similar to existing regulations in parts 50 and 52. Section 53.1100 addresses filing of applications for licenses, certifications, or approvals under oath or affirmation and is equivalent to § 50.30. Section 53.1100 does not include the current requirement in § 50.30(a)(2) that the applicant maintain the capability to generate additional copies, because it is unnecessary in the age of electronic submissions. In addition, the existing requirement on applications for OLs in § 50.30(d) is included in § 53.1124(g)(2), "Relationship between sections," covering OLs, rather than in § 53.1100. Section 53.1100(a)(1) also includes filing requirements equivalent to those in §§ 52.15, 52.45, 52.135, and 52.151. Section 53.1101 lays out activities requiring an NRC license and is equivalent to § 50.10(b). Section 53.1103 addresses combining applications and is equivalent to

§§ 50.31, 50.52, and 52.8. Section 53.1103(b) continues the Commission's practice of combining multiple authorizations for a facility under parts 30, 40, 50, 52, and 70 into one license based on the Commission's authority under section 161h of the AEA to combine NRC licenses. Section 53.1106 addresses elimination of repetition and is equivalent to § 50.32.

Section 53.1109 provides general information requirements for the content of applications submitted to the NRC under part 53 and is equivalent to § 50.33, with the exception of § 50.33(f) on financial qualifications, which is covered in subpart J, and § 50.33(h) on earliest and latest dates for completion of construction, which is covered in § 53.1306 of subpart H. Each application must include information to address the items in § 53.1109 as cited in the appropriate section of subpart H for the application type.

One change from current requirements can be found in § 53.1109(i), which is not limited to electricity generation as it is currently in part 50. Some prospective NRC applicants are considering development of nuclear plants for other commercial ventures, such as process heat generation or hydrogen production. In addition, § 53.1109(j), which requires applications containing classified information to separate that information from the unclassified information in the application, refers to "Restricted Data or classified National Security Information" instead of the term used in the corresponding provision in § 50.33(j), "Restricted Data or other defense information." This change was made to use the defined term in 10 CFR part 95, "Facility Security Clearance and Safeguarding of National Security Information and Restricted Data," rather than "defense information" as used in § 50.33(j). The usage in § 50.33(j) dates back to the Atomic Energy Commission amendment of that section on January 19, 1956 (21 FR 355, 357), and was not changed with the issuance of part 95 (45 FR 14476; March 5, 1980) after the establishment of the NRC and the 1975 reissuance of the former Atomic Energy Commission regulations. The revised terminology also aligns with its usage in § 53.1115.

Section 53.1112 addresses environmental conditions and is equivalent to § 50.36b. Section 53.1115 addresses requirements for agreements limiting access to classified information and is equivalent to § 50.37.

Section 53.1118 addresses ineligibility of certain applicants and is similar to § 50.38 but has been revised consistent with section 301 of the ADVANCE Act. That section of the ADVANCE Act designates certain exceptions from the foreign ownership, control, or domination (FOCD) provision set forth in the AEA. Specifically, section 301 states that if the Commission determines that issuance of the applicable license to that entity is not inimical to the common defense and security or public health and safety, then the FOCD restriction shall not apply to an entity that is owned, controlled, or dominated by: (1) the government of a country that is a member of the Organisation for Economic Co-operation and Development or the Republic of India; (2) a corporation that is incorporated in one of those countries; or (3) a citizen or national of one of those countries, subject to some additional exclusions. Those additional exclusions are based on whether any members of the excepted countries were on certain sanctions lists on the ADVANCE Act's date of enactment.

Section 53.1120 addresses exceptions and exemptions from licensing requirements for Department of Defense and DOE facilities and is equivalent to § 50.11. Section 53.1121 addresses public inspection of applications and is equivalent to § 50.39.

Section 53.1124 addresses the relationship between the various licenses, certifications, and approvals provided in this subpart, and the requirements are equivalent to a number of similar provisions in parts 50 and 52, including §§ 50.10, 52.13, 52.43, 52.73, 52.133, and 52.153. New provisions are provided in § 53.1124(c) and (d) that allow an application for either a standard design approval or a standard DC under part 53 to reference applicable licensing-basis information that supported issuance of an OL or COL under part 53. These provisions will offer additional flexibility

beyond what is currently allowed under parts 50 or 52 for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking generic approval or certification of the standard design.

Section 53.1124(e) addresses the limitation that a manufactured reactor may only be transported domestically to a site with a COL or CP and is generally equivalent to § 52.153. The NRC has not included specific requirements within part 53 directing how a CP application referencing an ML must be structured, including how the ITAAC required for an ML under § 53.1282 is to be addressed by a CP applicant. Instead, part 53 leaves the matter open to possible approaches to be addressed in future regulatory guidance or proposed by future applicants. Section 53.1124(e) includes an additional statement to make it clear that a manufactured reactor may be exported in accordance with part 110.

Section 53.1130 addresses LWAs and is equivalent to § 50.10.

Sections 53.1140 through 53.1188 address applications for, issuance of, and other provisions related to ESPs under part 53. Section 53.1140 describes how the contents of §§ 53.1140 through 53.1188 address ESPs and is equivalent to § 52.12. Section 53.1144 addresses general information requirements for the content of applications and is equivalent to § 52.16.

Section 53.1146 specifies requirements for the technical contents of applications and is equivalent to § 52.17. Section 53.1146(b)(2) provides applicants for ESPs a regulatory option to propose major features of the emergency plans or complete integrated emergency plans 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, as applicable.

Section 53.1149 addresses standards for review of ESP applications and administrative review of applications, including hearings, and is equivalent to §§ 52.18

and 52.21. Section 53.1155 addresses referral to the ACRS and is equivalent to § 52.23. Section 53.1158 addresses issuance of ESPs and is equivalent to § 52.24. Section 53.1161 addresses the extent of activities permitted and is equivalent to § 52.25. Section 53.1164 addresses the duration of an ESP and is equivalent to § 52.26. Section 53.1167 addresses provisions for requesting an LWA after issuance of an ESP and is equivalent to § 52.27. Section 53.1170 addresses transfers of ESPs and is equivalent to § 52.28. Section 53.1173 addresses applications for ESP renewals and is equivalent to § 52.29, although the final rule removes the requirement to refer the renewal to the ACRS consistent with current agency practice. Section 53.1176 addresses criteria for renewal of an ESP and is equivalent to § 52.31. Section 53.1179 addresses the duration of an ESP renewal and is equivalent to § 52.33. Section 53.1182 addresses the use of a site for purposes other than those described in the permit and is equivalent to § 52.35. Section 53.1188 addresses finality of ESP determinations and is equivalent to § 52.39.

Sections 53.1200 through 53.1221 address applications for, issuance of, and other provisions related to standard design approvals under part 53. Section 53.1200 describes how the contents of §§ 53.1200 through 53.1221 address standard design approvals and is equivalent to § 52.131. Section 53.1206 addresses general information requirements for the content of applications and is equivalent to § 52.136.

Section 53.1209 addresses requirements for the technical content of applications and is largely equivalent to § 52.137. In § 53.1209(a), the NRC includes text that expands the discussion of a “major portion” of standard design approvals. Additional discussion regarding standard design approvals for a major portion of a standard design can be found in the NRC’s “A Regulatory Review Roadmap for Non-Light Water Reactors,” which considers the Nuclear Innovation Alliance report “Clarifying ‘Major Portions’ of a Reactor Design in Support of a Standard Design Approval.”

Section 53.1209(b) outlines the required content of the Final Safety Analysis Report (FSAR). Requirements in § 53.1209(b)(2) for portions of the application addressing design information state that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements (specifically, those in § 53.1239(a)(2) through (27)) is an efficiency that prevents the need to repeat many of the same requirements for the content of a standard design approval application.

Section 53.1210 addresses requirements for the content of a standard design approval application other than the FSAR. Section 53.1210(a) requires the inclusion of a description of availability controls that are not included in the FSAR.

Section 53.1212 addresses standards for review of applications and is equivalent to § 52.139. Section 53.1215 addresses referral to the ACRS and is equivalent to § 52.141. Section 53.1218 addresses staff approval of designs and duration of design approvals and is equivalent to §§ 52.143 and 52.147. Section 53.1221 addresses finality of standard design approvals and information requests and is equivalent to § 52.145 with the exception that it extends such finality to a standard approval referenced in a DC application. Standard design approvals issued to date under part 52 have been issued during the NRC's review of the standard DC application and have relied on the same application content. However, a future scenario could arise where the DC application is not submitted until after a design approval has been granted. The NRC would apply the same finality provisions in this situation as in the situation where a standard design approval is referenced in a COL application.

There is no equivalent to § 53.1221(d) in part 52 for standard design approvals. This provision states that the Commission will require, before granting a CP, COL, OL, or ML that references a standard design approval, that information normally contained in engineering documents be completed and available for audit. A similar provision is

included in part 52 in relation to a standard DC; and the NRC would require that design and analysis information needed for the Commission to make its safety determination be complete and available for any application the NRC is reviewing. Making this explicit provides increased clarity to future standard design approval applicants under part 53.

Sections 53.1230 through 53.1263 address applications for, issuance of, and other provisions related to standard DCs under part 53. Section 53.1230 addresses general provisions for standard DCs and is equivalent to § 52.41. Section 53.1236 addresses general information requirements for the content of applications and is equivalent to § 52.46. Section 53.1239 addresses requirements for the technical content of applications and is equivalent to § 52.47(a). The requirements in § 53.1239 have been modified from the analogous requirements in § 52.47(a) to align with the technical requirements in part 53.

Section 53.1241 addresses requirements for the content of a standard DC application other than the FSAR and is equivalent to § 52.47(b) and (d).

Section 53.1242 addresses review of applications and is equivalent to §§ 52.48 and 52.51. Section 53.1242(c) includes a provision that allows a DC applicant to reference applicable licensing-basis information for an OL or COL issued under part 53. As explained previously, this provision explicitly allows flexibility for an applicant who may wish to license a first-of-a-kind reactor for operation prior to seeking certification of the generic reactor design. For NRC findings on a reactor design in an OL or COL proceeding, this provision provides finality in a subsequent DC application that references information on the OL or COL proceeding's docket. This finality accorded to the OL or COL findings would bind the NRC staff and the ACRS but would not bind members of the public or the Commission. (To the extent an Atomic Safety and Licensing Board (ASLB) might have a role in a DC rulemaking, the OL or COL findings would not bind the ASLB either.) Specifically, members of the public would have the

opportunity to comment on a proposed DC rule under well-established NRC practice. The rationale for binding the NRC staff and ACRS is similar to the rationale for a COL applicant referencing a standard design approval under part 52.

Section 53.1245 addresses referral to the ACRS and is equivalent to § 52.53. Section 53.1248 addresses issuance of standard DCs and is equivalent to § 52.54. Section 53.1251 addresses duration of certifications and is equivalent to § 52.55. Section 53.1254 addresses application for renewal and is equivalent to § 52.57, although the final rule removes the requirement to refer the renewal to the ACRS consistent with current agency practice. Section 53.1257 addresses criteria for renewal and is equivalent to § 52.59. Section 53.1260 addresses duration of renewals and is equivalent to § 52.61. Section 53.1263 addresses finality of standard DCs and is equivalent to § 52.63.

Sections 53.1270 through 53.1291 address applications for, issuance of, and other provisions related to MLs covering manufacturing activities at one or more licensee facilities under part 53. Section 53.1270 addresses the scope of these sections and is equivalent to § 52.151.

Section 53.1276 addresses general information requirements for the content of ML applications and is equivalent to § 52.156, with one exception. Section 53.1276 requires each application for an ML to also include the information required by § 53.1109(e). This information includes the type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator’s licenses, issued or applied for in connection with the proposed facility to address the potential variations in how MLs might be formulated under part 53.

Section 53.1279 addresses requirements for the technical content of applications for MLs to be included in the FSAR and is equivalent to § 52.157. In addition, the

requirements in § 53.1279(a) and (b) have been modified from the analogous requirements in § 52.157 to align with the technical requirements in part 53. Section 53.1279(a)(2) outlines the required content of the application addressing design information and states that the application must include design information equivalent to that required for a standard DC. This reference to the pertinent DC requirements is an efficiency that prevents the need to repeat the same requirements for the content of an ML application.

Section 53.1279(c) provides application requirements related to the deployment of the completed manufactured reactor. Section 53.1279(c)(1) requires inclusion of information related to the procedures governing the preparation of the manufactured reactor for shipping to the site where it is to be operated, the conduct of shipping, and the verification of the condition of the shipped items upon receipt at the site. Section 53.1279(c)(2) requires that the application include information on the interaction of the design, manufacture, and installation of a manufactured reactor within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, contractors, and any licensee of a facility in which the manufactured reactor is to be installed. Finally, § 53.1279(c)(3) requires that the application include a description of the measures used for the control of interfaces between the holder of the ML and the holder of the COL or CP for the commercial nuclear plant at which the manufactured reactor is to be installed. This information is necessary for the NRC to determine whether the applicant has appropriate controls in place to ensure coordination between parties involved in the design, manufacture, and eventual operation of any reactor manufactured under an ML.

Section 53.1279(d) includes additional requirements for application content for applicants seeking an ML for manufactured reactors that will be fueled at the factory under a part 70 license, consistent with the requirements in § 53.620(d). These

provisions require the application to include information related to loading fuel and the required features to prevent criticality and to otherwise provide assurance that the fueled manufactured reactor can be successfully transported, installed, and operated at a site for which the Commission has issued a COL or CP and OL that authorizes construction and operation of a commercial nuclear plant using the manufactured reactor.

Section 53.1282 provides requirements for other application content for MLs and is equivalent to § 52.158. Section 53.1282(a)(1) provides requirements to include in the ML application the ITAAC within the scope of the ML that the COL or CP holder referencing the ML must satisfy. Section 53.1282(a)(2) requires that the ITAAC from a referenced standard design apply to the portions of the ML design within the scope of the referenced standard design. Section 53.1282(a)(3) states that a COL application may include a notification that required referenced standard DC ITAAC have been satisfied at the manufacturing facility.

Section 53.1282(b) requires an ML application to include an environmental report and, consistent with existing requirements, § 53.1282(b)(2) notes that if the ML application references a standard DC, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

Section 53.1285 provides standards for review of applications and administrative review of applications for MLs, including hearings, and is equivalent to §§ 52.159 and 52.163.

Section 53.1286 addresses referral of applications to the ACRS and is equivalent to § 52.165. Section 53.1287 addresses issuance of an ML and is equivalent to § 52.167.

Section 53.1288 addresses finality of MLs and is equivalent to § 52.171, except that part 53 does not include the constraint that the Commission may only grant a

request for a departure from an ML for an applicant who references or uses a manufactured reactor if special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. This is consistent with the differences in the allowance for changes to a manufactured reactor in part 53 (as noted in the discussion of §§ 53.1530 and 53.1550 in this document) as compared to part 52. Section 53.1291 provides for a 40-year duration for an ML, consistent with the duration provided for a DC under § 53.1251. Section 53.1293 addresses the transfer of MLs and is equivalent to § 52.175. Section 53.1295 addresses the renewal of MLs and is equivalent to §§ 52.177, 52.179 and 52.181, with minor exceptions.

Section 53.1295(a)(3) states that an ML for which a timely application for renewal has been filed remains in effect until the Commission has made a final determination on the renewal application. However, this provision omits a limitation from the equivalent provision in § 52.177 which prohibits the holder of an ML from beginning the manufacture of a manufactured reactor less than 3 years before the expiration of the license. This limitation was omitted in part 53 because future reactor applicants may present smaller, simpler designs, to include microreactor designs, in ML applications than those that were envisioned when the existing requirements were written. Eliminating the 3-year constraint in this provision will provide greater flexibility for ML holders related to manufactured reactors being produced close to the time when the ML expires. Additionally, § 53.1295(c) provides for a 40-year term for a renewed ML, consistent with the term for an initial ML under § 53.1291. Finally, the final rule removes the requirement to refer the renewal to the ACRS consistent with current agency practice.

Sections 53.1300 through 53.1348 address applications for, issuance of, and other provisions related to CPs under part 53. Section 53.1300 sets out general requirements for CPs and is equivalent to § 50.23. Section 53.1306 addresses the

general information requirements for the content of applications for CPs and is similar to § 50.33(f) and (h). However, the requirements for demonstrating financial qualification are different for part 53 applicants than the existing requirements for applicants under part 50 or 52. The part 53 requirements do not include the existing requirements under part 50 or 52 for an applicant to provide information to demonstrate that it "possesses or has reasonable assurance of obtaining" the funds necessary for construction and operation along with associated financing details. Instead, part 53 replaces that requirement with a requirement to provide information that demonstrates that the applicant "appears to be financially qualified," similar to the standard used in § 70.23(a)(5).

Section 53.1309 addresses requirements for the technical content of applications for CPs and includes the requirement to submit a Preliminary Safety Analysis Report (PSAR) that describes the facility and presents a preliminary safety analysis of the facility as a whole. This is in contrast to an OL application, which is required to include an FSAR that describes the facility and presents a final safety analysis of the facility as a whole. Section 53.1309 is equivalent to § 52.17(a)(1)(iv) through (a)(1)(x) and 52.17(b), with two exceptions. First, § 53.1309 replaces the analysis of the dose criteria required by § 52.17(a)(1)(ix) with analysis to demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220. Second, § 53.1309(a)(2) adds a requirement for a CP application to include several categories of detailed design information, although § 53.1309(a)(2)(ii) allows certain relaxations of this requirement in view of aspects of a design that may not yet be fully developed. Section 53.1309 references the requirements for the content of an ESP application to address application requirements related to siting and references the requirements for the content of a DC application to address application requirements related to design of the commercial nuclear plant. Section 53.1309(a)(2)(ii) addresses the treatment of preliminary design information and

notes that information provided in the application may include some aspects of the design that are not fully developed. This provision requires that the completed design, including any changes during construction, be described in the FSAR in an application for an OL. This includes the requirement for a description of the PRA, other SREs, or a combination thereof required by § 53.450(a) and its results. Probabilistic risk assessments, other SREs, or a combination thereof developed for commercial nuclear plants prior to construction are based on the design and other information available at the time of the CP application. PRAs performed in early design stages or prior to construction may be inherently less detailed and may include projected information that will be subsequently verified or revised when the plant is built. Section 53.1309(a)(4) addresses preliminary description of the plans for coping with emergencies.

Section 53.1312 addresses other application content for CPs. Section 53.1312(a)(1) is equivalent to § 52.80(b) but is adapted for a CP application. Section 53.1312(a)(2) is equivalent to § 52.80(c) but is adapted for a CP application. Section 53.1312(b)(1) is equivalent to § 52.79(b), (c), and (d) but is adapted for a CP application. Section 53.1312(b)(2) is equivalent to portions of §§ 52.63(b)(1), 52.79(b)(1) through (b)(3), (c), and (d)(1) and (d)(3), 52.80, and 52.93(b) but is adapted for a CP application. Guidance for equivalent requirements in parts 50 and 52 is also addressed in RG 1.206, “Applications for Nuclear Power Plants,” Revision 1, section C.1.7.

Section 53.1315 addresses standards for review of applications and administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85 but is adapted for a CP application.

Section 53.1318 addresses finality of NRC approvals, licenses, and certifications referenced in a CP application and is equivalent to § 52.83(a) but is adapted for a CP application.

Section 53.1324 addresses referral to the ACRS and is equivalent to § 50.58(a) and to § 52.87 but is adapted for a CP application.

Section 53.1327 addresses authorization to conduct LWA activities and is equivalent to § 52.91 but is adapted for a CP application. Section 53.1327(a) is equivalent to § 52.91(a) but is adapted for a CP application. Section 53.1327(b) is equivalent to § 52.91(b) but is adapted for a CP application. Section 53.1330 addresses exemptions, departures, and variances for CP applicants.

Section 53.1333 addresses issuance of CPs. Section 53.1333(a) is equivalent to § 50.35(a). Section 53.1333(b) is equivalent to § 50.35(b) and to § 52.97(c) but is adapted for a CP application. Section 53.1336 addresses the effect of CPs and is equivalent to § 50.35(b). Section 53.1342 addresses the duration of CPs. Section 53.1342(a) is equivalent to § 50.55(a). Section 53.1342(b) is equivalent to § 50.55(b). Section 53.1345 addresses the transfer, assignment, and disposal of CPs and is equivalent to § 50.80. Section 53.1348 addresses the termination of CPs and is equivalent to §§ 52.3(b)(8) and 52.110(a)(1) but is adapted for a CP application.

Sections 53.1360 through 53.1405 address applications for, issuance of and other provisions related to OLs under part 53.

Section 53.1366 addresses requirements for the general content of applications for OLs. It refers to general content requirements in § 53.1109 and requires supplemental information. Section 53.1366 is similar to § 50.33(f). However, the requirements for demonstrating financial qualification are different for part 53 applicants than the existing requirements for applicants under part 50 or 52. The part 53 requirements do not include the existing requirements for an applicant to provide information to demonstrate that it “possesses or has reasonable assurance of obtaining” the funds necessary for construction and operation along with associated financing details. Instead, part 53 replaces that requirement with a requirement to provide

information that demonstrates that the applicant “appears to be financially qualified,” similar to the standard used in § 70.23(a)(5).

Section 53.1369 provides requirements for the technical content of applications for OLs to be included in the FSAR and is equivalent to § 50.34(b) but has been modified to align with the technical requirements in part 53. It requires that the FSAR include and, as needed, update information provided in the PSAR that was submitted and reviewed to support the associated CP application.

Similar to the requirements for the content of CP applications, § 53.1369(a) references the requirements for the content of an ESP application to address application requirements related to the site. Section 53.1369(b) references the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant.

Section 53.1369(d) requires a description of the Integrity Assessment Program that is required by § 53.870. Section 53.1369(e) is equivalent to § 50.34(e). Section 53.1369(g) provides requirements for OL application content to support § 53.730 related to the role of personnel in the operation of the commercial nuclear plant and is adapted from requirements in part 55 and § 50.34(f). Likewise, § 53.1369(h) provides requirements for OL application content related to training programs to support §§ 53.730(g) and 53.830 and includes requirements equivalent to § 50.34(b)(8), § 52.79(a)(33), and part 55. Section 53.1369(i) provides requirements for OL application content related to emergency plans to support § 53.855 and is equivalent to § 50.34(b)(6)(v).

Section 53.1369(j) provides requirements for OL application content related to the applicant’s organizational structure and is equivalent to § 50.34(b)(6)(i). Section 53.1369(k) provides requirements for OL application content related to the applicant’s proposed maintenance program to support § 53.715 and is equivalent to

§ 50.34(b)(6)(iv). Section 53.1369(l) provides requirements for OL application content related to the applicant's quality assurance program to support § 53.865 and is equivalent to § 50.34(b)(6)(ii). Section 53.1369(m) provides requirements for OL application content related to the applicant's proposed radiation protection program to support § 53.850 and is equivalent to § 50.34(b)(3).

Sections 53.1369(n) through (p) provide requirements for OL application content related to the applicant's proposed physical security program to support § 53.860(a) and are equivalent to § 50.34(c) and (d). Section 53.1369(q) provides requirements for OL application content related to the applicant's proposed cybersecurity plan to support § 53.860(d) and is equivalent to §§ 52.79(a)(36)(iv) and 73.54. Section 53.1369(r) provides requirements for OL application content related to the implementation of proposed security, safeguards, and cybersecurity plans to support § 53.860 and is equivalent to § 52.79(a)(35)(ii) and 52.79(a)(36)(iv) and (v).

Section 53.1369(s) provides requirements for OL application content related to the applicant's proposed fire protection program to support § 53.875 and is equivalent to § 52.79(a)(40). Section 53.1369(t) provides requirements for OL application content related to the applicant's proposed ISI and IST program to support § 53.880 and is equivalent to part of § 52.79(a)(11). Section 53.1369(w) provides requirements for OL application content related to the applicant's general employee training program to support § 53.830 and is equivalent to § 52.79(a)(33). Section 53.1369(x) provides requirements for OL application content related to the applicant's FFD program to support part 26 and is equivalent to § 52.79(a)(44). Section 53.1369(y) provides requirements for OL applicants' programs to demonstrate that any safety questions identified at the CP stage have been resolved and is equivalent to § 50.34(b)(5). Section 53.1369(z) provides requirements for OL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling

functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof to support § 53.440(a). It is largely equivalent to §§ 50.34(b)(5) and 50.43(e). Section 53.1369(aa) provides requirements for OL application content related to the applicant's proposed TS to support § 53.710(a) and is equivalent to § 50.34(b)(6)(vi).

Section 53.1372 addresses requirements for the content of OL applications other than the FSAR. Section 53.1372(a) requires submission of an environmental report and is equivalent to § 50.30(f) and § 51.53(b). Section 53.1372(b) does not have a direct parallel in parts 50 and 52 and requires the inclusion of a description of availability controls that are not included in the FSAR to support § 53.710(b).

Section 53.1375 addresses standards for review of OL applications and the administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85, except that the NRC has omitted 10 CFR part 54, "Requirements for Renewal of Operating Licenses for Nuclear Power Plants," from the list of standards in § 53.1375(a). Part 53 does not include detailed requirements related to renewal of licenses, although a general provision and possible placeholder for future requirements has been included as § 53.1595. The NRC will decide after the part 53 final rule is published whether this section will be retained in part 53 to address license renewal or whether the agency will take another approach to address license renewal for part 53 licensees, such as amending part 54 to address part 53 licensees.

Section 53.1381 addresses referral to the ACRS and is equivalent to §§ 50.58 and 52.87. Section 53.1384 addresses exemptions, departures, and variances for OL applicants. Section 53.1384(a) is equivalent to § 52.93 but is adapted for OLs. Section 53.1384(b) is equivalent to §§ 52.39(d) (with respect to ESPs) and 52.93 but is adapted for OLs.

Section 53.1387 addresses issuance of OLs. The introductory paragraph is equivalent to § 50.56. Section 53.1387(a)(1)(i) is equivalent to §§ 50.50 and 50.57(a)(1). Section 53.1387(a)(1)(ii) is equivalent to § 50.50. Section 53.1387(a)(1)(iii) is equivalent to § 50.57(a)(2). Section 53.1387(a)(1)(iv) is equivalent to § 50.57(a)(3). Section 53.1387(a)(1)(v) is equivalent to § 50.57(a)(4). Section 53.1387(a)(1)(vi) is equivalent to § 50.57(a)(6). Section 53.1387(a)(1)(vii) is equivalent to § 50.57(a)(5). Section 53.1387(a)(1)(viii) is equivalent to § 52.97(a)(1)(vi) but is adapted for OLs. Section 53.1387(c) is equivalent to § 50.57(b). Section 53.1387(d) is equivalent to §§ 50.36(b) and 50.50.

Section 53.1390 addresses backfitting of OLs and is equivalent to § 52.98(a) but adapted for an OL application. Section 53.1396 addresses duration of an OL and is equivalent to § 50.51(a) and § 52.104. Section 53.1399 addresses transfer, assignment, and other disposition of an OL and is equivalent to § 50.80. Section 53.1402 addresses applications for renewal of an OL and refers to § 53.1595. Section 53.1405 addresses continuation of an OL and is equivalent to § 52.109 but is adapted to address an OL.

Sections 53.1410 through 53.1461 address applications for, issuance of, and other provisions related to COLs under part 53. Section 53.1410 describes the contents of §§ 53.1410 through 53.1461 and is equivalent to § 52.71. Section 53.1413 addresses general information requirements for the content of applications for COLs and is equivalent to § 52.77, which references § 50.33. Most of the provisions from § 50.33 applicable to COLs are restated in § 53.1109. However, the requirements for demonstrating financial qualification are different for part 53 applicants than the existing requirements for applicants under part 50 or 52. The part 53 requirements do not include the existing requirements under part 50 or 52 for an applicant to provide information to demonstrate that it “possesses or has reasonable assurance of obtaining” the funds necessary for construction and operation along with associated financing details.

Instead, part 53 replaces that requirement with a requirement to provide information that demonstrates that the applicant “appears to be financially qualified,” similar to the standard used in § 70.23(a)(5).

Section 53.1416 addresses the technical content to be included in an FSAR for an application for a COL and is equivalent to § 52.79 except as modified to reflect the technical requirements in part 53 and with one addition. Section 53.1416 includes the statement that the Commission will require, before issuance of a COL, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. This statement is equivalent to DC application requirements in § 52.47 and is included in § 53.1416 for clarity.

Similar to the requirements for the content of OL applications, § 53.1416(a)(1) references the requirements for the content of an ESP application to address application requirements related to siting. Section 53.1416(a)(2) references the requirements for the content of a DC application to address some of the application requirements related to design of the commercial nuclear plant. The remaining items under § 53.1416(a) are likewise similar to the required content for OL applications under § 53.1369(a). Section 53.1416(b) requires COL applicants to provide a report documenting the resolution of any safety questions for SSCs for which research and development was necessary to confirm the adequacy of their design and is equivalent to § 50.34(b)(5). Section 53.1416(c) provides requirements for COL applicants to describe how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination

thereof to support § 53.440(a). It is largely equivalent to §§ 52.79(a)(24) and 50.43(e). Section 53.1416(d) addresses the content of COL applications referencing an ESP. Section 53.1416(e) addresses the content of COL applications referencing a standard design approval. Section 53.1416(f) addresses the content of COL applications referencing a standard DC. Section 53.1416(g) addresses the content of COL applications referencing an ML.

Section 53.1419 addresses other application content for COLs and is equivalent to § 52.80. Section 53.1419(a)(2) is new and requires the inclusion of a description of availability controls that are not required to be included in the FSAR.

Section 53.1422 addresses standards for review of applications and the administrative review of applications, including hearings, and is equivalent to §§ 52.81 and 52.85. The NRC has removed part 54 from the list of standards in § 53.1422(a). Part 53 does not include requirements related to renewal of licenses, in relation to §§ 53.1422 and 53.1595.

Section 53.1425 addresses the finality of NRC approvals referenced in a COL application and is equivalent to § 52.83(a). Section 53.1431 addresses the referral of COL applications to the ACRS for review and is equivalent to § 52.87. Section 53.1434 addresses the authorization to conduct LWA activities and is equivalent to § 52.91. Section 53.1437 addresses exemptions, departures, and variances and is equivalent to § 52.93. Section 53.1440 addresses issuance of COLs and is equivalent to § 52.97. Section 53.1443 addresses finality of COLs and is equivalent to § 52.98.

Section 53.1449 addresses inspection during construction and is equivalent to § 52.99. Section 53.1452 addresses operation under a COL and is equivalent to § 52.103. Paragraph § 53.1452(a) includes footnotes to provide that, for licensees installing fueled manufactured reactors under a COL, (1) the COL holder will notify the NRC of its scheduled date for initiating the removal of the features to prevent criticality

required under § 53.620(d)(1) rather than its scheduled date for the initial loading of fuel, and (2) the NRC will time its publication of the notice of intended operation based on the COL holder's schedule for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) rather than the COL holder's scheduled date for the initial loading of fuel. These footnotes are consistent with the provisions of § 53.620(d)(1)(iv), which state that, upon initiating the removal of the features to prevent criticality in the manufactured reactor's place of operation, the fueled manufactured reactor has commenced operation. For reactors without the features to prevent criticality under § 53.620(d)(1), operation begins with initial fuel load. In both cases, removal of the physical features to prevent criticality (for reactors with such features) and initial fuel load (for reactors without such features) put a fully constructed utilization facility in a position to sustain a nuclear chain reaction, and in both cases, the utilization facility cannot sustain a nuclear chain reaction (for lack of sufficient reactivity) until the action takes place. Therefore, the NRC believes that initiating the removal of the features to prevent criticality is the best analogue to initial loading of fuel for reactors without such features.

The footnote in § 53.1452(a) regarding timing of the notice of intended operation for fueled manufactured reactors with features to prevent criticality also addresses the requirements of section 189a.(1)(B)(i) of the AEA. This section requires, in part, that "[n]ot less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a combined construction permit and operating license under section 185b., the Commission shall publish in the *Federal Register* notice of intended operation." That section further requires that this notice provide a 60-day period in which to request a hearing "on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria of the license." In the case where a fueled manufactured reactor arrives at the site where it is to be operated by a COL holder, the manufacturer would have loaded fuel at the factory under its part 70 license.

Therefore, at the site of operation, there would not be "initial loading of fuel into a plant *by a licensee that has been issued a combined construction permit and operating license*" (emphasis added). Under a literal reading of the entry condition in Act section 189a.(1)(B)(i), this situation would not trigger its requirements. However, the purpose of the provision is to offer the hearing opportunity at least 180 days prior to when the fuel is loaded and ready for use at its authorized location. It would be contrary to that purpose if, in this situation, the Commission did not publish the notice of intended operation and opportunity for the public to request a hearing on conformance with the acceptance criteria in the COL for the site of operation. To fulfill the underlying purpose of the law, the NRC is timing the notice of intended operation based on the COL holder's schedule for initiating the removal of the features to prevent criticality required under § 53.620(d)(1). This action by the COL holder is the best analogue to initial fuel load by the COL holder for the reasons stated previously. This analogue is adopted in other sections of part 53 and related sections in parts 50 and 73 that use initial fuel loading to identify a transition point for the applicability of regulatory requirements. To address the possible loading of fuel into a manufactured reactor for subsequent transport to and use at a commercial nuclear plant, multiple sections that determine the applicability of regulations have been developed or revised to allow for either initial fuel load or initiating the removal of the features to prevent criticality required under § 53.620(d)(1) for a fueled manufactured reactor to determine the applicability of the requirement, as appropriate.

Section 53.1455 addresses duration of COL and is equivalent to § 52.104. Section 53.1456 addresses the transfer of a COL and is equivalent to § 52.105. Section 53.1458 addresses application for renewal and is equivalent to § 52.107. Section 53.1461 addresses continuation of COL and is equivalent to § 52.109.

Section 53.1470 addresses standardization of commercial nuclear plant designs and licenses to construct and operate commercial power reactors of identical design at multiple sites and is equivalent to appendix N to part 52, with one exception. Paragraph § 53.1470(b) provides flexibility regarding the timing of the applications to be treated together under § 53.1470. Each application can either list the other applications or specify that such other applications will be submitted to the NRC within 12 months of submittal of the first application. This section sets out the particular requirements and provisions applicable to situations in which applications for CPs and subsequent OLs, or COLs, under this part are filed by one or more applicants for licenses to construct and operate nuclear power reactors of identical design ("common design") to be located at multiple sites. Additional information related to this section is provided in the final rule to revise part 52 (72 FR 49352; August 28, 2007).

Subpart I—Maintaining and Revising Licensing-Basis Information

Part 53 establishes requirements for the maintenance of licensing-basis information in subpart I.

Section 53.1500 describes the purpose of the subpart in terms of the definition of licensing-basis information in subpart A. Subpart I is closely tied to the requirements in subpart H, which provides the requirements for contents of applications for the various types of licenses issued under part 53. Subpart I is generally organized into sections dealing with: (1) licensing-basis information that licensees are not authorized to change without NRC approval (e.g., licenses, regulations); and (2) licensing-basis documents that licensees may change provided specified criteria are satisfied (e.g., FSAR, program descriptions). The subpart also captures certain general conditions on licenses and changes to the licenses related to the transfer and termination of licenses.

Section 53.1502 defines specific terms and conditions of licenses. These terms and conditions are equivalent to the regulations in: (1) § 50.54(h) stating that each license is subject to the provisions of the AEA and requirements issued by the Commission; (2) § 50.54(s) stating the actions the Commission will take if it makes a finding that there is not reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency; (3) § 50.54(aa) stating that each license is subject to the specified sections of the Federal Water Pollution Control Act; and (4) § 50.54(dd) stating that a holder of an OL or COL may take reasonable actions that depart from the license in a national security emergency.

Section 53.1505(a) serves as an introduction to and overview of the sections that follow on changes to licensing-basis information requiring prior NRC approval, namely the elements of licensing-basis information defined by licenses, orders, and regulations. The related sections within these subparts primarily deal with the process of how a licensee requests and the NRC issues an amendment to a license or issues an order that modifies a license. Another important element of licensing-basis information that a part 53 licensee is not able to change or deviate from without NRC approval is the NRC regulations themselves. Section 53.1505(b) refers to § 53.080 in subpart A that provides the criteria for a licensee or other party to satisfy when requesting an exemption from NRC regulations.

Section 53.1510 is equivalent to § 50.90 and requires that a licensee submit an application to request an amendment to a license. The required assessments that are included within an application to amend a license under part 53 must address the safety criteria and analysis requirements of subparts B and C. As with parts 50 and 52, licensees must include in their applications an analysis of whether the amendment involves no significant hazards consideration using the standards in § 53.1520, which are equivalent to the standards in § 50.92. Although this rulemaking provided an

opportunity to revise the terminology related to no significant hazards consideration determinations, which dates to the early 1960s when applications were supported by final hazard summary reports, the NRC is maintaining the same terminology used in part 50 to minimize the need for associated changes in other regulations, guidance, and public notices.

Section 53.1515 establishes requirements for public notices and state consultations associated with the NRC's processing of a license amendment request. This section is equivalent to § 50.91 for the NRC's processes related to applications to amend an OL or COL. Section 50.91(b) stipulates that the Commission will make available to the licensee the name of the appropriate State official designated to receive such amendments. While the Commission intends to continue following this practice, the Commission has not included this administrative matter in part 53. Section 53.1515(b)(3) contains some modifications compared to § 50.91(b)(3) for clarity; these revisions are not intended to revise the substance of the provisions in part 53 compared to part 50.

Section 53.1520 is based on § 50.92. The section continues to use the criteria in § 50.92 for determining that a proposed amendment involves no significant hazards consideration. Although more specific terms such as event sequence are used throughout part 53, § 53.1520 uses the term "accident" to maintain consistency with the long history of making no significant hazards consideration determinations under part 50.

Section 53.1525 provides requirements for holders of an OL or COL requesting to revise information from a DC rule that was referenced in the initial license application and included in or incorporated by reference into the facility FSAR. In keeping with the current requirements in part 52, the portion of the part 53 facility licensing-basis information obtained from the certified design is divided into two categories. The most significant design information and the ITAAC are certified by rule and designated as "certification information." The remaining information, which makes up the majority of the

design information approved as part of the DC, is not certified by rule and is not considered “certification information.” Part 52 refers to these categories of information as Tier 1 and Tier 2 information, respectively, and refers to a change made to that information on a plant-specific basis as a departure. Under part 52, a departure from Tier 1 information requires an exemption and, for information incorporated into the license, a license amendment.

Part 53 dispenses with the Tier 1 and Tier 2 terminology. Rather, § 53.1525 uses the term “certification information” in place of Tier 1, and a plant-specific departure from the certification information requires both a request for an exemption from the associated DC rule and, for information such as ITAAC incorporated into the license, a license amendment. However, as provided in § 53.1525(c), a plant-specific departure from the information approved by the NRC as part of the DC rule but that is not certification information (i.e., Tier 2 information under part 52) will be assessed using the process and criteria defined in § 53.1550 for changes to a FSAR. An applicant or licensee must identify such a change as a departure from the referenced standard design in the updated FSAR. The process for making a generic change to a certified design is described in the associated section in subpart H.

Section 53.1530 allows the holder of an ML to make changes to the design of the manufactured reactor or procedures as described in a FSAR associated with the ML without requesting a license amendment from the NRC if the change satisfies the criteria in § 53.1550(a)(1) and (2). This section is different than the provisions in §§ 52.98 and 52.171 that do not allow any changes to the design of a manufactured reactor without requesting a license amendment. A COL or OL holder who references or uses a manufactured reactor may make changes to the facility or procedures described in an FSAR, including those portions incorporated by reference from the FSAR associated with the ML, using § 53.1550 to determine if a license amendment is required.

Section 53.1535 establishes requirements for license amendments during construction. The section provides the equivalent options and requirements for the holders of a CP as those in § 50.35(b). The regulations allow but do not require the holder of a CP or LWA to request an amendment under § 53.1510 if the licensee desires to obtain NRC approval of a specific design feature or specification. The requirements for obtaining an amendment to a COL to address changes during construction are also provided in § 53.1535. The process differs from the current requirements in part 52 by adopting a requirement that explicitly supports a change process like that described in RG 1.237, "Guidance for Changes During Construction for New Nuclear Power Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR Part 52." Section 53.1535 allows the holder of a COL to proceed at its own risk in making a change during the construction process and requires that licensee to submit a license amendment request no later than 45 days from the date the licensee begins to implement the change or departure requiring NRC approval.

Section 53.1540 serves as an introduction to the sections that follow on changes to licensing-basis information that are primarily under the control of a licensee but for which evaluations are made to determine if a submittal to the NRC requesting approval is required. The section also includes definitions that are applicable when using the processes in §§ 53.1545 through 53.1565. The definitions are largely equivalent to those in § 50.59(a) but include some revision to reflect the structure and terminology in other subparts in part 53. For example, the definition of "*Change*" in § 53.1540(b) addresses a "design feature or related functional design criteria" rather than a "design function," because the former are defined terms in part 53. Similarly, in § 53.1540(b), the phrase "design bases" from § 50.59(a)(2) is replaced with functional design criteria for SR SSCs.

Section 53.1545 provides the requirements for updating of FSARs. While the process-related requirements under § 53.1545 are largely the same as those in § 50.71, the specifics of information to be updated differ due to the role of PRA, other SREs, or a combination thereof in satisfying the requirements in subparts B and C. Additionally, the use of the risk-informed approach in subpart C will result in some but not all information related to PRA, other SREs, or a combination thereof being in the FSAR or another licensing-basis document and therefore a separate update requirement for PRA, other SREs, or a combination thereof similar to § 50.71(h) is not included in subpart I. Section 53.1545(e) addresses updating of FSARs associated with MLs and includes periodic updates to reflect the added flexibility for ML holders to revise the FSAR associated with the ML under § 53.1530.

Section 53.1239(a)(18) in subpart H and the related references to this requirement for the holders of OLs and COLs requires a description of the PRA, other SREs, or a combination thereof required by § 53.450(a) and its results to be included in FSARs. However, guidance documents are planned to clarify the division of information related to PRA, other SREs, or a combination thereof that must be in the FSAR, in other possible licensing-basis documents, and controlled as plant records subject to inspections and audits. At a minimum, the information from the PRA, other SREs, or a combination thereof that is needed to show compliance with subpart C will be included in the FSAR (e.g., summary of PRA, other SREs, or a combination thereof and analytical results for LBEs). The submittal of voluminous PRA information was initially required under part 52, but that proved to be impractical and was revised in the 2007 revision of part 52. Guidance is being developed to ensure sufficient information is submitted to the NRC to support the licensing process and the NRC’s regulatory findings under part 53 or similar applications using the LMP methodology under parts 50 or 52.

Section 53.1545(a)(3) and (4) are based on the inclusion of at least a summary of the results of the PRA, other SREs, or a combination thereof and the related margins to safety criteria in the FSAR and require updates to that information. The routine reporting of these margins also informs application of the criteria for allowing changes without an amendment in the following section (§ 53.1550) in subpart I.

Section 53.1550 establishes requirements for evaluating changes to a facility as described in its FSAR. This section provides the equivalent of the requirements in § 50.59 for evaluating changes to an FSAR (as updated) and determining if a license amendment is required to implement a change to a facility or procedures. The evaluation criteria in § 53.1550 reflect the role of the PRA, other SREs, or a combination thereof in the safety analyses under part 53 and include several measures related to the changes in plant risk resulting from a change in the plant design or plant procedures. Examples include criteria that rely on the identification of risk-significant event sequences in accordance with the analysis requirements of § 53.450; exceeding the LBE evaluation criteria as defined in § 53.450; the consideration of potential changes in estimated comprehensive risk metrics that exceed the associated risk performance objectives in the safety criteria in § 53.220; changes to the safety classification of SSCs; and consideration of reductions in defense in depth.

Section 53.1550 includes certain concepts taken from existing guidance for § 50.59 in the criteria related to DBAs and aligns with recently developed industry guidance in NEI 22-05, Revision 0, “Technology Inclusive Risk Informed Change Evaluation (TIRICE).” Specifically, criterion (iv) for changes made to a method of evaluation of DBAs under § 53.450(f) is equivalent to a change in a method of evaluation under § 50.59, and criterion (viii) on assessing if a change creates a possibility for an accident of a different type than previously analyzed in the FSAR is similar to the § 50.59 criterion (v). Criterion (v) in § 53.1550 differs from the corresponding criterion in NEI 22-

05 in that it does not include changes to safety classification of SSCs from non-safety related or NSRSS to SR because plant changes introducing new SR SSCs would require a change to technical specifications under § 53.710. Guidance documents will be prepared to address the content of applications for information related to PRA, other SREs, or a combination thereof under part 53, and this guidance will also influence how potential changes in the evaluation of LBEs other than DBAs analyzed under § 53.450(e) are evaluated and reported under criterion (iv).

Sections 53.1560 through 53.1565 in subpart I define the processes for a licensee to evaluate changes to the program documents included in the licensing-basis information submitted to the NRC and to modify such programs without NRC prior approval.

Section 53.1560 includes the requirements for updating program documents included in licensing-basis information and provides the equivalent of FSAR updates for key program documents. The requirements in these sections provide a uniform approach for updating program documents, which correspond to the programs required under subpart F.

Section 53.1565 provides a process for licensees to make changes to program documents included in licensing-basis information without obtaining prior NRC approval. The requirements include several generic criteria that, if not satisfied, will prompt the need for NRC approval of a change to a program document. These generic criteria include whether a change will comply with TS and NRC regulations. Another criterion for evaluating changes to program documents is conforming with program-specific requirements, including NRC-approved program documents with more specific criteria for a particular program, regulations, administrative controls sections of TS, and NRC-approved program documents.

Section 53.1565(d) includes specific criteria for evaluating changes to several program documents that have well established change processes and guidance for licensees under parts 50 and 52. The program documents specifically addressed in the section include quality assurance programs that are equivalent to § 50.54(a), an emergency preparedness program that is equivalent to § 50.54(q), and the security program that is equivalent to § 50.54(p).

Section 53.1570 establishes requirements for the transfer of commercial nuclear plant licenses by providing the equivalent requirements of § 50.80 for the possible transfer of an ESP, CP, OL, or COL. Likewise, § 53.1575 establishes requirements for the termination of an OL or COL by providing the equivalent requirements of § 50.82. Other requirements related to decommissioning and license termination are included in subpart G.

Section 53.1580 establishes requirements for information requests the NRC may send to the various types of licensees and provides requirements that are equivalent to requirements in § 50.54(f). Section 53.1585 provides the requirements that are equivalent to requirements in § 50.100 to address revocation, suspension, modification of licenses, and approvals for cause. Section 53.1590 addresses backfitting requirements by providing requirements that are similar to those in § 50.109.

Section 53.1595 addresses license renewals under part 53 with a simple statement that licenses may be renewed. This section may be expanded through future rulemakings to more fully describe or reference the processes related to requesting and processing applications to renew ESPs, OLs, and COLs issued under part 53.

Subpart J—Reporting and Other Administrative Requirements

Part 53 addresses various reporting and administrative requirements in subpart J.

Section 53.1600 explains the organization of the various sections within the subpart related to providing unfettered access to NRC inspectors; maintaining certain records and reporting specified events or conditions; demonstrating compliance with financial qualification requirements and providing specified financial reports; and maintaining financial protections to address potential accidents.

Section 53.1610 establishes requirements for the provision of facilities and unfettered access for inspections. These requirements are equivalent to § 50.70 with only minor changes to provide additional flexibilities and address possible differences related to reactors licensed under part 53 and the possibility that some commercial nuclear plants may not be assigned resident inspectors.

Section 53.1620 provides for maintenance of records and the making of various reports to the NRC. These requirements are largely equivalent to § 50.71. This section is not intended to reflect all provisions in § 50.71; several important requirements in § 50.71 are captured in other sections of part 53. For example, § 53.1545 within subpart I provides requirements that are equivalent to § 50.71(e) for updating FSARs. A reporting requirement related to completion of power ascension testing is added to § 53.1620 to support the assessment of annual fees under 10 CFR part 171, “Annual Fees for Reactor Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,” which normally commence upon completion of those testing activities.

Section 53.1630 establishes requirements for immediate notification requirements for operating commercial nuclear plants. These requirements are equivalent to § 50.72 with minor changes to make the reporting criteria technology-inclusive. In addition, a new version of NRC Form 361 (NRC Form 361S) has been created for use by part 53 licensees, but without LWR-specific terminology to ensure

technology-inclusiveness. The requirements in § 53.1630 and the new NRC Form 361S are consistent with changes to § 50.72 proposed to the Commission in SECY-24-0049, “Proposed Rule: Reporting Requirements for Nonemergency Events at Nuclear Power Plants (RIN 3150-AK71; NRC-2020-0036),” to eliminate those nonemergency event reporting criteria that are not important to safety, do not require prompt action from the NRC, or can be tracked using other existing agency processes.

Section 53.1640 addresses the licensee event report system. These requirements are equivalent to § 50.73 with minor changes to make the requirements inclusive of various reactor technologies and to reflect appropriate internal references to other sections in part 53. In addition, NRC Forms 366, 366A, and 366B are revised to include corresponding check boxes for part 53 licensees.

Section 53.1645 requires periodic reporting of the quantity of radionuclides released to unrestricted areas in liquid and gaseous effluents, doses to members of the public, and the results of environmental monitoring. These reporting requirements in part 53 are largely equivalent to those in the TSs required by § 50.36a, “Technical specifications on effluents from nuclear power reactors.” The section also includes an equivalent to the reporting requirement in section IV of appendix I to part 50 if the radiation exposure to a member of the public in any calendar quarter exceeds one-half of the annual design objective.

Section 53.1650 includes a reporting requirement to support safeguards agreements between the United States and the International Atomic Energy Agency (IAEA) and is equivalent to § 50.78.

Sections 53.1660 through 53.1700 address financial requirements and are somewhat different than existing regulations in parts 50 and 52. The part 53 requirements do not include the existing part 50 and 52 requirement for an applicant to demonstrate that it “possesses or has reasonable assurance of obtaining” the funds

necessary for construction and operation. Instead, part 53 replaces that requirement with an “appears to be financially qualified” standard similar to the standard in § 70.23(a)(5). Section 53.1670 is entitled “Financial qualifications” and requires applicants other than electric utilities to appear to be financially qualified for the activities for which the license is being sought. The remaining financial reports in part 53 are equivalent to § 50.76 for a change of status, § 50.54(cc) for the filing of a petition for bankruptcy, and § 50.81 for creditor regulations. Part 53 does not contain a requirement for annual financial reports equivalent to § 50.71(b) because these reports are not actively used by the NRC to assess a licensee but could be accessed in the event that the NRC deems it necessary to look into a licensee's financial situation due to events such as a declaration of bankruptcy.

Sections 53.1710 through 53.1730 address financial protection requirements. Section 53.1720 requires insurance to stabilize and decontaminate a plant following an accident. These requirements are taken from § 50.54(w), with the only notable change being the addition of a provision allowing plant-specific estimates of costs to stabilize and decontaminate a plant as an alternative to the $1.06 billion minimum coverage in § 50.54(w). An example of cost estimations that, in part, provided a basis for the requirements in § 50.54(w) is provided in NUREG/CR-2601, “Technology, Safety and Costs of Decommissioning Reference Light Water Reactors Following Postulated Accidents.” Section 53.1730 is equivalent to § 50.57(a)(5) and refers to the requirements in 10 CFR part 140, “Financial Protection Requirements and Indemnity,” related to financial protection requirements and indemnity agreements, including the financial protection requirements of the Price-Anderson Act.

Subpart M—Enforcement

Subpart M contains two provisions, § 53.9000 and § 53.9010, which are analogous to provisions contained in other parts of 10 CFR chapter I imposing requirements on regulated entities. Section 53.9000 provides notice of the Commission's authority under the AEA to obtain injunctions or other court orders for the enumerated violations. Paragraph § 53.9010(a) provides notice to all persons and entities subject to part 53 that they are subject to criminal sanctions for willful violations, attempted violations, or conspiracy to violate certain regulations under part 53. Criminal sanctions do not apply to the regulations listed in paragraph (b). The regulations for which criminal penalties do apply are limited to those that establish either a regulatory obligation or prohibition.

IV. Changes to Other Parts of 10 CFR Chapter I

10 CFR Part 26

A. Introduction

Through this final rule, the NRC is establishing a technology-inclusive, risk-informed, and performance-based approach for the application of drug and alcohol testing and fatigue management requirements for facilities licensed under part 53. The requirements applicable to these applicants, licensees, and other entities are commensurate with the radiological consequences presented by the applicants' facilities and the operation of these facilities.[2] The FFD framework consists of a two-tiered graded approach similar to that currently in part 26. This new FFD framework is established in subpart M, "Fitness-for-Duty Programs for Facilities Licensed Under Part 53," of part 26.

The NRC is using operating experience to provide regulatory flexibility in the subpart M of part 26 framework to help support a licensee's or other entity's response to

[2] The NRC uses the term "operation" in its part 26 discussion to focus on human performance, namely the necessity of individuals to operate, maintain, surveil, and protect the facility and respond to operational transients and unlikely event sequences.

changes in societal drug use, drug testing technologies and processes, and FFD program performance. The flexibility also helps in FFD program implementation because of the wide variety of staff sizes anticipated at commercial nuclear plants licensed under part 53 and the geographically remote locations in which commercial nuclear plants may be sited.

The first-tier FFD program requirements apply to part 53 licensees and other entities of commercial nuclear plants that demonstrate compliance with § 73.100(a)(1)(i), at their discretion, no later than the start of construction activities; licensees and other entities of facilities that do not demonstrate compliance with § 73.100(a)(1)(i) no later than the start of construction activities; and holders of MLs who are assembling or performing non-operational testing of manufactured reactors. These requirements are provided in § 26.605(a) and are essentially equivalent to those requirements in subpart K, “FFD Program for Construction,” of part 26 but have been supplemented by select requirements from subparts E, “Collecting Specimens for Testing,” and I, “Managing Fatigue,” of part 26, and the requirements in subparts A, “Administrative Provisions,” and O, “Inspection, Violations, and Penalties,” of part 26. The first-tier requirements involve policies, procedures, behavioral observation, fatigue management, drug and alcohol testing, determinations of fitness, appeals, training, sanctions, auditing, change control, evaluating FFD program performance, recordkeeping, and reporting. These § 26.605(a) FFD program requirements help deter individuals subject to this section from impairment from any cause, including drug use, alcohol misuse, and fatigue. These requirements also help licensees and other entities identify individuals using impairing substances and demonstrate compliance with § 26.23, “Performance objectives.”

The second tier includes all the first-tier requirements, plus the more comprehensive set of FFD program requirements in current subparts C, “Granting and Maintaining Authorization,” D, “Management Actions and Sanctions to be Imposed,”

H, “Determining Fitness-for-Duty Policy Violations and Determining Fitness,” and N, “Recordkeeping and Reporting Requirements,” of part 26. These requirements are provided in § 26.605(b) and are applicable to licensees and other entities that demonstrate compliance with § 73.100(a)(1)(i), if they do not choose to comply with § 26.605(a). These licensees and other entities need to implement the FFD program before they begin construction. Section 26.605(b) also applies to holders of manufacturing licenses if they possess a separate license to load fuel into a manufactured reactor. These licensees must implement their FFD program no later than when they begin loading fuel into the reactor. These requirements also apply to licensees or other entities that do not demonstrate compliance with § 73.100(a)(1)(i) that implement an FFD program under subpart M of part 26 before the loading of fuel onsite into a reactor vessel; before receiving a fueled manufactured reactor; or before operating, testing, performing maintenance of, or directing the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety.

The second-tier requirements are based on the additional risk presented by nuclear reactor assembly, testing, fueling, and operation and the necessity for human actions in certain event sequences. The inclusion of the current part 26 requirements aligns part 53 FFD and AA program requirements with the current FFD and AA programs required for facilities licensed under parts 50 and 52. This approach ensures effective and consistent AA and FFD program implementation across the commercial nuclear power industry, thereby ensuring uniform requirements for individuals who may perform roles and responsibilities for multiple facilities regardless of facility licensure.

Regarding fatigue management requirements, work hour controls are required for personnel at utilization and manufacturing facilities in accordance with the existing scoping criteria in § 26.4, “FFD program applicability to categories of individuals,” as

revised in this final rule. The amended § 26.4 also will be used to determine whether an individual is subject to drug and alcohol testing. The applicability of these scoping criteria for certain individuals (such as operators and maintenance personnel) will be determined by the licensee or other entity through its risk-informed evaluation process performed to assess the risk significance of the SSC upon which work is being performed or directed by the individual. These requirements also will be scaled based on the potential radiological consequences presented by the facility, as determined by whether the facility demonstrates compliance with § 73.100(a)(1)(i). However, fatigue management will be applied to all individuals subject to the FFD program, similar to FFD program implementation by the current fleet of commercial nuclear plants because fatigue management is a proactive requirement designed to help prevent on-shift impairment through work hour scheduling and time off. The behavioral observation program (BOP) is the principal requirement to provide reasonable assurance that individuals on shift are not mentally or physically impaired due to fatigue, which in any way could adversely affect their ability to safely and competently perform their duties.

This final rule establishes subpart M of part 26 for facilities licensed under part 53, in lieu of subjecting all part 53 licensees to the same part 26 requirements that apply to facilities licensed under part 50 or 52, for four principal reasons. First, subpart M of part 26 applies FFD requirements in a risk-informed manner commensurate with the radiological consequences presented by facilities licensed under part 53 (i.e., whether a facility demonstrates compliance with § 73.100(a)(1)(i)). This regulatory strategy is consistent with the current part 26, which provides a comprehensive set of deterministic requirements for licensees and other entities at facilities that are operating. This approach is also consistent with the current subpart K of part 26, which provides a more flexible framework for nuclear power reactors under construction.

Second, subpart M of part 26 enables a part 53 licensee or other entity to implement innovative drug testing technologies and behavior observation techniques while continuing to demonstrate compliance with the part 26 performance objective in § 26.23(b) of providing reasonable assurance that individuals are not under the influence of any substance or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform assigned duties. These technologies include drug testing of oral fluid, urine, and hair specimens and non-invasive portal area screening instruments that passively test for drugs, alcohol, or both. Part of the basis to enable the use of innovative drug and alcohol testing technologies, should they become available, is to maintain FFD program effectiveness should the staff size at a part 53 commercial nuclear plant be small and challenge the effective implementation of the behavioral observation and drug and alcohol testing programs. Also, a commercial nuclear plant that is sited at a geographically remote location may present additional challenges not encountered by traditional LWR facilities licensed under part 50 or 52, such as: efficiency of postal services for shipping and controlling biological specimens; proximity to drug and alcohol collection facilities that are reasonably equivalent to that described in subpart E of part 26; availability of internet and cellular services to enable same-time discussions among the Medical Review Officer (MRO), donor, and laboratory; accessibility to substance abuse treatment services described in subpart H of part 26; and proximity to an MRO (or management and clinical staff) to evaluate potential impairment caused by fatigue and/or substance use or abuse, for-cause and post-event occurrences, and the individual's potential to return to duty.

A part 53 commercial nuclear plant that is sited in a geographically remote location and has a small staff size may present implementation challenges and the potential for small group dynamics to impact FFD program effectiveness. Particularly in

isolated environments, psychological phenomena known as “groupthink” may take effect and could impact BOP effectiveness. For example, in circumstances where small staffs are drawn from the same small town and thereby have a potentially narrow experience base, it could be challenging to maintain a work environment in which personnel feel free to raise concerns without fear of retaliation, intimidation, harassment, or discrimination, and organizations may resultingly experience groupthink-like effects. Groupthink is particularly prevalent among cohesive and insulated groups that experience high levels of decisional stress.[3] Small staffs at part 53 commercial nuclear plants may therefore be more susceptible to groupthink if they are working in an isolated environment where decision-making pressures may be high.

In small group dynamics, groupthink could have adverse effects on team decision-making, as studies show that individuals will be more hesitant to speak out against practices they deem unsafe for fear of deviating from group norms.[4] Individuals may also be unaware of systematic biases in the group decision-making process and may then be less likely to scrutinize the potential risks of the group’s decision or sufficiently contemplate alternative paths of action.[5] Furthermore, the literature indicates that groups make riskier decisions than individuals acting alone due to the diffusion of

[3] See e.g., Irene Wærø, Ragnar Rosness, and Stine Skaufel Kilska, “Human performance and safety in Arctic environments,” SINTEF (2018).

[4] See e.g., Russell Mannion and Carl Thompson, “Systematic biases in group decision-making: implications for patient safety,” *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612 (arguing that small group dynamics in healthcare teams produce systematic biases in group decision-making because healthcare professionals may be reticent to vocalize concerns they have about quality of care).

[5] See e.g., Wærø, Rosness, and Kilska (arguing that groupthink leads teams to “develop shared rationalizations that bolster a proposed choice, rather than examining alternative options and identifying the risks associated with the proposed choice”). See also David Hofmann and Adam Stetzer, “A Cross-Level Investigation of Factors Influencing Unsafe Behaviors and Accidents,” *Personnel Psychology*, Vol. 49 (1996) (finding that in a study of fatal accidents involving offshore oil rigs, in the absence of standard operating procedures, workers “equated normal work methods (i.e. what everyone else does) with safe and/or ideal work methods,” revealing that the groupthink phenomena will further cement modes of work that do not reflect safety protocols in small groups that lack strong norms around workplace safety and tacitly reward short-cuts that prioritize efficiency over safety).

responsibility among group members.[6] This phenomenon is known as “the risky shift.” “Groupthink” and “the risky shift” may lead to group behaviors that render behavioral observation less effective. As such, alternative approaches to BOPs, such as the utilization of video-based surveillance by individuals separate from the onsite work unit, could serve to mitigate potential issues associated with groupthink. The incorporation of remote observation, performed by individuals physically separate from the site, could help to bring in independent and objective perspectives and help to break patterns of thought and communication that may result in groupthink.

Even without the influence of small group dynamics, there are other practical constraints to implementing FFD requirements, such as random drug and alcohol testing, among small staffs. Random testing is less effective when applied to small staff sizes because it may be easier for staff to communicate and predict when individuals will be subject to drug and alcohol testing. Furthermore, if a facility is sited in a remote location, program implementation could be challenged by the following factors: limited mail services to laboratories certified by the U.S. Department of Health and Human Services (HHS), availability of local clinical or medical options for treatment and determinations of fitness by an MRO or Substance Abuse Expert, and use of offsite drug and alcohol collection facilities.

The increased potential for small staff sizes to impact FFD policy compliance necessitates additional flexibilities be provided to implement various FFD program elements. The NRC is requiring that facilities with small staff sizes that cannot implement random drug and alcohol testing without predictability to use a consortium/third-party administrator (C/TPA) to include the workers from multiple licensees or other entities into a combined random testing pool under § 26.607(b)(2)(vi). Use of a C/TPA significantly

[6] Mannion and Thompson, “Systematic biases in group decision-making: implications for patient safety,” *International Journal for Quality I Health Care*, Vol. 26, No. 6 (2014): 606-612.

improves the effectiveness of the random testing programs of sites with small worker populations and ensures that individuals would not be able to predict whether random testing would be conducted in a given period of time. Use of C/TPAs is not new in Federally regulated testing, as the U.S. Department of Transportation has employed the use of C/TPAs in specific modal administrations, such as the Federal Motor Carrier Safety Administration under 49 CFR part 382, “Controlled Substances and Alcohol Use and Testing,” which, in part, covers independent owner-operator truck drivers that must be drug and alcohol tested. The U.S. Department of Transportation requirements in 49 CFR part 40, “Procedures for Transportation Workplace Drug and Alcohol Testing Programs,” also enable the use of C/TPAs to perform a variety of functions for employers, such operating random testing programs, and contracting with specimen collection sites and HHS-certified laboratories for services.

Another flexibility is in § 26.607(g)(2), where the NRC is enabling the virtual collection of oral fluid specimens for drug and alcohol testing at facilities that must use a C/TPA to implement random testing under § 26.607(b)(2)(vi). These sites have small staff sizes and could be in remote locations where accessing an in-person specimen collector might be difficult, untimely, and/or costly. Because all aspects of a virtual oral fluid collection are directly observed by the specimen collector, a video teleconference could accomplish many key elements of the collection process. The use of video teleconference technology also is not new to the NRC, as some clinicians complete other required evaluations using video teleconferencing technology, such as performing a psychological assessment under the personnel access authorization requirements in § 73.56(e)(4) or a determination of fitness performed under § 26.189(b) by a Substance Abuse Expert when potentially disqualifying FFD information is discovered about an individual that is subject to this part. In addition, existing § 26.31(b)(1)(iii) enables the use of a monitor to assist a specimen collector in completing aspects of a urine

collection when a trained collector is not able to complete the activity, and existing § 26.109(b)(1) permits a hydration monitor to observe a donor during the shy bladder process in lieu of the collector conducting the activity. In both cases, the monitor must receive information from the collector on his or her responsibilities.

Also, the NRC is establishing a change control requirement to allow a licensee or other entity to change its subpart M of part 26 FFD program while ensuring that FFD program effectiveness is maintained.

Lastly, subpart M of part 26 consolidates the applicable FFD requirements by placing in one subpart all part 26 requirements (either new requirements or cross-references to existing part 26 requirements) for part 53 licensees and other entities. This should help licensees and other entities implement the requirements because it enables easy cross-reference to similar requirements in other subparts that are being implemented by non-part 53 licensees and entities subject to part 26. Understanding how other licensees or other entities implement similar FFD requirements may facilitate the sharing of operating experience in program implementation.

The use of innovative technologies and a risk-informed performance-based framework parallels the considerations presented in the Advanced Reactor Policy Statement. As stated in the policy statement, “[S]implified systems should facilitate operator comprehension, reliable system function, and more straightforward engineering analysis.” Furthermore, these same attributes may reduce potential radiation exposures, help prevent the theft of nuclear materials, and use technology and design innovations. Should these components and systems be designed, implemented, and maintained to minimize reliance on human actions and leverage technology and innovation, then the robust and prescriptive FFD requirements in, for example, subparts B, “Program Elements,” and E of part 26 could be scaled to the part 53-licensed facility and its operation. This strategy is implemented in the subpart M of part 26 framework.

Even though current subpart K of part 26 provides a more flexible FFD program framework than the framework comprising all the subparts of part 26 except subparts I and K, subpart M of part 26 does not allow part 53 licensees and other entities to implement the requirements in subpart K. The principal reasons are that (without significant changes to subpart K that are outside the scope of this rulemaking): (1) subpart K does not apply to holders of MLs who assemble or test a reactor; (2) subpart K only applies during construction (and prior to the receipt of special nuclear material in the form of fuel assemblies), whereas subpart M applies during construction, operation, and decommissioning through implementation of the insider mitigation program (IMP) required by § 73.55 or § 73.100; (3) subpart K does not address training, authorization as defined in § 26.5, and MRO performance; (4) subpart K does not expressly authorize the use of innovative drug and alcohol testing technologies; (5) subpart K does not describe the use of time-dependent alcohol limits or special analysis testing of urine specimens; and (6) subpart K has less rigor in the protection of worker rights and sensitive information than that required in subpart M.

Despite the differences between subparts K and M of part 26, the requirements in subpart M are essentially equivalent to many in subpart K that were implemented by the licensees of Vogtle Nuclear Station and V.C. Summer Nuclear Station when they were constructing four commercial nuclear power reactors and NRC inspection and operating experience evaluation determined that the use of subpart K contributed to adequately protecting the public health and safety and the common defense and security. Further, given the risk profile posed by facilities licensed under part 53 and the additional requirements in subpart M of part 26 that were developed from operating experience and other part 26 subparts (but are not included in subpart K of part 26), the NRC concludes that if licensees and other entities effectively implement the requirements in subpart M of part 26, then their FFD programs would provide reasonable

assurance that individuals subject to this final rule are fit for duty and trustworthy and reliable.

B. Changes to Part 26, Subparts A through E and I

Section 26.3(d) is the applicability paragraph for contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in § 26.3(a) through (c) rely on those C/V FFD programs or program elements to satisfy the requirements of part 26. This final rule amends § 26.3(d) to address part 53 licensees and other entities in § 26.3(f).

Section 26.3(f) places part 53 licensees or other entities within the scope of part 26. For licensees and other entities of a part 53 commercial nuclear plant, except a holder of an ML, the FFD program is required to be implemented no later than the start of construction activities. The holder of an ML needs to implement its FFD program before commencing activities that assemble a reactor.

Current § 26.4 describes FFD program applicability to categories of individuals. These categories are based on the duties, responsibilities, and the types of access an individual may possess. The NRC is amending § 26.4 to include licensees and other entities described in § 26.3(f). The NRC expects that not all categories of individuals described in current § 26.4 are applicable to all part 53 facilities. The NRC is establishing regulatory guidance in RG 5.99, “Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” to help address program applicability to certain individuals.

This final rule amends § 26.4(a)(1) and (a)(4) to account for the possibility that certain individuals may perform or direct the performance of operational and maintenance activities from a remote facility (for example, a remote-control station) for licensees or other entities licensed under part 53.

The framework of the current part 26 does not account for individuals who perform operating and maintenance duties at remote facilities. Although current § 26.4(a)(1) does not limit the operating of applicable SSCs to onsite operating, § 26.5 limits the definition of "*Maintenance*," for the purposes of § 26.4(a)(4), to include only "onsite maintenance activities." In the 2008 part 26 final rule (73 FR 16966, March 31, 2008), the NRC explained that the work hour requirements apply to those individuals who perform maintenance activities within the licensee's owner-controlled area. Furthermore, regarding the direction of applicable operations and maintenance activities, current § 26.4(a)(1) and (4) address only individuals who perform "onsite direction."

Under this final rule's amendments to part 26, the limitation of "onsite" activities to those performed within the owner-controlled area still applies to facilities licensed under part 50 or 52. However, for licensees and other entities described in § 26.3(f), the NRC is removing the "onsite" limitation to include activities performed both within the owner-controlled area as well as operations and maintenance duties performed at remote facilities where safety-significant systems and components are expected to be operated within the design basis of the commercial nuclear plant.

In the 2008 part 26 final rule, the purpose of limiting "directing" activities to those "directing" activities that are conducted onsite was to avoid requiring work hour controls for individuals performing incidental duties, consistent with § 26.205(b)(5), from an offsite location in instances where those duties might be considered to be "directive" in nature. Under this final rule's amendments to part 26, the exclusion of incidental duties while calculating work hours is still applicable for licensees and other entities licensed under part 53. However, for these licensees and other entities, beyond instances of incidental duties, the direction of operations and maintenance activities associated with safety-significant SSCs, when performed at remote facilities, is considered in an equivalent

fashion as direction performed at non-remote facilities, for the purposes of administering work hour controls.

Section 26.4(b) includes in an FFD program individuals who are granted unescorted access to the protected area of a facility licensed under part 53 and do not perform or direct the performance of the duties described in § 26.4(a). This requirement contributes to the defense-in-depth regulatory framework that helps provide reasonable assurance that individuals who have unescorted access are fit for duty, trustworthy, and reliable. For example, through this final rule, the NRC is amending part 73 to require a part 53 licensee to subject individuals to a series of reviews to help determine whether those individuals are trustworthy and reliable before granting them unescorted access to the facility's protected area.

Through this final rule, the NRC is amending § 26.4(c) to include in an FFD program individuals who are assigned to physically report to the part 53 licensee's emergency response facility (or facilities) or participate remotely in emergency response activities, and individuals without unescorted access to the part 53 facility who, remotely or otherwise, make decisions and/or direct actions regarding plant safety or security. Part 53 commercial nuclear plants may be licensed for and rely upon offsite facilities to fulfill the role of a Technical Support Center or Emergency Operations Facility. Therefore, this final rule accounts for such offsite facilities or remotely performed activities. Further, the use of personnel to operate systems and components, maintain and surveil SSCs, and respond to plant conditions and security events may be different than those included in the Technical Support Center or Emergency Operations Facility team for power reactors currently licensed under part 50 or part 52.

For the individuals whose duties for the licensees and other entities in § 26.3(c) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) at the location where the commercial nuclear plant will be

constructed and operated, current § 26.4(e) requires them to be subject to an FFD program that satisfies all the requirements of part 26 except subparts I and K. This final rule amends § 26.4(e) to except subpart M as well as subparts I and K. This final rule also amends § 26.4(e) to include in an FFD program the individuals whose duties for the licensees and other entities in § 26.3(f) require the individuals to have the types of access or perform the activities listed in § 26.4(e)(1) through (6) or perform construction activities as defined in § 26.5.

This final rule revises § 26.4(e)(4) to include in an FFD program individuals who witness or determine inspections, tests, and analyses certifications required under part 53 because current § 26.4(e)(4) includes the individuals who perform the same duties under part 52.

This final rule amends § 26.4(f) to require individuals who construct or direct the construction of safety- or security-related SSCs at facilities licensed under part 53 to be subject to an FFD program under subpart M of part 26 or an FFD program that demonstrates compliance with all of the requirements of part 26 except for subparts I, K, and M of part 26.

Section 26.4(g) is the applicability paragraph for FFD program personnel (e.g., the FFD manager, MRO, and technicians) and persons who perform AA determinations (e.g., the licensee- or other entity-designated Reviewing Official). This final rule amends this section to address part 53 licensed facilities. Specifically, a part 53 licensee or other entity will use FFD program personnel to implement its FFD program as well as other assigned individuals who are not involved in the day-to-day operations of the program to implement specific elements of its FFD program, such as the collection of a specimen for drug or alcohol testing. These individuals will be held accountable for program implementation, including consistent implementation of protections afforded to all individuals subject to the FFD program.

This final rule amends § 26.4(h) to include subpart M of part 26.

Through this final rule, the NRC includes several new definitions in § 26.5, "Definitions," and amends some existing definitions. The NRC is adding a definition for "*Biological marker*." The definition is consistent with "*Biomarker*" defined by the HHS in its Mandatory Guidelines for Federal Workplace Drug Testing (HHS Guidelines) using oral fluid as the biological specimen to be tested (84 FR 57554; October 25, 2019). However, the definition for § 26.5 adds that the endogenous substance used to validate that the biological specimen "was produced by the donor" because subpart M of part 26 requires the MRO to evaluate any discrepant biological marker identified in a biological specimen collected from a donor.

The NRC is including a definition for the word "*Change*" as used in the § 26.603(e), "FFD program change control," process. The definition is consistent with the definition of "*Change*" for a part 50 or 52 licensee's emergency plans in § 50.54(q)(1)(i).

The NRC is including a definition for "*Consortium/Third-party administrator (C/TPA)*," which is used in § 26.607(b)(2)(vi), with respect to administering the random testing pool and random testing selections for licensees and other entities with facilities with small staff sizes. A C/TPA also could provide access to, for example, services of medical review officers, substance abuse experts, employee assistance programs, and HHS-certified laboratories under contract to perform drug testing. This definition is based, in part, on the Federal Motor Carrier Safety Administration regulations in 49 CFR part 382 and the U.S. Department of Transportation regulations in 49 CFR part 40.

The NRC is revising the definition of "*Constructing or construction activities*" to clarify that for licensees or other entities in § 26.3(f), the definition of "*Construction*" is consistent with the definition in § 53.020.

This final rule revises the definitions of "*Contractor/vendor*" (C/V) and "*Other entity*" to make them applicable to part 53 licensees. A holder of an ML under part 53 could be a C/V under the new C/V definition.

The NRC is including a definition for "*Illicit substance*" because this phrase is used in subpart M of part 26 and addresses substances that cause impairment and possible addiction but are not an "illegal drug" as defined in § 26.5. This is based on operating experience where individuals have admitted to using common household, non-drug substances to achieve a high or satisfy an addiction. These common household items include, but are not limited to nitrous oxide, butane, propane, glue, paint vapors, lighter fluid, nail polish remover, degreasers, permanent markers, and methyl alcohol (which is found in hand sanitizer and mouthwash).

The NRC is including a definition for "*Reduction in FFD program effectiveness*" because this phrase, similar to the definition for "*Change*," is used in § 26.603(e). The definition is generally consistent with the definition of "*Reduction in effectiveness*" provided for emergency plans in § 50.54(q)(1)(iv).

This final rule makes the current definition of "*Reviewing official*" applicable to those licenses and other entities in § 26.3(f).

This final rule amends the current part 26 definition of "*Safety-related structures, systems, and components*" to use the NRC's definition in § 53.020 for the part 53 licensees and other entities described in § 26.3(d) and (f).

This final rule amends the definition of "*Security-related SSCs*" in § 26.5 to make it applicable to a licensee or other entity described in § 26.3(d) and (f).

The NRC is including a definition for "*Special nuclear material*" that refers to the definition in § 70.4, "Definitions," of part 70 to ensure consistency.

This final rule revises the definition of "*Unit outage*" to account for the potential use of commercial nuclear plants for purposes other than electricity generation.

This final rule amends § 26.21, an applicability statement for part 26 FFD programs, to include licensees and other entities described in § 26.3(f) that choose to implement an FFD program that implements all part 26 requirements, except those in subparts K and M of part 26.

This final rule amends § 26.35(c)(3) to include a reference to § 26.606(b)(2)(vii), which ensures that licensees and other entities take immediate action upon receiving notice from the employee assistance program (EAP) that an individual's condition or actions pose or have posed an immediate hazard to themselves or others.

This final rule amends § 26.51, "Applicability," to apply to licensees and other entities described in § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

This final rule amends § 26.53(e), (e)(1) and (3), and (g) through (i), which are general provisions for granting and maintaining authorization, to apply to licensees and other entities described in § 26.3(f).

This final rule amends § 26.63(d), a suitable inquiry requirement, to apply to licensees and other entities described in § 26.3(f).

This final rule amends § 26.73, the applicability statement for subpart D of part 26, to apply to licensees and other entities described in § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

This final rule amends § 26.81, the purpose and applicability statement for subpart E of part 26, to apply to licensees and other entities described in § 26.3(f) that elect not to implement the requirements in subpart M of part 26 for the categories of individuals in § 26.4 and those licensees and other entities that implement § 26.605(a) or

(b). The subpart E requirements to be implemented are listed in § 26.607(c)(2)(i) and (ii), and (c)(3).

This final rule revises § 26.97(a) and (b) to enable the virtual collection of oral fluid specimens for drug and alcohol testing, as permitted under § 26.607(g)(2).

This final rule amends § 26.201, the applicability statement for subpart I of part 26, to apply to licensees and other entities described in § 26.3(f). Also, the applicability statement is divided into two paragraphs for clarity.

The NRC is adding § 26.202, “General provisions for facilities licensed under part 53,” for licensees or other entities described in § 26.3(f) that elect to implement the requirements in subpart I of part 26 in accordance with § 26.605. Section 26.202 establishes requirements equivalent to those in current § 26.203, “General provisions,” which is applicable to parts 50 and 52 licensees. The NRC is adding the separate § 26.202 because § 26.203 refers to various requirements under subpart B of part 26, which are not applicable to facilities licensed under part 53 that implement subpart M of part 26.

Additionally, § 26.202(c), “Training and assessments,” unlike § 26.203(c), “Training and examinations,” does not include a comprehensive examination requirement because trainee assessment is conducted as part of a SAT that would be required under the FFD program training requirements in § 26.608.

Changes in §§ 26.205, 26.207, and 26.211 add references to new requirements in subparts I and M of part 26 that are applicable specifically to licensees and other entities in § 26.3(f). The NRC is not changing the specific provisions for work hour requirements in current § 26.205(d). However, as addressed in the discussion of changes to § 26.4(a), whether a licensee or other entity under part 26 needs to implement work hour controls for certain individuals or groups is dependent, in part, on determinations reached by that licensee’s risk-informed evaluation process.

Changes to §§ 26.207(a)(1)(ii) and 26.211(b) allow licensees and other entities in § 26.3(f) to perform face-to-face assessments to support the approval of work hour control waivers and the conduct of fatigue assessments, respectively, using electronic communications. These changes allow supervisors to conduct such assessments from a remote location under appropriate circumstances. Such remotely conducted assessments need to be supported by someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either §§ 26.29 and 26.203(c), or §§ 26.608 and 26.202(c). The reasoning for these changes and the associated need for in-person support to augment electronic communications is addressed further in the preamble discussion of § 26.619.

C. Requirements for Part 26, Subpart M

This final rule adds a new subpart M to part 26 that provides alternative FFD requirements for part 53 licensees and other entities.

Section 26.601 describes which entities can implement subpart M. Section 26.601(a) makes subpart M of part 26 applicable to part 53 licensees and other entities, at their discretion. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that demonstrates compliance with the requirements of subpart M, then the individuals specified in § 26.4 will be subject to an FFD program that demonstrates compliance with all part 26 requirements, except for those requirements in subparts K and M.

For a licensee or other entity in § 26.3(f) that elects to implement an FFD program that satisfies the requirements of subpart M, § 26.601(b) and (c) describes which provisions of subpart M apply. Under § 26.601(b), a licensee or other entity that demonstrates compliance with § 73.100(a)(1)(i) has the option to implement an FFD program under either § 26.605(a) or (b). Under § 26.601(c), if a licensee or other entity

elects to implement an FFD program under subpart M but does not demonstrate compliance with § 73.100(a)(1)(i), then that licensee or other entity must implement an FFD program under both § 26.605(a) and (b).

Section 26.603(a) requires an applicant to provide a description of its FFD program and its implementation within its application for a license. This requirement is equivalent to the existing requirements in §§ 26.401(b) and 52.79(a)(44). The entities required to submit these FFD program descriptions are certain applicants that comply with the part 53 application requirements in subpart H. In subpart H, § 53.1309(a)(6) requires an applicant for a CP to provide a description of its FFD program in its PSAR. Under §§ 53.1279(b)(4), 53.1369(x), and 53.1416(a)(24), this final rule requires an applicant for an ML, OL, and COL, respectively, to provide a description of its FFD program in its FSAR.

Unlike an application for a license, a description of an FFD program does not receive NRC review for possible approval. The applicant provides the NRC with information about the applicant's proposed FFD program to inform the NRC's inspection program and to demonstrate that the FFD program will be effectively implemented before a licensee or other entity commences any activity making individuals at the NRC-licensed facility subject to the FFD program.

Section 26.603(a)(1) requires the applicant to state whether it demonstrates compliance with § 73.100(a)(1)(i), which is necessary to understand FFD program applicability under § 26.605(a) and (b).

Section 26.603(a)(2) requires the applicant to state what FFD program it plans to implement under subpart M (i.e., § 26.605(a), § 26.605(b), or § 26.605(a) and (b)), or the existing FFD program (i.e., all parts of part 26, except for subpart K and M).

Section 26.603(a)(3) requires a discussion that informs the NRC of the applicability of the applicant's FFD program to individuals who perform safety- or

security-significant activities. This description should summarize any key differences between the staff at the site and any remote facility and the categories of individuals in § 26.4. The principal purpose of providing this description is to inform the NRC of any substantial differences in the applicability of the FFD program to the categories of individuals in § 26.4.

Section 26.603(a)(4) requires a description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected and tested, and sanctions to be imposed for FFD policy violations. This process includes how individuals who test positive for a drug or alcohol will be evaluated before being afforded unescorted access to the protected area to perform or direct those duties or responsibilities making them subject to the FFD program.

Section 26.603(b) establishes the longevity of a license's or other entity's FFD program. Unlike the current part 26 regulations, § 26.603(b) expressly states that an FFD program is not applicable during decommissioning of a part 53 facility for licensees and other entities specified in § 26.3(f). However, holders of an operating or combined license should be aware that the physical protection program regulations in § 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," and § 73.100 include a requirement for the implementation of an IMP, even during decommissioning. Section 26.603(b) also requires the holder of an ML under part 53 to maintain its FFD program until expiration of the ML.

In § 26.603(e), this final rule implements a change control requirement for subpart M of part 26 FFD programs. Requiring licensees and other entities to demonstrate compliance with certain requirements before implementing changes to their

FFD programs is necessary for two primary reasons. First, compliance with § 73.100(a)(1)(i) determines which FFD program requirements may be implemented. If a licensee makes changes to its facility that impact the licensee's ability to comply with § 73.100(a)(1)(i), then the set of applicable FFD program requirements under § 26.605 may change and would need to be documented under § 26.603(e). Second, FFD program implementation may change periodically in response to societal changes in substance abuse. Change control therefore relies on the licensee or other entity maintaining its procedures in a manner that details how its FFD program is to be implemented while incorporating changes, with documentation that justifies the changes to support audits and NRC inspection.

Section 26.603(e)(1) permits the licensee or other entity to implement changes to its FFD program if it performs and retains an analysis demonstrating that the change does not reduce the effectiveness of the FFD program or the change was necessitated or justified by a change to part 26, laboratory processes, or guidance issued by the HHS or NRC. The change control requirement enables flexibility in program implementation should the NRC or HHS change its drug testing procedures (as implemented by the licensee or other entity through its procedures) in response to changes in societal substance abuse or drug testing technologies.

The change control requirement was developed from the change control requirements in § 50.54(p) and (q)—the change control requirements for security and emergency plans, respectively. However, unlike these two requirements, the NRC does not review and approve a licensee's or other entity's FFD program or its implementing procedures, and the FFD program is not licensing-basis information as described in § 53.1300.

Section 26.603(e)(2) requires that if a change reduces FFD program effectiveness, then the licensee must implement a mitigating strategy so the FFD

program, as revised, will continue to demonstrate compliance with the performance objectives in § 26.23 and not result in a reduction in FFD program effectiveness.

Section 26.603(e)(3) prohibits, with one exception, the use of the change control process to reduce the minimum panel of drugs to be tested and references the drugs listed in § 26.607(c)(1). Section 26.607(c)(1) references current § 26.31(d)(1), which states that, at a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opioids (codeine, morphine, 6-acetylmorphine, hydrocodone, hydromorphone, oxycodone, and oxymorphone), amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine, and methylenedioxyamphetamine), phencyclidine, and alcohol. The testing of these drugs and drug metabolites, except phencyclidine, and alcohol is necessary for the FFD program to remain effective. Also, there is no subpart M of part 26 requirement stating that this panel of drugs and drug metabolites needs to consist of only scheduled drugs.[7] This flexibility accounts for the situation where an impairing substance becomes prevalent in society and a licensee or other entity elects to add the substance to their panel of substances to be tested prior to it being scheduled by the Drug Enforcement Administration.

The exception in § 26.603(e)(3) is that, should HHS elect to remove phencyclidine from the panel of drugs and drug metabolites to be tested, a licensee or other entity could make this change in its FFD program without resulting in a reduction in FFD program effectiveness. This outcome is justified based on the very infrequent

[7] The Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five (5) distinct categories, depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. These categories appear as Schedules I through V of section 202 of the Controlled Substances Act (21 U.S.C. 812). Schedule I drugs have a high potential for abuse, have no currently accepted medical uses in treatment in the United States, and lack accepted safety for use under medical supervision. At the other end of the classification scheme, Schedule V drugs have the least potential for abuse among the five categories of drugs, have a currently accepted medical use in treatment in the United States, and abuse of the drug may lead to limited physical dependence or psychological dependence. For more information, see https://www.dea.gov/drug-information/drug-scheduling.

occurrence rate of FFD policy violations due to phencyclidine use since 2010. However, if HHS proposes to remove a class of drugs from the panel of drugs to be tested that is listed in § 26.31(d)(1), except for phencyclidine, then a licensee or other entity may not make a similar change to its panel of drugs to be tested, because this change would be a reduction in FFD program effectiveness even with a mitigative strategy implemented.

Changes in the HHS panel of drugs and drug metabolites to be tested could potentially shift from one metabolite to a different metabolite for the same drug. Should HHS issue such a change to its panel, this is not expected to result in a reduction in FFD program effectiveness because HHS would be targeting a more effective metabolite for identifying an existing drug already being tested in its panel. This situation could occur as HHS gathers more operating experience from Federal Government implementation of its HHS Guidelines, or data generated by drug testing laboratories and Federally mandated drug testing programs required by Federal agencies such as the NRC and U.S. Departments of Transportation, Energy, and Defense.

Section 26.603(e)(4) requires that change control records be maintained for a 5-year record retention period based on the current NRC practice to conduct triennial inspections of licensees' and other entities' FFD programs. This affords the NRC an opportunity to review the licensee's or other entity's determination that FFD program changes have not reduced the effectiveness of their FFD program. Licensees and other entities are also required to summarize each change made under § 26.603(e) in their annual FFD performance reports required by § 26.617(b)(2) or § 26.717, as applicable.

Section 26.605 establishes requirements in a graded manner similar to the regulatory framework established by the requirements in subparts A through I, N, O, and K of part 26. This graded approach consists of less prescriptive FFD program requirements in § 26.605(a) and more robust program requirements in § 26.605(b).

The FFD programs under § 26.605(a) and (b) include FFD program elements similar to those in subpart B of part 26, but the new requirements are less prescriptive, enabling more flexibility in program implementation like that offered in subpart K of part 26. For example, the requirements in subpart B of part 26 are explicit requirements for, in part, the collection and testing of urine specimens. Subpart B of part 26 does not enable the use of oral fluid for drug testing, except under very limited situations as described in subpart E of part 26, or the use of hair specimens, unlike § 26.605. Section 26.605 requires drug and alcohol testing based on either the requirements in part 26 or the HHS Guidelines. The principal benefits of the § 26.605 FFD program are that it provides a regulatory framework that is consistent with the radiological consequences for a facility that demonstrates compliance with § 73.100(a)(1)(i), and affords flexibilities in the conduct of drug and alcohol testing.

Section 26.605(a) applies to part 53 licensees and other entities of commercial nuclear plants that demonstrate compliance with § 73.100(a)(1)(i), at their discretion (no later than the start of construction activities as defined in § 26.5); licensees and other entities of commercial nuclear plants that do not demonstrate compliance with § 73.100(a)(1)(i) (no later than the start of construction activities as defined in § 26.5); and holders of MLs before the start of activities performed under an ML that allows the assembly, non-operational testing, or both, of a manufactured reactor. The timing element of the applicability statement of § 26.605(a) is equivalent to that for an LWR licensee or other entity who is performing those same activities at a facility licensed under part 50 or 52 and helps provide assurance that those individuals who assemble, test, or perform construction activities as defined in § 26.5 or direct these activities are fit for duty and trustworthy and reliable. This is important because assembly and non-operational testing of a manufactured reactor and the construction and testing of SSCs required for facility operation require, in part, adherence to procedures, possible

implementation of unique and precise assembly techniques, and quality assurance and controls. Additionally, SSCs within a manufactured reactor may not be accessible, testable, or available for quality assurance and verification after the reactor is assembled. This requirement also addresses solo-assembly activities that may cause latent failures and passive SSCs located internal to a reactor (for example, a fusible link designed to melt at a particular temperature to trigger an actuation mechanism) that are relied upon for safe operation but cannot be inspected or tested for proper installation, configuration, or operation after installation. A § 26.605(a) FFD program for these types of activities is equivalent to the FFD program applicable to the assembly of the reactor vessel internals and testing of the SSCs internal to the reactor at an LWR licensed under part 50 or 52.

Section 26.605(a) requires the holder of an ML to implement its FFD program no later than the start of activities that assemble a reactor, non-operational testing of a manufactured reactor, or both. The holder of the ML should establish in its procedures when reactor assembly commences and what constitutes assembly. For example, the FFD program does not need to be implemented for the receipt, storage, inspection, and staging of components and systems used to assemble (i.e., build or fabricate) the reactor because this is not a current requirement for LWR facilities licensed under part 50 or 52. Furthermore, the NRC currently does not require that an FFD program be applied to the assembly or manufacturing of components (or basic components as defined in § 21.3), or systems that were fabricated or assembled outside the footprint of a commercial power reactor, and this regulatory position also applies to a manufacturing facility.

Section 26.605(b) also contains timing requirements for implementing FFD programs under that paragraph. Licensees and other entities that demonstrate compliance with § 73.100(a)(1)(i) and elect to implement FFD programs that satisfy the

requirements of § 26.605(b) must establish, implement, and maintain the program no later than the start of construction activities. Holders of MLs that also possess a separate license to load fuel into a manufactured reactor must establish, implement, and maintain the program no later than the start of reactor fuel load. For all other licensees and other entities implementing an FFD program under § 26.605(b), they must establish, implement, and maintain the program before the earliest of the loading of fuel onsite into a reactor vessel; receiving a fueled manufactured reactor; or individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety.

These entities must establish, implement, and maintain an FFD program that implements all the requirements in § 26.605(a), except §§ 26.610, “Sanctions”; 26.617, “Recordkeeping, reporting, and FFD program performance”; and 26.619, “Suitability and fitness determinations”; plus additional requirements due to the increased radiological consequences presented by a part 53 commercial nuclear plant as the licensee readies it for operation. These additional requirements include those in subparts C, D, H, and N of part 26, some of which replace §§ 26.610, 26.617, and 26.619.

Section 26.605(b) also enables the licensee or other entity to better integrate its facility with the LWR fleet and Category I fuel cycle facilities because subparts C, D, and H of part 26 are required. These subparts are required, in part, because it is expected that: (1) individuals will be able to work at any part 50, 52, or 53 commercial nuclear plant and will possess a nuclear safety culture and desirable qualifications, skills, expertise, or services; and (2) licensees and other entities of facilities licensed under parts 50, 52, and 70 may venture to construct or operate a facility licensed under part 53. Therefore, the implementation of these subparts helps ensure that all individuals subject to part 26, whether under subpart M, subpart K, or all subparts except M and K,

are subject to FFD programs that provide reasonable assurance that the individuals are fit for duty, trustworthy, and reliable.

Section 26.606, “Written policy and procedures,” requires licensees and other entities to implement and maintain an FFD policy and procedures for their FFD programs. This section establishes requirements equivalent to those in current § 26.403, “Written policy and procedures,” of subpart K. However, a principal difference is that § 26.606 is written to enable the drug testing of urine, oral fluid, and hair specimens.

Section 26.606(a)(1) requires each licensee and other entity to provide a written FFD policy statement to individuals subject to the FFD program before the individuals are subjected to any FFD program drug and alcohol test. This is a protection measure afforded to individuals subject to the FFD program to help ensure that they know what is expected of them before being subject to the FFD program and potential consequences should they violate the FFD policy or procedures. This requirement also contributes to safety and security because understanding FFD program responsibilities may enhance an individual’s safety culture or the individual may self-select out of the licensee’s or other entity’s hiring process.

Section 26.606(a)(2) requires that the FFD policy statement describe the performance objectives in § 26.23, which are the same FFD program performance objectives required for facilities licensed under parts 50, 52, or 70. Having a standard performance outcome based on a licensee or other entity satisfying the § 26.23 performance objectives enhances consistency in FFD program implementation across all entities subject to part 26. It also generates confidence that individuals subject to part 26 will safely and competently perform their duties and responsibilities and use NRC-licensed materials in a manner that will protect the public health and safety and common defense and security.

Section 26.606(a)(3) requires that the FFD policy statement describe the licensee's or other entity's implementation of the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7).

Section 26.606(a)(4) requires the FFD policy statement be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in § 26.603(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations. This requirement is equivalent to § 26.403(a) of subpart K but includes an additional description of what the policy statement must include. For example, the policy describes the NRC-required sanctions to help deter substance abuse and required medical/clinical treatment and follow-up testing for FFD policy violations. This provision provides a protection measure by helping the individual get the assistance they need and help ensure that the individual refrains from substance abuse.

Section 26.606(a)(5) requires that the FFD policy statement describe the individual's responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

Section 26.606(a)(6) requires that the FFD policy statement must prohibit the consumption of alcohol, at a minimum, within an abstinence period of 5 hours preceding the individual's arrival at the licensee's or other entity's facility.

Section 26.606(a)(7) requires that the FFD policy statement must convey that abstinence from alcohol for the 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty.

Section 26.606(b) requires licensees and other entities implementing an FFD program in accordance with subpart M of part 26 to establish, implement, and maintain written procedures for their FFD programs. This requirement is equivalent to that in § 26.403(b) of subpart K.

Section 26.606(b)(1) establishes requirements for the licensee or other entity to develop and maintain written procedures for its drug and alcohol testing program. This provision is equivalent to the requirements in current § 26.403(b)(1) of subpart K, but § 26.606(b)(1)(i) through (iv) requires additional clarity and specificity that licensees and other entities must detail in their procedures to address new testing methods in subpart M of part 26 that are not permitted under the current part 26 framework. Clarity and specificity in procedural instructions support consistent program implementation, which protects all individuals subject to the program.

Section 26.606(b)(1)(iv) requires that if the licensee or other entity elects to use the HHS Guidelines for the conduct of drug testing, the FFD program procedures must include the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented, including specimen collections, drug testing, laboratory procedures, and evaluation of test results. This requirement helps ensure the following: the validity and accuracy of drug testing because the specimens are subject to laboratory testing that has been certified by the HHS; protection of worker rights equivalent to the privacy, information, and due process protections afforded to Federal workers under the HHS Guidelines because the HHS Guidelines are used in the Federally mandated drug testing programs; consistency in program implementation because all individuals subject to the FFD program are subject to the same collection, testing, and evaluation processes; and FFD program effectiveness because the effectiveness of the HHS Guidelines have been verified by HHS's National Laboratory Certification Program

(NLCP). Detailed procedures will enhance MRO and FFD program personnel reviews of individual test results because instructions will be provided for, in part, the evaluation of specific test results (e.g., positive, negative, biological markers), the conduct of additional testing for invalid or dilute specimens, and the assessment of subversion attempts (e.g., adulterated or substituted). This benefits FFD program effectiveness and helps prevent misunderstanding of program requirements and processes.

Section 26.606(b)(2) requires licensees and other entities to include in their written procedures the immediate and follow-up actions that will be taken, and the procedures that will be used, in certain situations specified in § 26.606(b)(2)(i) through (vi). Section 26.606(b)(2) is equivalent to the requirements in current § 26.403(b)(2), which provides the same requirement under an FFD program for construction for part 50 or 52 licensees and other entities. This helps ensure the effectiveness of the FFD program and its consistent implementation, because part 53 licensed facilities will be implementing procedures to address the same requirements and with individuals who understand what is expected of them no matter what part 53 facility they were assigned.

The situation specified in § 26.606(b)(2)(i) arises when individuals subject to the FFD program have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances. This provision is equivalent to current § 26.403(b)(2)(i), except that the phrase “illegal drugs” is replaced with “illegal substances, illegal drugs, or illicit substances.” Illegal substances include legal substances used in a manner inconsistent with Federal or State law.

The situation specified in § 26.606(b)(2)(ii) arises when individuals who are subject to the FFD program are impaired by any substance or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration, as defined in § 26.5. Except for a few differences, this provision is equivalent to current § 26.403(b)(2)(ii) of subpart K. The NRC does not include the

phrases “to excess” and “accurately” in § 26.606(b)(2)(ii). Subpart M of part 26 is a performance-based framework that focuses on impaired human performance, and for alcohol, impairment is determined by blood alcohol concentrations exceeding the limits in § 26.103, “Determining a confirmed positive test result for alcohol,” using an evidential breath testing device (EBT) for alcohol (not whether an individual drank “to excess”).

The NRC is including the phrase “illegal substances, illegal drugs, and illicit substances” in § 26.606(b)(2)(ii) based on operating experience and the terminology in current § 26.23(b). There are far more substances that may cause impairment than those designated by the Drug Enforcement Administration as controlled substances (i.e., those that appear on Schedules I through V of section 202 of the Controlled Substances Act), and alcohol. The phrase “before or while constructing or directing construction of safety- or security-related SSCs” in current § 26.403(b)(2)(ii) is not included in § 26.606(b)(2)(ii) because § 26.606 applies during construction, operation, and decommissioning, if applicable. The NRC is including the term “behavioral observation” in § 26.606(b)(2)(ii) because impairment can be visibly or audibly observed in an individual, and individuals subject to subpart M of part 26 will be trained in behavioral observation under § 26.608.

The situation specified in § 26.606(b)(2)(iii) arises when individuals attempt to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means. This provision is equivalent to current § 26.403(b)(2)(iii). The purpose underlying this requirement has increased in significance since issuance of the 2008 part 26 final rule because subversion attempts have accounted for about one-third of all drug testing violations of the FFD policy every year since 2016.

The situation specified in § 26.606(b)(2)(iv) arises when individuals refuse to provide a specimen for analysis or refuse to follow instructions provided by FFD program

personnel. Except for one difference, this provision is equivalent to current § 26.403(b)(2)(iv). The NRC is including the phrase “or follow the instructions provided by FFD program personnel” based on an existing requirement in § 26.89(c) that the collector must inform the donor that if the donor refuses to cooperate in the specimen collection process, then such refusal will be considered a refusal to test and sanctions for subverting the testing process will be imposed.

The situation specified in § 26.606(b)(2)(v) arises when individuals who are subject to an FFD program had legal action taken relating to drug or alcohol use. This requirement is equivalent to current § 26.403(b)(2)(v).

The situation specified in § 26.606(b)(2)(vi) is when individuals subject to an FFD program demonstrate character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This includes character traits beyond those attributed to drug or alcohol use. This requirement helps ensure that the licensee or other entity will implement an FFD program designed to demonstrate compliance with the § 26.23(c) performance objective that FFD programs must provide “reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program.” An individual who is not trustworthy and reliable is not fit to perform or direct the performance of those duties and responsibilities or be afforded those types of access that make the individual subject to an FFD program.

This requirement also helps to align the subpart M of part 26 BOP with the BOP implemented under § 73.56(f) and § 73.120 and the purpose of the IMP as described in

§ 73.55(b)(9) and § 73.100(b)(10).[8] The demonstrated character and actions of an individual can indicate whether the individual can be trusted and relied upon to safely and competently perform assigned duties and responsibilities or be afforded those types of access making the individual subject to the FFD program. This holds true for any demonstrated adverse character indication or action on- or offsite.

The phrase “character or actions” is used in § 26.606(b)(2)(vi) to focus on observed examples that indicate an individual subject to subpart M of part 26 may not be fit for duty or trustworthy and reliable. Character traits include but are not limited to personality, temperament, honesty, carelessness, apathy, psychosis, and commitment to safety culture. Assessment of an individual’s character should consider the potential for changes in these traits when compared to a previous baseline. Actions include a physical or verbal demonstration of a character trait that could call into question an individual’s fitness, trustworthiness, or reliability. For example, the individual does something physically, verbally, or in writing (e.g., falsifying records, driving while impaired, or harming or threatening to harm oneself, others, or property) that compels another individual to conclude that the observed individual cannot be trusted or relied upon. Unlike the background investigation and reviews of “character and reputation” in § 73.56(d)(6) and (k)(1)(v) and § 73.120, which are principally retrospective reviews of an individual and may be based on third-party information (i.e., information from individuals not subject to NRC requirements), the “character or action” focus of § 26.606(b)(2)(vi) is a present observation of an individual subject to the FFD program and performed by an individual who is also subject to the FFD program. Whether the information is received from an individual subject to the FFD program or someone who is

[8] The IMP must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted AA to a protected or vital area and implement defense-in-depth methodologies to minimize the potential for an insider to adversely affect, either directly or indirectly, the licensee’s capability to protect against radiological sabotage.

not subject to the FFD program, the licensee or other entity will need to review this information (i.e., determine if the information and its source are credible) to determine whether the individual should maintain authorization.

Section 26.606(b)(3) requires licensees and other entities to address in their procedures the process, including the duties and responsibilities of FFD program personnel, to be followed if an individual's behavior or condition raises an FFD concern. This provision also requires a process to be conducted when credible information is received by the licensee or other entity that the individual is not fit for duty, trustworthy, and reliable.

With a few exceptions, § 26.606(b)(3) is equivalent to current § 26.403(b)(3). Instead of the phrase "while constructing or directing the construction of safety- or security-related SSCs" in current § 26.403(b)(3), the NRC uses "on the NRC-licensed facility" in § 26.606(b)(3), because this provision applies during commercial nuclear plant construction, operation, and decommissioning, if applicable, in addition to holders of an ML as described in § 26.3(f). The requirement that the roles and responsibilities of FFD program personnel be described was developed from current §§ 26.4(g) and 26.31(b) and operating experience, which has demonstrated that clear job descriptions help ensure that individuals know who is designated by the licensee or other entity to make decisions regarding FFD program implementation and who can be approached when physiological or psychological help is needed. This is principally a protection consideration afforded to individuals subject to the FFD program.

The requirement also includes two conditions not found in current § 26.403(b) that clarify the initiation of the fitness determination process should an individual's behavior or condition raise an FFD concern. The phrase, "impairment from any cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties," reflects the § 26.23(b) performance objective. The

condition, “the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part,” reflects the § 26.23(a) performance objective. In either case, as required by § 26.23(c), the FFD program must provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program.

Section 26.606(b)(4) requires licensees and other entities to have written procedures that address the operation and oversight of onsite and offsite collection facilities. This requirement is equivalent to current §§ 26.403(b) and 26.405(e) and is developed from § 26.41(b), which states that each licensee and other entity who is subject to subpart B of part 26, shall ensure that the entire FFD program is audited, which is part of a licensee’s or other entity’s oversight of the facility, and § 26.87(a), which states that each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Having procedures for the operation and oversight of onsite and offsite collection facilities enhances consistency in program implementation, protects individuals subject to testing, and accounts for the flexibilities afforded in the types of biological specimens that may be collected under an FFD program subject to subpart M of part 26. Section 26.606(b)(4), when used with the audit requirement in § 26.615, helps maintain FFD program effectiveness and prevent subversion attempts at facilities that may not be under the direct day-to-day oversight of FFD program personnel.

Section 26.606(b)(5) requires licensees and other entities to have written procedures that address the fatigue management requirements in § 26.202(b), “Procedures,” and either § 26.205(d)(3) or (d)(7).

Section 26.606(b)(6) requires licensees and other entities to have written procedures that provide measures to prevent subversion of drug and alcohol tests conducted onsite and offsite. This requirement was developed from § 26.27(c)(1).

Section 26.607, “Drug and alcohol testing,” establishes drug and alcohol testing requirements for licensees and other entities implementing § 26.605. Except for a few differences, § 26.607 is equivalent to current § 26.405, which requires licenses and other entities implementing an FFD program under subpart K of part 26 to have a drug and alcohol testing program that demonstrates compliance with the requirements in § 26.405(b) through (g). The differences are commensurate with the risk consequences presented by a part 53-licensed facility as compared to a part 50 or 52 nuclear power plant. These requirements improve flexibility in the conduct of drug and alcohol testing while maintaining protections afforded to individuals subject to the FFD program.

Section 26.607(a) requires licensees and other entities to obtain a split specimen for all drug tests using oral fluid or urine for all test conditions in § 26.607(b) and (j). Neither current subpart K nor current subparts B or E of part 26 require a split specimen. However, many of the LWR fleet use split specimens for drug testing and commercially available drug screening products use a split specimen technique. Since publication of the 2008 part 26 final rule, the HHS has issued guidelines for urine and oral fluid specimen testing that require split specimen collections. The U.S. Department of Transportation regulations under 49 CFR part 40 also require split specimen collections for urine and oral fluid. The proposed HHS Guidelines for hair testing also require split specimen collections.

The required use of a split specimen process protects the individual because, upon a donor-alleged discrepant or questionable test result, the donor may provide permission to test the split specimen (specimen B) in an effort to refute the laboratory test results for specimen A. The requirement also enables the MRO to direct laboratory

testing of specimen B if specimen A were invalid; though the NRC expects specimens becoming invalid at the laboratory to be a rare occurrence as testing will be conducted by HHS-certified laboratories. If a specimen is determined to be invalid, the occurrence would warrant further investigation by the MRO and laboratory to identify the cause. This protocol is equivalent to the special analysis testing in current § 26.163(a)(2) for dilute specimens and specimens collected under most directly observed collection conditions in that additional laboratory analysis is performed because of a questionable test result.

If a split specimen is tested by an HHS-certified laboratory, then the test result from specimen B must be used as part of the determination for an FFD policy violation as required by § 26.185(n), “Evaluating results from a second laboratory.” However, this is not to say that the test results from specimen A should be discarded. Since the HHS-certified laboratory should report all test results from all specimens tested to the MRO, like the information described in § 26.169, “Reporting results,” test result differences between specimens A and B can be used to inform the MRO as to what should be reported to the licensee or other entity to either facilitate medical or clinical assistance for the individual, inform an FFD-policy violation determination, or both.

Section 26.607(a) states that split specimen collections of oral fluid or urine must be used for the test conditions described in § 26.607(b). In addition, testing of the split specimen (specimen B) requires the donor’s permission unless ordered by the MRO to resolve an invalid test result obtained for specimen A.

Section 26.607(b) requires the licensee or other entity to subject individuals identified in § 26.202 to drug and alcohol testing under the five conditions listed in § 26.607(b)(1) through (5). Section 26.607(b) is equivalent to current § 26.405(c).

Section 26.607(b)(1) requires pre-access testing similar to current § 26.405(c)(1), which requires testing before assignment to construct or direct the construction of safety- or security-related SSCs. Unlike current § 26.405(c)(1), the requirement does not include

the phrase, “construct or direct the construction of safety- or security-related SSCs,” because, for licensees or other entities under part 53, the pre-access test condition applies to construction, operation, and decommissioning, if applicable, to help inform a licensee’s or other entity’s authorization determination. The requirement also uses “pre-access” instead of “pre-assignment,” which is used in current § 26.405(c)(1).

A pre-access test requires the collection of an oral fluid or a urine specimen no more than 14 days before the individual is granted unescorted access. Although this change has roots in the 2008 part 26 final rule, which reduced the period within which pre-access testing must be performed from 60 days to 30 days or less, the 14-day requirement is based on two lessons learned from operating experience.

First, the 14-day period is a large enough window of time to collect the specimen and evaluate test results because licensees or other entities typically receive laboratory test results within 5 business days of laboratory receipt of the biological specimen. At the same time, the 14-day period is small enough to help ensure that the test results are representative of the individual’s recent drug use before being granted authorization.

Second, the NRC does not expect licensees and other entities licensed under part 53 to have the large and periodic influxes of individuals (either licensee employees or C/Vs) that LWRs have to support facility operation, maintenance, engineering design changes, or nuclear refueling. Therefore, these licensees or other entities will not be periodically challenged to in-take a large workforce within the 14-day pre-access testing window.

Section 26.607(b)(2) requires the licensee or other entity to conduct random drug and alcohol testing of all individuals subject to the FFD program. With notable exceptions, this requirement is equivalent to current § 26.405(b). Section 26.405(b) gives licensees and other entities that implement an FFD program subject to subpart K of part 26 the option to impose random drug and alcohol testing. Section 26.607(b)(2)

does not offer that option because subpart M of part 26, unlike subpart K, does not allow a licensee or other entity to implement a fitness monitoring program under current § 26.406 instead of a random testing program. The principal reasons for not allowing this flexibility are that no licensee or other entity has ever implemented a fitness monitoring program (i.e., there is no operating or regulatory experience on which to judge the effectiveness of a fitness monitoring program), and the subpart M framework already uses behavioral observation to help ensure FFD program effectiveness. Supplementing the § 26.609 BOP with an additional observation technique (i.e., the fitness monitoring program) would not result in a level of deterrence or detection equivalent to that which will be obtained through behavioral observation and random drug and alcohol testing.

Section 26.607(b)(2)(i) through (v) provides specific requirements for the conduct of a random testing program. These paragraphs are equivalent to § 26.405(b)(1) through (4), although with a few differences. The similar provisions are in § 26.607(b)(2)(i), (b)(2)(iii), and (b)(2)(iv).

The differing provisions include § 26.607(b)(2)(ii), which refers to an “FFD program procedure” instead of the reference to an “FFD program policy” in § 26.405(b)(2) because procedures contain the instructions that implement FFD program requirements, but the FFD policy need not contain specific instructions. Section 26.607(b)(2)(ii) also requires individuals who are selected for random testing to report to the onsite collection site, as opposed to the collection site in § 26.405(b)(2), because alcohol metabolism necessitates a timely alcohol test. This change is also being implemented because the NRC expects that part 53 licensees and other entities may use a combination of onsite (for random, for-cause, and post-event testing) and offsite (for pre-access, post-event, and follow-up testing) collection facilities for drug and alcohol testing and may have to afford reasonable accommodation to certain individuals,

which would add complexity in the licensee's or other entity's procedurally determined time period in which an individual must report to the collection facility.

Another difference from § 26.405(b) is § 26.607(b)(2)(v), which establishes the random testing rate for the population of individuals subject to testing. Subpart K of part 26 does not establish a random testing rate. The new requirement is equivalent to current § 26.31(d)(2)(vii), which requires that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program.

Section 26.607(b)(3) requires for-cause testing equivalent to that used in current FFD programs implementing § 26.405(c)(2). The NRC is requiring for-cause testing, like random testing, to be conducted onsite to ensure that the test is conducted as soon as reasonably practicable. This is an important consideration when for-cause testing for alcohol or using oral fluid for drug screening or testing because human metabolism continually lowers the concentrations of the drugs, drug metabolites, and alcohol perhaps to concentrations lower than the initial or confirmatory testing cutoffs. Additionally, for facilities that are sited in geographically remote locations, an offsite collection facility might be too far away or not readily accessible.

Section 26.607(b)(4) requires post-event testing in a manner equivalent to current § 26.405(c)(3), with a few adjustments. For part 53 licensees or other entities, the NRC is requiring post-event testing under two conditions: events involving human errors that may have caused or contributed to the events (§ 26.607(b)(4)(i)), and events not involving human error that result in adverse health consequences or damage to any safety- or security-related SSC (§ 26.607(b)(4)(ii)). The word "significant" is not used in § 26.607(b)(4)(ii)(A) to describe the "illness or personal injury" as used in § 26.405(c)(3)(i) because § 26.607(b)(4)(ii)(A) describes which illnesses or injuries are

covered. Section 26.607(b)(4)(ii)(B), unlike § 26.405(c)(3)(ii), does not use the word "significant" to describe the damage to safety- or security-related SSCs because any damage to safety- or security-related SSCs requires testing within four hours of the event unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the event. Section 26.607(b)(4)(ii)(B) also does not use the word "construction" as in § 26.405(c)(3)(ii) because § 26.607(b)(4) applies to construction, operation, and decommissioning, if applicable.

Section 26.607(b)(4)(i) requires the licensee or other entity to define in its procedures the term "human error." This term may take on various meanings and it is not defined in the current or final rule, so the licensee or other entity is required to describe or define this term to help ensure consistent implementation of subpart M of part 26 and that the post-event test condition is consistently applied to all individuals subject to the FFD program. The § 26.405(c)(3)(i) requirement that "the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments thereto," is not carried over to § 26.607(b)(4). Instead, the NRC is prescribing the post-event test conditions in § 26.607(b)(4), in part so they will not change unless the NRC amends the requirement.

Section 26.607(b)(5) requires follow-up testing. This requirement is equivalent to current § 26.405(c)(4), although § 26.607(b)(5) further describes follow-up testing. This final rule describes follow-up testing as part of a series of tests for drugs, alcohol, or both, which are performed after an individual subject to part 26 has violated the FFD policy on substance use or abuse, or the sale, use, or possession of illegal drugs. Follow-up testing will be used to verify an individual's continued abstinence from substance abuse. This final rule does not include a reference to a follow-up plan as in § 26.405(c)(4) because the intent of a follow-up plan is to conduct a series of drug tests, alcohol tests, or both, to verify continuing abstinence from substance abuse.

Nevertheless, individuals who violate an FFD policy on substance use or abuse, or the sale, use, or possession of illegal drugs, should have a follow-up plan that includes a definition of “abstinence” from the medical professional prescribing the plan.

Section 26.607(c) provides additional testing requirements. This requirement is equivalent to § 26.405(d) and requires implementation of select requirements from current subpart E of part 26. The requirements govern directly observed collections, shy bladder situations, special analysis testing, and alcohol testing. These requirements are necessary to maintain FFD program effectiveness equivalent to that currently implemented by the LWR fleet.

Section 26.607(c)(1) requires validity testing and establishes the minimum panel of drugs and drug metabolites to be tested. This panel is the same as those in §§ 26.31(d)(1) and 26.405(d) because, based on operating experience from LWR FFD program implementation, this panel has been determined to contribute to a licensee or other entity satisfying the FFD performance objectives in § 26.23(a) through (d).

Section 26.405(d) requires that urine specimens collected for drug testing be subject to validity testing. Like § 26.405(d), § 26.607(c)(1) requires validity testing of urine specimens. Oral fluid specimens could also be subject to validity testing, including a biological marker, as specified in either part 26 or the HHS Guidelines.

Section 26.607(c)(2) includes requirements that already exist in the part 26 framework that provide protections for individuals subject to the FFD program and contribute to testing effectiveness when collecting and assessing a urine specimen. Specifically, current § 26.115, “Collecting a urine specimen under direct observation,” describes the exclusive grounds for performing a directly observed collection and the process to be followed to protect the privacy of the individual. Section 26.119, “Determining ‘shy’ bladder,” establishes the process to be followed when a donor is not

able to produce a sufficient amount of urine for testing, and § 26.163(a)(2) requires special analysis testing when a specimen is dilute to help prevent a subversion attempt.

Section 26.607(c)(3) requires implementation of all the current alcohol testing requirements in § 26.91, “Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use,” through § 26.103, “Determining a confirmed positive test result for alcohol.” Using the same alcohol testing framework for parts 50, 52, 70, and 53 licensees and other entities provides for regulatory consistency, protections for individuals subject to the FFD program (e.g., the quality controls and verification applied to the EBT), and FFD program effectiveness (e.g., accuracy of test results). For alcohol testing, unlike drug testing, there is a preponderance of evidence that correlates blood alcohol concentrations to impairment and intoxication. Furthermore, FFD performance data has demonstrated that the time-dependent alcohol cutoffs in § 26.103 have increased the detection of individuals who are under the influence of alcohol. For these reasons, the current alcohol requirements in part 26 are required for FFD programs under subpart M.

Section 26.607(c)(4) establishes additional testing requirements. This is equivalent to current § 26.405(f) for facilities licensed under part 53 for the conduct of drug testing. Unlike § 26.405(f), § 26.607(c)(4) does not reference validity screening and initial drug and validity tests at licensee testing facilities. Another minor difference between § 26.405(f) and § 26.607(c)(4) reflects the requirement in subpart M of part 26 to use an HHS-certified laboratory for all biological specimens collected and not just for urine specimens.

Consistent with § 26.405(f), § 26.607(c)(4) requires the use of an HHS-certified laboratory for all test conditions listed in § 26.607(b), MRO-directed tests, and the testing of a split specimen. Further, HHS-certified laboratory test results using urine or oral fluid are required for the issuance of an FFD policy violation and part 26-required sanction.

All drug testing needs to be performed at an HHS-certified laboratory to help ensure FFD program effectiveness and to protect the donor from a false positive test result and an unwarranted FFD policy violation. The donor will be protected because laboratory procedures for specimen accessioning, testing, custody and control, and evaluation of test results and the training and qualification of laboratory personnel are evaluated by HHS as part of the NLCP. This provides assurance that the drug testing results are accurate and attributed to the donor. Hair specimens may also be pre-access tested for drugs as described in § 26.607(i) and positive test results may only be used as potentially disqualifying information for a licensee's or other entity's authorization determination (i.e., used to assess the fitness, trustworthiness, and reliability of the individual). A positive hair test result may not be used for the administration of an FFD policy violation and sanction, except as provided for in §§ 26.607(i)(3) and 26.610(b)(4) for attempts to subvert the testing process, as defined in § 26.5.

There are three phrases or requirements in § 26.405(f) that the NRC is not using in § 26.607(c)(4). The first is the phrase, "consistent with its standards and procedures for certification," regarding the operation of an HHS-certified laboratory, because the laboratory would not be HHS-certified if it were not following "its standards and procedures for certification." The second is the requirement that urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. This requirement is not used because, under subpart M of part 26, licensees or other entities are required to use an HHS-certified laboratory. For a laboratory to be HHS-certified, it must follow the HHS Guidelines and include procedures that describe when a specimen cannot be tested. Lastly, the § 26.405(f) requirement that other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that demonstrates compliance

with stringent quality control requirements that are comparable to those required for certification by the HHS, is not used because subpart M of part 26 requires the use of an HHS-certified laboratory.

Section 26.607(c)(4) requires the licensee or other entity to contract with a primary and backup HHS-certified laboratory. This provision helps ensure that specimens are processed and tested to maintain FFD program effectiveness should the primary laboratory be unable to perform specimen testing. This helps maintain protections afforded to individuals subject to the FFD program (e.g., should the donor or MRO request testing of the split specimen, a different laboratory could be used). This requirement also states that the primary and backup laboratories must have a different certifying scientist. Having a back-up HHS-certified laboratory and a different certifying scientist benefits the program and donor because the drug testing instruments, technicians, and certifying scientist are independent of the primary laboratory testing and review process. The back-up HHS-certified laboratory may be of the same corporate entity as the primary laboratory.

Section 26.607(c)(4) also states that the laboratory is subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premises to support the inspection or audit. This requirement is equivalent to current § 26.41(d), except that laboratories are not able to limit the use and dissemination of documents copied or taken from the laboratory by a licensee or other entity. This is necessary to ensure the continuing effectiveness of FFD programs, because NLCP findings and audit results could adversely impact FFD program effectiveness. Pertinent information includes and should not be limited to NLCP-identified weaknesses (e.g., custody and control, accessioning, instrumentation, procedures, training, supervision, review of test results, and resolution

of previously identified corrective actions) that may impact the effectiveness of FFD programs.

Section 26.607(d) helps protect the donor from mistakes made during the drug and alcohol testing processes and helps ensure FFD program effectiveness. This final rule requires the licensee or other entity to protect the individual's privacy and the integrity of the specimen and to implement quality controls to ensure that test results are valid and attributable to the correct individual. This requirement is equivalent to the first sentence of current § 26.405(e), except that the word "stringent" was removed from the phrase "stringent quality controls," because the word "stringent" is not defined.

Section 26.607(e) describes the requirements for licensees and other entities that use offsite collection facilities. Consistent with current § 26.405(e), a licensee or other entity will be able to conduct specimen collections and alcohol testing at a local hospital or other facility, except for those specimens that must be collected onsite under § 26.607(b)(3) and (4). Unlike § 26.405(e), § 26.607(e) does not restrict licensees and other entities to use hospitals and other facilities that meet the U.S. Department of Transportation requirements in 49 CFR part 40 because subpart M of part 26 is intended to provide flexibilities beyond those in the current part 26 framework. Licensees and other entities may use these Department of Transportation requirements to inform their procedures under § 26.606(b)(1) as long as the procedures do not conflict with the requirements in part 26 or the HHS Guidelines.

Section 26.607(e) also requires licensees and other entities to audit offsite collection facilities before their use and biennially to confirm that the facility procedures are comparable to those described in subpart E of part 26 or the HHS Guidelines for urine and oral fluid. This requirement is based on current § 26.41(a) and (b). The § 26.607(e) audit requirement is a program effectiveness consideration because offsite collection facilities may not require vigilance of their collectors (e.g., identification of

subversion attempts), diligence in the protection of worker rights (e.g., privacy and specimen custody and control), or procedural compliance.

The offsite facility used by a licensee or other entity under § 26.607(e) must be licensed to conduct specimen collections and perform alcohol testing, and be audited, by the State or a State-designated entity. This requirement helps provide assurance of adequate collection facility performance and may help reduce the burden on the licensee or other entity and the collection facility. Crediting a State audit (or State licensure, oversight, or regulation) is established in §§ 26.4(i)(4) and (j), 26.91(e)(5), 26.153(f)(1), and 26.183(a).

Section 26.607(f) provides the requirements for initial drug testing. This provision is equivalent to § 26.405(f) except to account for the testing of urine and oral fluid specimens under subpart M of part 26. The initial test must use an immunoassay or an alternative technology, as specified in the HHS Guidelines for the specific biological specimen that is to be tested. Examples of alternative technologies include liquid or gas chromatography and mass spectrometry. Another difference from § 26.405(f) is changing the word “urine” in § 26.405(f) to “biological specimens” in § 26.607(f). Lastly, § 26.607(f) includes the phrase “discrepant biological marker” as a drug screening result that must be analyzed by an HHS-certified laboratory and evaluated by the MRO to help inform the MRO’s determination of a subversion attempt.

Section 26.607(g) enables a part 53 licensee to use oral fluid as a biological specimen for testing. This requirement is equivalent to § 26.31(d)(5), which enables the MRO to conduct drug and alcohol testing using alternative methods, and § 26.405, which does not preclude the use of oral fluid specimens for FFD programs that implement subpart K of part 26 requirements. In order to provide assurance that drug testing is effective and protects the worker, § 26.607(g) requires that the licensee’s or

other entity's procedures incorporate the HHS Guidelines or the requirements in part 26 for the conduct of urine or oral fluid testing.

Section 26.607(g) requires that the oral fluid device must not expire before the date of the collection of the specimen. Also, the drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by the HHS Guidelines for oral fluid drug testing and the alcohol cutoffs in part 26. If they are not established by the HHS Guidelines or this part for the paneled drugs and drug metabolites, then they will be determined and documented by a forensic toxicologist review under § 26.31(d)(1)(i)(D).

Section 26.607(g)(2) permits the virtual collection of oral fluid specimens for drug and alcohol testing but only at facilities that must use a consortium/third-party administrator to implement random testing under § 26.607(b)(2)(vi). A virtual collection monitor is permitted in the location where the specimen collection is to be performed to assist the virtual collector, such as by completing Federal custody and control form (Federal CCF) paperwork; observing activities outside the viewable area of the video teleconference equipment to ensure that the donor does not attempt to subvert the testing process; providing information to the virtual collector if/when requested; and ensuring that the oral fluid specimen(s) once packaged for shipping are secured until picked up for transportation to the HHS-certified laboratory.

Section 26.607(i) enables the collection of hair specimens for drug testing to supplement pre-access testing of urine or oral fluid specimens. Hair testing is a new feature in the part 26 framework. The NRC is permitting the use of hair testing for only Schedule I or II drugs or their metabolites to inform a licensee's or other entity's determination whether the individual is trustworthy and reliable. For example, if an individual stated no prior use of illegal drugs, a pre-access hair test could be performed to ascertain the validity of the individual's statement. However, if the HHS-certified

laboratory reports a positive test result, an FFD policy violation may not be administered. This laboratory information must be treated as potentially disqualifying FFD information, unless the individual is determined to have attempted to subvert the testing process, in which case a permanent denial of authorization must be issued under § 26.610(b)(4). To provide assurance of testing effectiveness and protections afforded to individuals subject to the FFD program, § 26.607(i) requires that an HHS-certified laboratory must be used to test the hair specimen. The forensic toxicologist review is necessary if the panel of drug or drug metabolites to be tested and their cutoffs are not established by HHS or part 26 for hair.

Section 26.607(j) enables the use of portal area screening instruments to test for drugs, alcohol, or both, should these types of screening tests become available for use. This technology could substantially contribute to a licensee or other entity satisfying the § 26.23 performance objectives by helping ensure that all individuals who arrive at the NRC-licensed facility to perform or direct those duties and responsibilities or maintain those types of access making them subject to the FFD program are fit for duty and deterred from arriving onsite in a physiological condition that may be adverse to safety and security. Additionally, screening could be conducted when individuals exit the NRC-licensed facility to provide assurance that substance abuse had not occurred onsite (see § 26.23(d)). The screening instrument could be electronically linked to temporarily prevent ingress or egress and could automatically inform licensee- or other entity-designated officials of the portal area alarm. The use of portal area screening technologies may also represent cost savings because, for NRC-licensed facilities that have small staff sizes or are geographically remote, passive drug and alcohol screening technologies could be an innovative alternative to a random testing program, although the license or other entity would need to request and receive an exemption.

Section 26.607(j) also provides that if the portal area screening instrument detects a substance that exceeds the instrument's established setpoint, the individual then must be for-cause tested under § 26.607(b)(3) for drugs, alcohol, or both, depending on the screening test result received. A portal area screening test result is to be considered credible use information, which strengthens the effectiveness of a licensee's or other entity's BOP. The requirements do not allow an individual to be rescreened by the portal area screening instrument following an initial screening detection that exceeded an established setpoint in order to prevent a subversion attempt. To ensure the accuracy of any portal area screening testing performed by a licensee or other entity, a performance-based approach must be used to verify the continuing accuracy of the testing for each substance tested by the instrument. A portal area screening test can be used so long as the accuracy of the test result for a specific substance is confirmed by the resultant for-cause testing performed on an oral fluid or urine specimen for drugs, oral fluid or breath specimen for alcohol, or both. If a portal area screening result for a specific drug or drug metabolite is confirmed by drug testing performed at an HHS-certified laboratory, or oral fluid or breath alcohol testing for at least 85 percent of the specimens testing positive on portal area screening in the past 12-month data reporting period for a specific substance, the portal area screening test for that substance can continue to be used. This performance-based measure balances the use of the technology with the protection afforded to individuals from unnecessary testing. If these instruments and alcohol screening devices have the capability, they could also be used to determine the true identity of individuals to facilitate the implementation of the FFD BOP, which may be very practicable at facilities that operate with small staff sizes.

Section 26.607(k) enables the use of a blood specimen for drug, alcohol, or other testing for certain medical conditions as determined by the licensee- or other

entity-designated MRO. This requirement is equivalent to current § 26.31(d)(5). The use of a licensee- or other entity-designated MRO and not one designated by a third party, such as an MRO employed by an offsite specimen collection facility, is important because the MRO must be familiar with the subpart M of part 26 requirements. To help ensure testing effectiveness and protect the worker, the blood test needs to be conducted by a laboratory that demonstrates compliance with quality control requirements that are comparable to those required for certification by the HHS, such as a hospital or clinic certified by the State, Commonwealth, or territory.

Section 26.607(l) requires licensee and other entities to use a Federal custody and control form (Federal CCF) as defined in § 26.5 for the collection and packaging of hair, oral fluid, and urine specimens for drug testing. This requirement is based on the Federal CCF documentation requirements in current subpart E of part 26 because subpart K of part 26 does not require the use of a Federal CCF under § 26.117(e).

Section 26.607(m) establishes requirements for the licensee- or other entity-designated MRO. Section 26.607(m)(1) is equivalent to § 26.405(g), however, the word “designated” is added to the first sentence to clarify that the MRO is designated by the licensee or other entity, and not by a third party. As stated with regard to § 26.607(k), this change clarifies that it is the licensee’s or other entity’s responsibility, through their designated MRO, to determine whether an individual is fit for duty and trustworthy and reliable. This is consistent with the description of FFD program personnel in current § 26.31(b) and helps provide FFD program effectiveness and protections to individuals subject to the FFD program. The paragraph was also modified from § 26.405(g) to address the determinations of FFD policy violations and fitness required by subpart H for a part 53 licensee or other entity that implements the FFD program described in § 26.605(b).

Section 26.607(m)(2) helps ensure that MRO reviews are consistent with those MRO reviews conducted at other NRC-licensed facilities subject to part 26 and that the MRO maintains knowledge of drug collection, testing processes and procedures, and evaluation of testing results.

The NRC is also requiring that if an MRO performed the duties and responsibilities in §§ 26.185 and 26.187 for at least three continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity, then the MRO would not need to repeat the initial training and examination requirements. The basis for 3 years is that the MRO has experienced three annual cycles of evaluating drug and alcohol test results, contributed to the annual FFD program performance data reported to the NRC, experienced a refueling or maintenance outage, understood the duties and responsibilities of individuals subject to the FFD program to make informed determinations of fitness, demonstrated a safety culture that helps ensure FFD program effectiveness, and been subject to NRC inspection. The basis for 10 years is the relatively long periods between significant changes to part 26 and the HHS Guidelines.

Section 26.607(m)(3) requires that the MRO attend a medical- or clinical-based training session every 5 years. This requirement was developed, in part, from section 13.1 of the HHS Guidelines for the testing of urine and oral fluid specimens and 49 CFR 40.121 of the U.S. Department of Transportation's requirements. The NRC did not include an examination requirement as part of this refresher training requirement because it could limit the types of trainings that MROs may attend. The new requirement is justified to maintain currency on changes in societal drug use, forensic toxicology, determinations of fitness, and other part 26 technical areas necessary to perform required responsibilities as an MRO performing services under subpart M of part 26.

Section 26.607(m)(4) requires the MRO to evaluate drug testing results by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's

or other entity's procedures. This requirement helps ensure FFD program effectiveness and enhances consistency across the commercial nuclear industry for the evaluation of drug testing results. This also helps protect individuals because they are subject to the same evaluation criteria. If § 26.185 provides insufficient information for an MRO to make a determination on a drug testing result (including adulterant and discrepant biological markers), the guidance issued by a State agency in the State in which the NRC-licensed facility is located, Federal agency, or nationally recognized MRO training and certification organization may be used to inform an MRO determination. This provision ensures that the MRO has the flexibility to inform their evaluation of the drug testing results and fitness determination, if necessary, considering the drug- and alcohol-related flexibilities afforded in subpart M of part 26.

The § 26.607(m)(4)(ii) requirement also states that an MRO need not review alcohol test results, including positive confirmatory alcohol test results determined by an EBT under § 26.607(c)(3)(vi) and (vii), which are equivalent to the current requirements in §§ 26.101 and 26.103, respectively. Section 26.607(c)(3)(i) requires the use of an EBT under § 26.91, which ensures that confirmatory alcohol test results are precise and accurate to issue FFD policy violations.

Section 26.607(m)(5) requires the licensee- or other entity-designated MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a requested specimen for testing. This requirement is equivalent to § 26.31(d)(5), which enables the use of an alternative specimen collection if a medical condition makes the collection of the biological specimen difficult. This determination and the retest must be completed as soon as reasonably practicable and documented to support recordkeeping, auditing, and NRC inspection.

Section 26.607(m)(6) requires that the MRO review all specimen test results associated with a drug-related FFD policy violation. This includes split specimens and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt, impairment without a known cause, or a donor-requested or MRO-directed retest. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs. The broad scope of this MRO evaluation is necessary because of the variety of different screening and testing methods that may have been associated with the FFD policy violation. All information learned from the conduct of part 26 drug and alcohol testing should be used in the evaluation of an individual's trustworthiness and reliability, issuance of a sanction, and development of a follow-up treatment and testing plan, if administered.

Section 26.607(n) is equivalent to current § 26.31(d)(6) and establishes limits on the screening and testing of biological specimens. This is a protection consideration afforded to individuals subject to the FFD program and was not provided in subpart K of part 26. This requirement states that specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, deoxyribonucleic acid (i.e., DNA) testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes.

The NRC is requiring that no biological specimens may be passively sampled and analyzed in a manner different than described in subpart M of part 26 to ensure workers are protected from non-consensual passive screening. The subpart M framework enables passive detection of drugs and alcohol, whereas passive detection is not afforded in subparts A through I, N, and O of part 26.

Section 26.607(o) is equivalent to current §§ 26.31(b)(1)(iii)(A) and 26.89 and requires that all specimen collections be conducted by a licensee- or other entity-designated and -trained individual. For subpart M of part 26, this includes onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j).

Section 26.608 requires licensees and other entities to provide FFD program training to individuals subject to the FFD program. The performance-based § 26.608 requirement was developed from the prescriptive training requirements in current § 26.29 and modeled on current § 50.120 and the requirements in §§ 53.725 and 53.830 because there is no training requirement in subpart K of part 26.

Section 26.608(a)(1) requires an FFD training program that includes the licensee's or other entity's FFD policies and procedures, including fatigue management, and the individuals' FFD program responsibilities. Individuals who collect specimens for testing must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. For individuals specified in § 26.4, a licensee or other entity of a commercial nuclear plant is required to use a SAT, as defined in § 53.725(c)(13). These requirements are based on requirements in § 26.29(a)(2), (3), (9), and (10).

Section 26.608(a)(2) requires training on the BOP. This requirement is based on §§ 26.29(a)(8), (9), and (10), and 26.33. The provision requires individuals to be trained in the detection of behaviors or conditions that may indicate the use of illegal drugs, as in the current § 26.33 BOP requirements, and also the use of illicit drugs and substance abuse onsite and offsite. Also, in reference to impairment from fatigue or any cause if left unattended, the phrase in § 26.33, "may constitute a risk to public health and safety or the common defense and security," is replaced in § 26.608(a)(2)(iii) with "could result in

inattentiveness or human errors," because subpart M of part 26 is focused, in part, on ensuring individuals are fit for duty to perform or direct the performance of assigned duties and responsibilities safely and competently.

Section 26.608(a)(2)(iv) focuses on training to inform individuals that they are responsible for their own conduct, as well as observing others. Specifically, individuals will be trained to recognize when they feel unable to safely and competently perform assigned duties and responsibilities, as well as to recognize when others appear unable to safety and competently perform assigned duties and responsibilities or act in a untrustworthy and unreliable manner. The training requirement and the self-reporting requirement in § 26.606(a)(5) are in the interest of safety and security because the individual is proactively announcing that assistance may be necessary. This is consistent with the performance objectives in § 26.23(b) and (c), where certain behavior or stress conditions may be indicative of an individual not being fit for duty, trustworthy, and reliable.

Section 26.608(a)(3) helps ensure that individuals subject to the FFD program understand that FFD policy violations result in an FFD program sanction and that program information learned or generated by FFD program implementation will be used to aid licensee or other entity authorization determinations and be shared, as requested, with other licensees or other entities subject to parts 26 and 73. This requirement is equivalent to § 26.29(a)(1). Section 26.608(a)(3) is a protection measure afforded to individuals subject to the FFD program because they will understand that licensees and other entities subject to parts 26 and 73 will be informed of, in part, an individual's character, reputation, and ability to follow policies, procedures, and instructions to safely and competently perform assigned duties and responsibilities in a trustworthy and reliable manner. FFD-related information includes drug and alcohol testing results (not quantitative testing values), issuance of any sanctions, FFD determinations regarding

trustworthiness and reliability, testing programs, treatment, and other remedial or corrective action.

Section 26.608(b) requires individuals to be trained on the FFD program and to receive a trainee assessment before pre-access testing. Section 26.608(b) also requires that FFD program refresher training and trainee assessments be conducted on a nominal 24-month frequency or more frequently if the need is indicated. These requirements are similar to § 26.29(c)(1). However, § 26.608(b) was developed from the SAT-based training requirements in § 50.120 and training elements from the annual FFD program refresher training requirements in § 26.29(c)(2). A trainee assessment is the same as in currently required SAT-based training programs.

Section 26.608(c) requires licensees and other entities to periodically evaluate their FFD training programs and revise them as appropriate. This training focus is not required by subpart K of part 26 or § 26.29 but addresses the flexibilities afforded in subpart M of part 26. This section is equivalent to § 50.120(b)(3).

Section 26.609 requires the implementation of a BOP. The requirement is equivalent to that in §§ 26.33 and 26.407, “Behavioral observation,” and applies during construction, operation, and decommissioning, if applicable. Because subpart M of part 26 applies during decommissioning through a licensee’s IMP, § 26.609(a) and (b) were developed, in part, from new § 73.100(b)(9) and current §§ 73.55(b)(9) and 73.56(f) to help ensure consistency in the conduct of behavioral observation whether conducted for FFD or security purposes.

Under the FFD program, the purpose of the BOP is to help ensure that individuals subject to the FFD program are fit for duty and trustworthy and reliable to perform or direct those duties and responsibilities and maintain those types of access that make the individual subject to the FFD program. This assurance is accomplished by requiring each individual subject to subpart M of part 26 to be subject to behavioral

observation, and by requiring all individuals to perform behavioral observation of others and report FFD concerns to the licensee- or other entity-designated representative(s). The intent of the BOP requirement is not to require that all individuals be observed at all times by others; NRC-licensed operators, maintenance professionals, security officers, and others routinely perform solo operations periodically throughout the day. However, individuals must be subject to observation while they are performing or directing the performance of duties and responsibilities or maintaining the types of access making them subject to the FFD program. Observing behavior only at the beginning of a work shift is not sufficient to ascertain whether an individual is fit for duty, trustworthy, and reliable. Impairing substances may have a delayed effect between use (e.g., ingestion of a controlled substance) and the onset of physiological or psychological effects, and fatigue accumulates with time. Behavior must be continually observed throughout the work shift to detect any changes from baseline human performance characteristics, including mental or physical health and mannerisms, or any activities that may indicate that the individual is not trustworthy and reliable.

Section 26.609(a) differs from §§ 26.33 and 26.407 in that it places the responsibility for performing behavioral observation on “all individuals subject to this subpart,” rather than only those “individuals specified in § 26.4(f) [who] are constructing or directing the construction of safety- or security-related SSCs” in § 26.407 or “individuals who are trained under § 26.29 to detect behaviors” in § 26.33 to improve clarity.

Section 26.609(b) requires all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM or may cause harm to others. The NRC is requiring this description of reportable conduct because an individual’s

activities (e.g., use of illegal substances) and communications (e.g., hate speech or threats of violence) offsite are a direct indication of the individual's fitness, trustworthiness, and reliability and must be evaluated as to whether authorization should be granted or maintained. Section 26.609(b) includes a description of this conduct instead of the § 26.33 undefined phrase, "FFD concerns," to enhance the clarity of the requirement. This BOP reporting requirement includes any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information. This better aligns with the § 73.120 BOP requirement, which states that each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security. Section 26.609(a) and (b) were written broadly to include offsite conduct that the reporting individual considers serious enough to call into question the character or reputation of the subject individual.

Section 26.609(c) requires that licensees and other entities perform behavioral observation visually, in-person, and, when necessary, remotely by live video and audible streaming and capture. This requirement was developed from the security observation requirements in § 73.55(e)(7)(i)(B) and (C), (h)(2)(v), and (i)(2) and (i)(5)(ii). Conducting an in-person observation of another individual is the preferred method to ascertain whether the observed individual can safely and competently perform assigned duties and responsibilities. When in-person observations are not feasible (e.g., during solo operations), the requirement enables the use of video monitoring. This is addressed, for example, in § 26.609(d) regarding NRC-licensed operator manipulation of reactor controls. Additionally, certain duties (such as maintenance activities performed by a single worker outside of a control room) may not present an opportunity for video

monitoring; in these situations, behavioral observation should be conducted on a sampling basis (i.e., a planned observation of the work activity) as outlined in a licensee's or other entity's FFD program.

In situations involving small staff sizes, facilities sited in geographically remote locations, or both, additional observers enhance the effectiveness of a BOP. Technological developments in automated safety and security systems may enable licensees or other entities to reduce staff sizes to 10 to 40 percent of the staff size of an LWR facility licensed under part 50 or 52. Smaller staff sizes may translate into more solo operations, less teamwork, fewer peer checks, or infrequent management oversight of field activities, leading to fewer behavioral observations. Therefore, a licensee or other entity may have fewer opportunities to observe whether individuals are fit for duty. Enabling video and audible streaming and capture to enhance the BOP is consistent with the security-related behavioral observation requirement in § 73.120(c)(2)(ii), which also enables video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely.

Section 26.609(d) requires that licensees or other entities perform behavioral observation of NRC-licensed operators who manipulate the controls of any commercial nuclear plant licensed under part 53, remotely by live video and audible streaming capture for those part 53 facilities where individual task loading does not allow for the effective conduct of behavior observation in addition to assigned operational tasks. The purpose of this paragraph is similar to that of § 26.609(c), where the possibility of in-person observation is significantly diminished because of solo operations or because the facility may only require a minimum staff size onsite.

Section 26.610(a) is similar to § 26.409, "Sanctions," and requires the licensee or other entity to establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties

and responsibilities or maintaining authorization making them subject to subpart M of part 26. To be consistent with § 26.75, “Sanctions,” the severity of the sanction as described in § 26.610(b) escalates with the number of occurrences and severity of the FFD policy violation. The sanction is long enough to help deter future FFD policy violations and facilitate counseling and treatment before the licensee reinstates the individual’s access to the facility.

Equivalent to § 26.75(c), § 26.610(b)(3) also requires a minimum 5-year denial of access to the NRC-licensed facility for certain violations of the FFD policy within the protected area of a commercial nuclear plant and by an individual or individuals who are the operators of the conveyance to transport or use formula quantities of strategic SNM. Equivalent to § 26.75(b), § 26.610(b)(4) requires a permanent denial of authorization be issued for any subversion attempt.

Section 26.611 protects information collected from FFD program implementation and is equivalent to current § 26.411, “Protection of information.” The protected information includes, but is not limited to, privacy and medical information. Section 26.611 does not include the § 26.411 requirement that FFD programs must maintain and use the personal information with the highest regard for individual privacy because such a requirement is unnecessary in light of the § 26.611(a) requirement that licensees and other entities must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

Section 26.611(b), although equivalent to § 26.411(b), requires licensees and other entities to have all individuals sign a consent to be subject to the FFD program before subjecting the individual to the FFD program (e.g., before being subject to a pre-access test in § 26.607(b)(1), unlike § 26.411(b)). The purpose of this requirement is to enhance protections afforded to individuals subject to the FFD program and their knowledge of, in part, why they are subject to drug and alcohol testing, behavioral

observation, information collection, MRO reviews, and other FFD program elements. Like the consent required by § 26.411(b), the consent authorizes disclosure of the collected information. Consent is not needed for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.613, “Appeals process.”

Section 26.613 is equivalent to § 26.413, “Review process.” The title was changed to an appeal process to clarify that § 26.613 is the process implemented when an individual elects to appeal a licensee or other entity determination that the individual had violated the FFD policy. The provision also requires that the process include a schedule for the completion of the review of the determination that the individual had violated the FFD policy. The NRC is establishing this requirement because operating experience demonstrates that workers may not be protected from a continuous review process that does not result in an outcome.

Section 26.615 requires licensees and other entities to perform audits of the FFD program. The section is similar to § 26.415, “Audits.” Under § 26.615(a), audits are performed at a frequency that ensures the FFD program’s continuing effectiveness. Corrective actions will be taken as soon as reasonably practicable to resolve any problems identified and preclude recurrence. Section 26.615(b) requires the subject matter, scope, and frequency of audits to be revised as necessary to improve or maintain FFD program performance based on annual FFD program performance data reviews performed under § 26.617(d) and unsatisfactory performance or programmatic weaknesses identified under § 26.617(b)(3) and (e).

Section 26.615(c) is equivalent to § 26.415(b) and enables licensees and other entities to conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

Section 26.615(d) is equivalent to § 26.415(c) by establishing requirements for the auditing of HHS-certified laboratories. Unlike § 26.415(c), the new requirement does not contain a reference to the U.S. Department of Transportation drug and alcohol testing requirements. This broadens the regulatory flexibility afforded to a licensee or other entity in that they may use an offsite collection or testing facility that does not meet the Department of Transportation requirements.

Section 26.615(d) states that licensees and other entities need not audit an HHS-certified laboratory if the licensee's or other entity's panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. The NRC affords this flexibility because the NRC is aware that HHS desires to streamline changes in its guidelines to its panel of drugs and drug metabolites to be tested. Therefore, if a licensee or other entity elects to implement the HHS Guidelines in its procedures and maintains the minimum panel of drugs and drug metabolites to be tested as required by subpart M of part 26, a licensee or other entity may still use (and not audit) the HHS-certified laboratory because the § 26.603(e) change control process maintains FFD program effectiveness.

To help ensure FFD program effectiveness, § 26.615(d) also requires that collection facility procedures are comparable to those required in subpart E of part 26, including a requirement that the offsite facility's specimen collection and testing procedures are audited on a biennial basis, which is also a protection consideration afforded to individuals subject to the FFD program. Conducting this audit on a biennial basis is equivalent to that required in § 26.41(b) and helps ensure that the specimen collection process at the facility remains effective.

Section 26.617 establishes recordkeeping, reporting, and FFD program performance requirements similar to those in current § 26.417. However, § 26.617

requires retention of records pertaining to administration of the FFD program and FFD performance data required by § 26.717 until license termination, which is based on current § 26.711(a) because § 26.417 does not provide for a retention period.

Section 26.617(b)(1) is identical to the reporting requirements in § 26.417(b)(1) regarding the licensee's or other entity's FFD program.

Section 26.617(b)(2) requires the reporting of annual (i.e., January through December) FFD program performance data for each FFD program subject to subpart M. Licensees and other entities must submit the program performance data to the NRC before March 1 of the following year. This reporting is equivalent to the annual program performance requirement in § 26.417(b)(1), and the March 1 due date is based on the reporting deadline in § 26.717(e). Licensees and other entities are required to report FFD performance information using NRC-provided forms (e.g., new NRC Forms 893, "Single Positive Test Form, 10 CFR Part 26, Subpart M FFD Program" and 894, "Annual Reporting Form, 10 CFR Part 26, Subpart M FFD Program").

Section 26.617(b)(3) requires the reporting of drug and alcohol testing errors to the NRC within 30 days of completing an investigation of any testing errors or unsatisfactory performance, discovered at an HHS-certified laboratory or through the processing of appeals under § 26.613, or matters that could adversely reflect on the integrity of the random selection or random testing process. Licensees and other entities must describe in the reports the incident and any corrective actions taken or planned.

Section 26.617(c) requires that FFD-related information be shared within the commercial nuclear industry when requested to support authorization determinations. This requirement helps individuals seeking employment by another NRC-licensed facility subject to subpart C of part 26, complete their NRC-required sanctions and licensee-administered or -directed drug and/or alcohol abuse treatment plans before the restoration of authorization by a licensee or other entity. Information sharing may also

enhance FFD program effectiveness because FFD-related lessons learned from, for example, substance testing, subversion attempts, and laboratory and MRO performance must be shared when requested.

Section 26.617(d) requires licensees and other entities to analyze FFD program performance data at least annually and take appropriate actions to correct any identified program weakness.

Section 26.617(e) requires licensees and other entities to document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee or other entity's corrective action program. However, to protect individual privacy, drug and alcohol test results may not be tracked in a manner that would permit the identification of any individuals.

Section 26.619 requires licensees or other entities to establish a process to evaluate individuals when their fitness or trustworthiness and reliability are in question. Section 26.619 is equivalent to § 26.419, "Suitability and fitness determinations," but, unlike § 26.419, applies during the construction and operation phases. Also, § 26.619 requires that a suitability or fitness determination conducted for cause be conducted face-to-face. This requirement is based on current § 26.189(c); however, unlike § 26.189(c), § 26.619 does not prohibit augmenting determinations via electronic means of communication (i.e., provides sufficient visual and aural clarity to complete the process). Instead, § 26.619 explicitly permits determinations to be performed via electronic means and explains when a trained individual must be present in-person with the individual being assessed (i.e., only to assist in completing for-cause drug and alcohol testing determinations and fatigue assessments).

In considering the current restriction on the use of electronic means of communication for determinations of fitness conducted for cause, the NRC finds that since publication of the 2008 part 26 final rule, there have been developments in using

electronic means of communication (i.e., videoconferencing) as an alternative to conducting face-to-face interactions. To address these considerations, the NRC contracted the Pacific Northwest National Laboratory (PNNL), DOE, to study whether a medical and mental health assessment via electronic communication could be an acceptable alternative to an in-person, face-to-face assessment.[9] Based on this study, if electronic means were to be used to conduct a face-to-face assessment, an in-person element would still be integral to the assessment process. However, under certain circumstances, face-to-face determinations and assessments conducted as part of an FFD program for an entity licensed under part 53 (i.e., those determinations and assessments performed in accordance with § 26.619, § 26.207, or § 26.211) may be augmented via electronic communications. Such remotely conducted determinations and assessments are required to be conducted with someone who is present in-person with the individual being assessed and who is trained in accordance with the requirements of either § 26.29 and § 26.203(c) or § 26.608 and § 26.202(c). Permitting the use of electronic communications helps ensure FFD program effectiveness, especially in instances where the part 53 commercial nuclear plant is sited in a geographically remote location, when the facility has a small staff size, and when an urgent determination is required.

D. Changes to Part 26, Subpart N

Section 26.709 makes the recordkeeping and reporting requirements in subpart N of part 26 applicable to licensees and other entities of facilities licensed under part 53 that elect not to implement the requirements in subpart M of part 26 or elect to implement the requirements in § 26.605(b).

[9] PNNL, Technical Letter Report, "The Use of Electronic Communications to Perform Determinations of Fitness," dated August 2017.

This final rule amends § 26.711(c) and (d) to make these requirements applicable to licensees or other entities described in § 26.3(f). Section 26.711(c) provides protection to individuals subject to part 26 by enabling an individual's right to review FFD-related information and correct any inaccurate or incomplete information. Section 26.711(d) requires, in part, that any FFD-related information shared with other licensees or other entities is correct and complete.

E. Changes to Part 26, Subpart O

Most of the changes to part 26 are new or revised substantive provisions that establish a regulatory obligation or prohibition or are conforming edits to reflect the addition of part 53. The only new provision that is not substantive, such that violation of it would not result in a criminal penalty, is § 26.601. Therefore, the NRC is adding § 26.601 to the list of regulations in § 26.825(b) to which criminal sanctions do not apply.

10 CFR Part 50

A. Section 50.160 Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities

This final rule revises § 50.160(b)(3) and (c)(2) to make that section applicable to applicants and licensees under part 53. Section 50.160 provides an alternative to other part 50 emergency preparedness requirements focused on large light-water reactors to provide an optional emergency preparedness framework specifically for small modular reactors (SMRs) and other new technologies. These alternative emergency preparedness requirements adopt a performance-based, technology-inclusive, risk-informed, and consequence-oriented approach. Commercial nuclear reactor applicants complying with § 50.160 must submit as part of the application the 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 emergency planning zone (EPZ). An EPZ bounds the area surrounding a facility within which detailed planning is needed to implement predetermined, prompt protective actions. The criterion in § 53.1109(g)(2)(i)(A) is that public dose, as defined in § 20.1003, is projected to exceed 10 mSv (1 rem) 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 criterion in § 53.1109(g)(2)(i)(B) is that pre-determined, prompt protective measures are necessary. These are the same criteria that are in § 50.33(g)(2)(i)(A) and (B) and are used to assess the need for and size of an EPZ in applications under parts 50 and 52.

Applicants choosing to comply with § 50.160 must determine the radiological releases from the facility that are evaluated in the determination of the plume exposure pathway EPZ. Applicants should consider quantitative and qualitative information on the potential radiological releases that make up the spectrum of accidents used to develop the basis for the applicant's site-specific EPZ. This information is derived from the licensing basis. The NRC plans to update the risk-informed approach in RG 1.242 for part 53 while maintaining its flexibility for using information already developed and available in licensing-basis documents, including PRA results, deterministic dose quantities, accident timing, target set analyses, mitigation capabilities, and site-specific factors such as meteorology.

Applicants choosing to comply with § 50.160 must determine the radiological releases from the facility that are evaluated in the radiological dose assessment to inform the determination of the plume exposure pathway EPZ size. In its Safety Analysis Report, the applicant will describe the LBEs relevant to the facility and consider these LBEs as candidates for the spectrum of accidents used to develop the site-specific EPZ.

The LBEs assessed include a wide range of events that are appropriate for considering in the facility's emergency preparedness and response planning. In addition, § 50.160(b)(1)(iv)(A)(2) requires licensees to be capable of implementing their approved emergency response plan in conjunction with their safeguards contingency plan.

An appropriate EPZ and pre-determined, prompt protective measures are elements of an effective emergency plan. The EPZ size is primarily informed by the consequences and release characteristics of the LBEs derived from the safety case. Each licensee should ensure that its emergency plan documents the onsite protection strategies and, as warranted, off-site preparedness capabilities to reasonably respond to, monitor, and protect against the potential events associated with the facility. The characteristics of seismic and security events should be provided in the analysis required by § 53.1109(g)(2), but the calculated dose consequences may be, but do not need to be, explicitly considered in the EPZ size determination in the same manner as LBE consequences, if the consequences from these events are less than the consequences from the LBEs. Rather, the characteristics of these events (consequence, timing, radionuclides of release) may be discussed and used to justify that the EPZ size and pre-determined, prompt protective measures to address the LBEs are sufficient to ensure that capabilities exist to reduce consequences of those events.

Part 53 applicants and licensees should consider security events in their EPZ-sizing analysis under § 53.1109(g)(2). If any such events lead to consequences greater than licensing-basis events already being considered in the EPZ size justification and would warrant preplanned prompt protective measures, then the applicant or licensee should include the security event(s) in its EPZ-sizing analysis or provide an adequate alternate method(s) for addressing them. If any of the events do not lead to consequences greater than licensing-basis events already being considered in the EPZ

size justification or would not warrant preplanned prompt protective measures, then the applicant or licensee would not need to include those events in the EPZ-sizing analysis.

B. Appendix B to Part 50: Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

This final rule amends appendix B to part 50 to make it applicable to applicants and licensees under part 53. This results in the need for some revisions to recognize differences in terminology between parts 50 and 53. Namely, the term “design bases,” which is defined in § 50.2, is not used in part 53. For this reason, this final rule adds text in both section III, “Design Control,” and section IV, “Procurement Document Control,” to refer to “functional design criteria, as defined in § 53.020,” as the part 53 equivalent of the term “design bases.”

C. Appendix E to Part 50: Emergency Planning and Preparedness for Production and Utilization Facilities

This final rule amends appendix E to part 50 to make it applicable to applicants and licensees, under part 53, that choose to comply with the requirements in appendix E to part 50 and the planning standards of § 50.47(b) in accordance with § 53.855. Because the regulations contained in § 50.160 are not applicable to large LWR designs, NRC has revised appendix E to recognize the applicability of the appendix to part 53 applicants and licensees. The conforming changes made to appendix E allow its use in conjunction with § 50.47 to provide emergency preparedness framework for large LWR or other designs under part 53.

10 CFR Part 73

A. Section 73.100: Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage

Section 73.100 provides a performance-based regulatory framework for the design, implementation, and maintenance of a physical protection program and security organization for certain commercial nuclear plants licensed under part 53. The current § 73.55 physical security requirements for nuclear power reactors licensed under part 50 and part 52 use a combination of performance criteria (e.g., § 73.55(b)(1) through (3)) and numerous prescriptive requirements developed to achieve performance objectives (e.g., § 73.55(k)(5)(ii)). By contrast, in the performance-based approach to physical security for part 53, performance objectives and requirements are the primary bases for regulatory decision-making, giving the licensee the flexibility to determine how to demonstrate compliance with the established performance criteria for an effective physical protection program. This physical protection program provides reasonable assurance that activities involving SNM are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

Section 73.100(a) requires each part 53 licensee that elects to demonstrate compliance with this section rather than § 73.55 to implement the requirements therein through a graded approach based on achievability of target sets. For licensees that identify achievable target sets, all of the requirements of § 73.100 apply, and must be implemented prior to initial fuel load into the reactor (or, for a fueled manufactured reactor, before initiating the removal of the features to prevent criticality required under § 53.620(d)(1)). For licensees that demonstrate they have no achievable target sets, the requirements are further graded based on whether that demonstration relies on the implementation of active measures, such as operator action, mitigative action, detection, assessment, or armed response. Licensees that do not rely on active measures are exempt from the remaining requirements of § 73.100 (but must still meet physical

protection requirements for SNM or radioactive material, as applicable). Licensees that rely on active measures may limit the scope of their physical protection program by ensuring that the credited active measures will be implemented when needed in response to threats.

Based on experience from recent new reactor licensing reviews, the NRC recognizes that licensees may seek to receive unirradiated fuel onsite before carrying out the security requirements in § 73.100. However, these security requirements must be implemented at some point before reactor operation to address the increased risk arising from irradiated fuel onsite. This final rule makes clear that part 53 applicants and licensees using § 73.100 may bring unirradiated nuclear fuel onsite and protect it in accordance with the NRC's requirements for physical protection of SNM of moderate and low strategic significance under § 73.67 until initial fuel load into the reactor (or, for a fueled manufactured reactor, until initiating the removal of the features to prevent criticality required under § 53.620(d)(1)).

Section 73.100(b) outlines the general performance objective and design requirements of the licensee physical protection program. A licensee's program is required to provide protection against any deliberate act within the design-basis threat (DBT) of radiological sabotage, including spent fuel sabotage, that could directly or indirectly endanger the public health and safety by exposure to radiation. The physical protection program is supported by the AA program, cybersecurity program, and IMP to demonstrate compliance with the general performance objective of § 73.100(b).

Section 73.100(b)(2) was developed, in part, from § 73.55(b)(3). To satisfy the general performance objective of § 73.100(b)(1), the physical protection program must protect against the DBT of radiological sabotage. The existing fleet of LWR satisfies this objective by preventing significant core damage and spent fuel sabotage. Some non-LWR reactor licensees' physical protection programs may be designed to prevent a

significant release of radionuclides from any source. Therefore, the performance objective focuses on radiological sabotage in general, rather than a specific focus on core damage or spent fuel sabotage, to be technology-inclusive and allow for flexibility for different reactor technologies.

Under § 73.100(b)(2)(ii), licensees must provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures. This requirement applies defense-in-depth concepts as part of the physical protection program to ensure the capability to demonstrate compliance with the performance objective of § 73.100(b)(1) is maintained in the changing threat environment. The defense-in-depth philosophy applies to measures against intentional acts as required by § 73.100(b), and the designs of physical security systems should employ defense in depth through systems diversity, independence, and separation under § 73.100(b)(2). The most common defense-in-depth measures apply concepts of redundancy, diversity, independence, and safety margin to ensure systems reliability and availability. The defense-in-depth philosophy applies to the design of a physical protection program, which integrates engineered controls and administrative controls, to provide protection against the DBT for radiological sabotage.

Section 73.100(b)(3) requires a physical protection program that prevents the release of radionuclides from any source from exceeding the dose reference values defined in § 53.210 of this chapter. Dose reference values are intended to assess the performance of systems for design basis scenarios. These values were not originally designed for application to security events. However, because of the analogous nature of the design basis accident and design basis threat concepts, the application of dose reference values to design basis security events is a logical extension of this well-established NRC licensing tool. There are two dose reference values, but typically the 2-

hour 25 rem TEDE value is the most limiting and will, therefore, be the focus of an applicant's assessment. Although this provides less prescriptive defense in depth in achieving performance requirements, the 2-hour 25 rem dose reference value remains protective of public health and safety.

A Part 53 applicant or licensee could voluntarily choose to establish or maintain a physical protection program that prevents significant core damage or spent fuel sabotage (in other words prevent consequences in excess of the DBA consistent with 10 CFR 73.55), and this program will meet the new performance metric without additional analyses.

The NRC notes that the 25 rem TEDE reference dose was originally introduced as a screening criterion in proposed § 53.860 (89 FR 86918), such that below 25 rem TEDE licensees would not be required to meet the provisions of §§ 73.55 or 73.100. For the final rule, the NRC relocated the 25 rem TEDE reference dose to the requirements of § 73.100(b)(3), in response to public comments. The Commission's use of the 25 rem TEDE reference value for this assessment does not imply that the Commission considers it to be an acceptable limit for a security event, but only that it represents a reference value to be used for evaluating plant features and site characteristics.

Section 73.100(b)(4) requires the physical protection program to be designed and implemented to achieve and maintain the reliability and availability of SSCs required for demonstrating compliance with specified performance requirements. These physical protection performance requirements were informed by § 73.55(b) and the Commission's Advanced Reactor Policy Statement.

The performance objective of protecting against the DBT of radiological sabotage is achieved by the design and implementation of the physical protection program, maintained at all times, with the following required performance capabilities in the provisions in § 73.100(b)(4): intrusion detection, intrusion assessment, security

communication, security response, protecting against land and waterborne vehicle bomb assaults, and access control portals. The physical protection program must maintain the reliability and availability of SSCs relied upon for demonstrating compliance with the performance requirements. The terms ‘‘reliability and availability’’ are intended to describe defense in depth in a performance-based manner and are critical elements for demonstrating compliance with the requirement for protection against the DBT of radiological sabotage as described in § 73.100(b)(2).

The first element, “intrusion detection,” is provided through the use of detection equipment, patrols, access controls, and other program elements and provides notification to the licensee that a potential threat is present and where the threat is located.

The second element, ‘‘intrusion assessment,” provides a mechanism through which the licensee identifies the nature of the threat detected. This is accomplished through the use of video equipment, patrols, and other program elements that provide the licensee with timely information about the threat for use in determining how to respond.

The third element, “security communication,” provides a mechanism through which the licensee communicates the necessary information to the response force to ensure effectiveness of the physical protection program. This is accomplished through the redundant, independent, and diverse design of physical security and/or plant SSCs relied on for onsite and offsite security communications. The continuity and integrity of communications should account for the DBT’s ability to affect the reliability and availability of communications.

The fourth element, “security response,” provides a mechanism through which the licensee is capable of timely security response to interdict and neutralize threats up to and including the DBT of radiological sabotage. The security response may include

the use of onsite armed responders, law enforcement responders (local, State, or Federal), or other offsite armed responders (e.g., licensee proprietary or contract security personnel who are positioned offsite), or a combination thereof, as appropriate.[10] The licensee must provide protection against any element of the DBT, to include those that do not rise to the full capability of the DBT. Structures, systems, and components relied on to provide delay functions must be designed to provide for timely response to adversary attacks with adequate defense in depth. Delay allows the licensee to take necessary actions to counter any attempt by the threat to advance toward the protected target or target set element. The overall response objective is to place the threat in a condition from which the threat no longer has the potential for, or capability of, doing harm to the protected target.

The fifth element, “protecting against land and waterborne vehicle bomb assaults,” provides a mechanism through which the licensee is capable of protecting the plant against the DBT vehicle bomb assault. The methods that are relied on to protect against a DBT land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building, structures containing safety or security-related systems, and components from explosive effects.

The sixth element, “access control portals,” provides a mechanism through which the licensee is capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiary devices, explosives) to

[10] The NRC’s security regulations for commercial nuclear power reactors have historically considered onsite armed responders to be the only acceptable method for interdicting and neutralizing threats up to and including the DBT of radiological sabotage. This final rule permits advanced power reactor licensees to use any interdiction and neutralization method, which is an extension of the Commission’s position in SRM-SECY-17-0100, “Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies,” dated October 8, 2018, and SRM-SECY-20-0070, “Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants,” dated June 6, 2024. Under this final rule, a licensee retains the responsibility to detect, assess, interdict, and neutralize threats up to and including the DBT of radiological sabotage, but may rely on law enforcement or other offsite armed responders as a method for fulfilling the required interdiction and neutralization capabilities. For licensees that choose to rely on law enforcement to fulfill these capabilities, this final rule does not create any NRC regulatory jurisdiction over, or requirements for, law enforcement.

protected areas. Integrity of the access control system is maintained through licensee oversight and ensures that attempts to circumvent or bypass the established process will be detected and access denied.

The performance requirements permit the applicant or licensee to determine how to design the physical protection program to protect the plant against the DBT of radiological sabotage without prescriptive requirements such as those currently found in § 73.55. RG 5.97, “Guidance for Technology-Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” has been developed by the NRC to describe one acceptable approach to demonstrate compliance with requirements in § 73.100.

Section 73.100(b)(5) requires the licensee to identify target sets. Target sets are defined in RG 5.81, “Target Set Identification and Development for Nuclear Power Plants,” Revision 2, as the minimum combination of equipment, operator actions, and/or structures that, if all are prevented from performing their intended safety function or prevented from being accomplished, barring extraordinary actions by plant operations, would likely result in a release of radionuclides from any source that would exceed the dose reference values defined in § 53.210. The licensee must further identify which of its target sets are “achievable” (i.e., those that are within the capabilities of the DBT and, if destroyed or disabled, can lead to a significant offsite release of radionuclides that cannot be mitigated).

Section 73.100(b)(6) requires that each licensee perform a site-specific analysis for the purpose of identifying and analyzing site-specific conditions that affect the design of the onsite physical protection program.

Section 73.100(b)(7) requires licensees to implement a performance evaluation program, which ensures that a licensee will periodically test and evaluate the effectiveness of the physical protection program to protect against the DBT. This

program will ensure that licensees are able to demonstrate that the physical protection program satisfies the response requirements of § 73.100 and that the site's protective strategy effectively protects against the DBT. Licensee performance evaluations will include methods to assess, test, and challenge the integration of the physical protection programs functions and demonstrate the effectiveness of security plans, licensee protective strategy, and implementing procedures in accordance with § 73.100(g).

Section 73.100(b)(8) requires licensees to implement an AA program in accordance with § 73.56. Section 73.100(b)(9) requires licensees to establish, maintain, and implement protection against a cyberattack based on either the cybersecurity program described in § 73.110 or the program described in existing § 73.54.

Section 73.100(b)(10) requires an IMP that monitors the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted AA to a protected or vital area. The IMP must also implement defense-in-depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect the licensee's capability to protect against radiological sabotage. Because no one element of the AA program, FFD program, cybersecurity program, or physical protection program would, by itself, provide the level of protection against the insider necessary to demonstrate compliance with the performance objective of § 73.100(b), the effective integration of these programs is a necessary requirement to achieve defense in depth against the potential insider.

Section 73.100(b)(11) requires that the licensee have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements in § 73.100.

Section 73.100(b)(12) requires the coordination of the security plans and associated procedures with other onsite plans to manage the safety and security interface during normal or emergency operations.

Section 73.100(b)(13) requires firearms background check requirements for all members of the security organization whose official duties require access to covered weapons or who inventory enhanced weapons.

Section 73.100(c) was developed from § 73.55(c)(7), “Security implementing procedures,” and § 73.55(d), “Security organization,” and outlines the requirements for the composition, equipping, and training of the security organization. The purpose of the security organization is to effectively implement the physical protection program. Individuals assigned to perform physical protection or contingency response duties must be trained, equipped, and qualified to perform assigned duties and responsibilities.

Section 73.100(d) establishes a performance requirement for searches of personnel, vehicles, and materials for the protection against radiological sabotage. The requirement describes broad categories of material (explosives, firearms, incendiary devices, etc.) to be detected and prevented from entry into the protected area; specific items that will be prohibited are not prescribed in the regulation but will be stated in the licensee security plans with detailed descriptions being identified in implementation procedures.

Section 73.100(e) requires a training and qualification program, described in the training and qualification plan, that ensures personnel are able to effectively perform their assigned security-related job duties. This high-level requirement allows flexibility in how the licensee chooses to train its security personnel. One method for accomplishing this requirement would be to provide a training and qualification program that is equivalent to appendix B to part 73.

Section 73.100(f) requires periodic security reviews of the physical protection program to ensure effective implementation of the program by independent individuals. The evaluation process provides a systematized approach for assessing the physical protection program as a basis for further development and improvement. Program

reviews should be designed to ensure that the physical protection program maintains effectiveness and demonstrates compliance with NRC requirements.

Section 73.100(f)(1) was developed from § 73.55(m) and requires review of each element of the physical protection program. Section 73.100(f)(2) requires licensees to perform self-assessments of physical protection program functions to ensure that the capability to detect, assess, interdict, and neutralize the DBT of radiological sabotage is maintained. Section 73.100(f)(3) requires an audit of the effectiveness of the physical protection program; security plans; implementing procedures; cybersecurity programs; management of the safety/security interface activities; the testing, maintenance, and calibration program; and response commitments by local, State, and Federal law enforcement authorities. Section 73.100(f)(4) requires that results and recommendations, management findings, and any actions taken be documented and maintained to be available for inspection by the NRC. These reviews are independent of the ongoing performance evaluations described in § 73.100(b)(7) and (g).

Section 73.100(g) requires that licensee performance evaluations, described in § 73.100(b)(7), include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the DBT. The performance evaluations must also address the licensee's measures to protect against cyberattacks, in accordance with the required cybersecurity plan, and engineered systems designed to protect against the DBT standalone ground vehicle bomb attack.

Section 73.100(h) establishes performance requirements for maintaining security SSCs relied on to perform security functions to protect against the DBT. It requires that corrective actions and compensatory measures be taken by a licensee in response to a degradation of security equipment or failure of the equipment to perform its intended

functions. The licensee must maintain the SSCs described in its design and licensing basis to ensure that they are reliable and available.

Section 73.100(i) establishes requirements for the suspension of security measures in response to emergency and extraordinary conditions. The requirements of this paragraph, which were developed from § 73.55(p), are intended to provide flexibility to a licensee for taking reasonable actions that depart from a security plan in an emergency when such actions are immediately needed to protect the public health and safety and no action consistent with license conditions and TS that can provide adequate or equivalent protection is immediately apparent in accordance with § 53.740(h).

Section 73.100(j) establishes requirements regarding the inspection, retention and maintenance of records required to be kept by the NRC regulations, orders, or license conditions. These requirements are developed from § 73.55(q).

B. Section 73.110: Technology-inclusive requirements for protection of digital computer and communication systems and networks

Section 53.860(d) requires that a licensee establish, implement, and maintain a cybersecurity program in accordance with § 73.54 or § 73.110. Part 53 applicants and licensees may demonstrate compliance with either of these sections, regardless of whether they elect to comply with the physical security requirements in § 73.55 or § 73.100.

Section 73.110 establishes requirements for the development and maintenance of a cybersecurity program for commercial nuclear plants licensed under part 53. This section implements a graded approach to determine the level of cybersecurity protection required for digital computers, communication systems, and networks. The section is informed by: (1) the operating experience from power reactors and insights from

cyber-related assessments of fuel cycle facilities; and (2) the existing § 73.54 framework, which addresses some of the basic issues for cybersecurity regardless of the type of reactor. Differences between the § 73.54 requirements and those in § 73.110 are primarily based on the implementation of a consequence-based approach to cybersecurity that provides flexibility to accommodate the wide range of reactor technologies to be assessed by the NRC. A graded approach based on consequences is intended to account for the differing risk levels among reactor technologies. Specifically, the section requires licensees to demonstrate protection against cyberattacks in a manner that is commensurate with the potential consequences from those attacks.

Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features, as stated in 10 CFR 53.440(f). This approach ensures considerations are given for safety and security together throughout the plant's lifetime, including the design process and prior to implementing changes to plant configurations, to ensure risks are effectively managed. The requirements in § 73.110 align with this approach by requiring licensees to evaluate whether a cyberattack could lead to the consequences outlined in the rule. This evaluation helps determine whether enhancements to the design basis or physical protection system are warranted. Incorporating cybersecurity strategies and design features early in the design process can be significantly more efficient and cost-effective than retrofitting these measures after the plant has been designed or constructed.

Under § 73.110(a), licensees need to ensure that digital computer and communications systems and networks associated with safety, security, and emergency preparedness functions are adequately protected against a potential cyberattack that would result in: (1) offsite radiation doses that would endanger public health and safety (i.e., the resulting consequence exceeds the reference dose values in § 53.210); or

(2) adversely impacting[11] the security functions necessary to prevent unauthorized removal of material or radiological sabotage. Security digital assets include those used for nuclear MC&A. A cyberattack that results in the consequence defined in § 73.110(a)(1) requires the protection of digital assets associated with safety, security, and emergency preparedness functions. Emergency preparedness functions are included within the scope of this final rule because they are essential for recovering from and mitigating the consequences of radiological sabotage that may result from a successful cyberattack, as required by § 73.110(d)(2) and (d)(3) (i.e., they are part of the defense-in-depth strategy). Digital assets associated with safety-related and non-safety-related but safety-significant systems that perform or support safety functions are within the scope of this final rule as these systems are needed to satisfy the safety criteria in § 53.210 and § 53.220 per § 53.460.

Section 73.110(b) requires licensees to protect the communication system and networks associated with the functions described in § 73.110(a)(1) and (a)(2) from cyberattacks. To accomplish this, the licensee will establish, implement, and maintain a cybersecurity program for protecting digital assets within the scope of § 73.110 that makes use of risk insights, including threat information, and considers the resulting level of consequences of the threats. If the outcome of the assessment by the licensee under § 73.110(b)(1) revealed that a potential cyberattack would not compromise any digital assets that support safety, security, and emergency preparedness functions and

[11] As defined in Regulatory Guide 5.71, "Cybersecurity Programs for Nuclear Power Reactors," Revision 1, adverse impact means a direct deleterious effect on safety-related, important-to-safety, security, or emergency preparedness functions; or the operation of systems, networks, and associated equipment; or the integrity and confidentiality of data and software. Examples include loss or impairment of function; reduction in reliability; reduction in ability to detect, delay, assess or respond to malevolent activities; reduction of ability to call for or communicate with offsite assistance; or the reduction in emergency response ability to implement appropriate protective measures in the event of a radiological emergency. If the direct or indirect compromise of a support system causes a safety-related, important-to-safety, security, or emergency preparedness system or support system to actuate or "fail safe" and not result in radiological sabotage (i.e., causes the system to actuate properly in response to established parameters and thresholds), this is not considered to be an adverse impact.

therefore would not result in the consequences listed in § 73.110(a) (e.g., would not exceed the reference dose values), then only a narrow set of the cybersecurity program requirements in § 73.110(d) and (e) would apply. For example, the licensee would only need to develop a cybersecurity program that implements the following requirements:

- Analyze modifications of any asset before implementation to demonstrate compliance with the potential consequences in § 73.110(a);
- Ensure employees and contractors are aware of cybersecurity requirements and have some level of cybersecurity training;
- Evaluate and manage cybersecurity risks to the plant;
- Review the cybersecurity plan for any required changes; and,
- Retain records of the cybersecurity plan along with any plan changes.

Section 73.110(c) through (e) were developed from § 73.54(a)(2), and (c) through (h), respectively.

The requirements address the need for the licensee to develop a cybersecurity program that implements a defense-in-depth protective strategy as required by § 73.110(d)(2). A defense-in-depth protective strategy for cybersecurity is represented by collections of complementary and redundant security controls that establish multiple layers of protection to safeguard critical digital assets. Under a defense-in-depth protective strategy, the failure of a single protective strategy or security control should not result in the compromise of safety and security functions.

C. Section 73.120: Access authorization program for commercial nuclear plants

Section 73.120 addresses AA for certain commercial nuclear plants licensed under part 53. The language in § 73.120 provides an alternate approach to the existing framework for AA under §§ 73.56 and 73.57, commensurate with risk and consequences

to public health and safety. It is available to part 53 applicants and licensees who demonstrate compliance with § 73.100(a)(1)(i). The requirements in § 73.120 are similar to the existing AA program elements for those NRC-licensed facilities issued additional security measures (ASMs) orders and for materials licensees under § 37.21. Applicants not meeting § 73.100(a)(1)(i) will need to establish, implement, and maintain a full AA program, including an IMP, in accordance with § 73.56.

Section 73.120(a) is based on an applicant demonstrating that they do not exceed the dose reference values defined in § 53.210, as demonstrated through compliance with § 73.100(a)(1)(i). Section 73.120(b) identifies the categories of individuals who are subject to an AA program in accordance with this section. The applicability statement in § 73.120(b)(1)(i) encompasses individuals whom the licensee intends to grant unescorted access to the facilities' most sensitive areas, consistent with § 73.56(b)(1)(i) for power reactors and the ASM orders and license conditions issued to any NRC-licensed facility or material licensee. Sections 73.120(b)(1)(ii) through (iv) are consistent with § 73.56(b)(1)(ii) through (iv), respectively. The program will include individuals who may be onsite or offsite (e.g., remote operators or information technology staff) and have virtual access to important plant operational and communication systems based upon assigned duties and responsibilities. An individual who has remote access to plant equipment and communication systems may have trusted privileges greater than the personnel at the plant site. Section 73.120(b)(1)(iii) states that offsite law enforcement personnel on official duty are not subject to the licensee AA program.

Section 73.120(c) provides general performance objectives and requirements largely consistent with the AA program requirements for nuclear power reactors under § 73.56 and provides licensees and applicants the flexibility in establishing their AA program to demonstrate compliance with various performance objectives.

Section 73.120(c)(1) includes background investigation requirements consistent with § 37.25, as well as ASMs and license conditions that are applied to non-power reactor licensees. Background investigations include important elements to establish the trustworthiness and reliability of an individual, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. These include the following: (1) personal history disclosure, (2) verification of true identity, (3) employment history evaluation, (4) unemployment/military service/education, (5) credit history evaluation, (6) character and reputation evaluation, and (7) Federal Bureau of Investigation criminal history record check.

Section 73.120(c)(2) establishes behavioral observation requirements, which are an awareness initiative for recognizing behaviors adverse to the safe operation and security of the facility through observing the behavior of others in the workplace and reporting aberrant behavior or changes in behavior that might reflect negatively on an individual's trustworthiness or reliability. Maintaining behavioral observation will assist and/or improve worker safety and reduce the risk of an insider threat. This requirement in § 73.120(c)(2) is a scaled version of the full BOP required under § 73.56(f).

Section 73.120(c)(2) provides licensees greater flexibility to implement behavioral observation options for individuals granted unescorted access to the commercial nuclear plant's protected area. Such options on reporting questionable behavior may include a program similar to the Department of Homeland Security's program, "If you see something, say something," or to a corporate behavioral awareness program. Commensurate with the potential lower safety and security risks of a commercial nuclear plant that does not exceed the dose reference values defined in § 53.210, as demonstrated through compliance with § 73.100(a)(1)(i), § 73.120(c)(2) does not require the establishment of a comprehensive training program for behavioral observation (i.e., initial and refresher training including knowledge checks) as required for power reactors

under § 73.56 and part 26. Under § 73.120(c)(2)(ii), behavioral observation can be performed in-person or remotely by video, and identified behavior of concern must be reported to plant supervision. The remote access alternative to face-to-face interactions provides substantial flexibility for licensees and applicants. Any video conferencing or other acceptable electronic means promoting face-to-face interaction for those individuals working remotely will demonstrate compliance with this regulation.

Section 73.120(c)(3) captures and maintains the self-reporting of legal actions as an essential performance element to enhance the licensee's behavioral observation initiative similar to the current requirements under § 73.56(g), assuring that personnel who are granted and who maintain unescorted access are trustworthy and reliable.

Section 73.120(c)(4) provides a scalable approach for granting and maintaining unescorted access. One component not included from § 73.56 is the need for a psychological assessment and reassessment under § 73.56(e) for granting unescorted access and § 73.56(i)(v)(B) for individuals who perform one or more of the job functions described in § 73.120(b)(1)(ii) for maintaining unescorted access. Moreover, the requirement permits criminal history updates to be completed within 10 years of the last review, compared to the 3- or 5-year reinvestigation periodicity for personnel at an operating commercial nuclear plant. In addition, no credit check re-evaluation is required for these individuals.

The continued need to maintain unescorted access will be evaluated on an annual basis by the reviewing official. Guidance in RG 5.95, "Access Authorization Program for Commercial Nuclear Plants," specifies that this evaluation should be based on a compilation of personnel interactions as described in the licensee's or applicant's policy and procedures for behavioral observation and the maintenance of an approved AA list.

Section 73.120(c)(5) requires licensees and applicants to determine when a

person no longer requires the need for unescorted access or no longer satisfies the AA requirement found within this section. Guidance in RG 5.95 further explains that licensees have the flexibility to terminate unescorted access to specific areas of the site if individuals lack the continued need for that access to perform their duties and responsibilities.

Section 73.120(c)(6) is consistent with the purpose of § 37.23(e) and includes the individual's right to correct and complete information as required under § 37.23(g). The section includes a requirement for designating a reviewing official. The language provides clarity regarding the roles and responsibility of a reviewing official, who is the only individual authorized to make unescorted access determinations.

Section 73.120(c)(7) aligns with the corresponding requirements under § 37.23(f), and § 73.120(c)(8) aligns with the corresponding requirements under § 37.31. These requirements encompass the roles and responsibilities for licensees, applicants, and, if applicable, the contractor/vendors to establish, implement, and maintain a system of files and records to ensure personal information is not disclosed to unauthorized persons.

Section 73.120(c)(9) aligns with the requirements of § 37.33.

Section 73.120(c)(10) requires licensees, applicants, and contractors or vendors to maintain the records that are required by the regulations in this section and retain them for a period of 3 years after the record is superseded or no longer needed. The record retention period of 3 years is consistent with § 37.23(h), contrasting with the 5-year retention period under § 73.56(o). Records maintained in any database(s) must be available for NRC review, consistent with the requirements found under § 73.56(o)(6)(ii).

V. Opportunities for Public Participation

The NRC published the proposed rule on October 31, 2024 (89 FR 86918), and the comment period was open until December 30, 2024. On November 22, 2024 (89 FR 92609), the NRC extended the public comment period by an additional 60 days to February 28, 2025, to allow more time for members of the public and other stakeholders to develop and submit their comments.

The NRC hosted two public meetings to engage with external stakeholders on the proposed rule and associated draft guidance documents during the public comment period. The first public meeting was held on November 19, 20, and 21, 2024. The second public meeting was held on January 8, 2025. A summary of both public meetings is available in ADAMS, as provided in the "Availability of Documents" section. The feedback from these public meetings informed the development of this final rule.

VI. Public Comment Analysis

The NRC prepared a summary and analysis of public comments ("Comment Response Document for the Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Volumes I and II) received on the proposed rule and draft RGs, as referenced in the "Availability of Documents" section. In response to the proposed rule and draft RGs, the NRC received 152 unique comment submissions. They can be generally separated into the following classes of stakeholders:

- Industry Groups and Licensees – 68 comment submissions
- Non-Government Organizations – 14 comment submissions
- States, Tribes, and Local Governments – 3 comment submissions
- General Public/Individuals – 67 comment submissions

The public comment submissions are available from the Federal e-Rulemaking website at https://www.regulations.gov under Docket ID NRC-2019-0062. Responses to the public comments, including a summary of how this final rule and the guidance

changed as a result of the public comments, can be found in the public comment response documents as indicated in the “Availability of Documents” section of this document.

For more information about the associated guidance documents, see the “Availability of Guidance” section of this document.

VII. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980, as amended at 5 U.S.C. 601 *et seq*, requires that agencies consider the impact of their rulemakings on small entities and, consistent with applicable statutes, consider alternatives to minimize these impacts on the businesses, organizations, and government jurisdictions to which they apply.

In accordance with the Small Business Administration's (SBA's) regulation at 13 CFR 121.903(c), the NRC has developed its own size standards for performing an RFA analysis and has verified with the SBA Office of Advocacy that its size standards are appropriate for NRC analyses. The NRC size standards at § 2.810, “NRC size standards,” are used to determine whether an applicant or licensee qualifies as a small entity in the NRC's regulatory programs.

Number of Small Entities Affected

The NRC is currently not aware of any known small entities as defined in § 2.810 that are planning to apply for a commercial nuclear plant ESP, CP, OL, ML, or COL under part 53 that would be impacted by this final rule. Based on this finding, the NRC has determined that the final rule does not have a significant economic impact on a substantial number of small entities.

Economic Impact on Small Entities

Although the NRC is not aware of any small entities that are affected by the final rule, there is a possibility that future applications for a commercial nuclear plant permit or license could be submitted by small entities. Commercial nuclear plants of a size

operated by a small entity would most likely be used to support electrical demand for military bases or small remote towns and would provide process heat, so they would not directly compete with a larger commercial nuclear plant that would typically produce electricity for the grid. As a result of these differing purposes, the NRC would expect that small and large entities would not be in direct competition with each other.

Therefore, the NRC concludes that this final rule will not have a significant economic impact on a substantial number of small entities.

VIII. Regulatory Analysis

The NRC has prepared a final regulatory analysis for this rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in the “Availability of Documents” section of this document. The conclusion from the analysis is that this final rule and associated guidance will result in net averted costs to the industry and the NRC of $152 million using a 7-percent discount rate and $203 million using a 3-percent discount rate, using a 66-year analysis period. Detailed information on the costs and cost savings is presented in Table 1.

Table 1—Total Costs and Cost Savings of Final Rule

[In 2024 dollars]

Attribute	**Costs**		
	Undiscounted	Discounted (7%)	Discounted (3%)
Industry Total:	$63,823,000	$11,078,000	$25,492,000
NRC Total:	35,942,000	5,499,000	13,630,000
Net:	99,765,000	16,577,000	39,122,000
Annualized:		1,174,000	1,368,000
Attribute	**Cost Savings**		
	Undiscounted	Discounted (7%)	Discounted (3%)
Industry Total:	($346,524,000)	($139,576,000)	($203,353,000)
NRC Total:	(55,609,000)	(28,685,000)	(38,582,000)
Net:	(402,133,000)	(168,261,000)	(241,935,000)
Annualized:		(11,915,000)	(8,461,000)

Attribute	Net Cost Savings		
	Undiscounted	Discounted (7%)	Discounted (3%)
Industry Net:	($282,700,000)	($128,500,000)	($177,860,000)
NRC Net:	(19,670,000)	(23,190,000)	(24,950,000)
Net:	(302,370,000)	(151,690,000)	(202,810,000)
Annualized:		(10,741,000)	(7,093,000)
Qualitative Benefits:	Improvements in Knowledge, Regulatory Efficiency, and Increased Public Confidence		

IX. Backfitting and Issue Finality

This section describes the backfitting and issue finality implications of this final rule and the final guidance documents described in section XVIII, "Availability of Guidance," in this document, as applied to pertinent NRC approvals and certain applicants that reference NRC approvals in their applications. The NRC's current backfitting provisions associated with nuclear power plants appear in § 50.109, "Backfitting," and apply to CPs and OLs under part 50. Issue finality provisions (analogous to the backfitting provisions in § 50.109) for approvals under part 52 are located in various provisions of part 52. The NRC Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," describes the Commission's policies on backfitting and issue finality.

This final rule provides a regulatory scheme for entities to apply for approvals under part 53. The part 50 backfitting provisions and part 52 issue finality provisions apply to actions taken by the NRC under part 50 or part 52, respectively, or actions taken by the NRC under other parts of 10 CFR chapter I that, for holders of certain approvals under part 50 or part 52, inextricably affect their activities regulated under part 50 or part 52. Issuance and implementation of part 53 will not constitute actions taken under part 50 or part 52. Also, part 53 does not allow an applicant to reference approvals issued under part 50 or part 52. Therefore, the issuance and implementation of part 53 will not affect part 50 or part 52 entities' activities regulated under part 50 or part 52.

Therefore, the addition of part 53 through this final rule is not within the scope of the part 50 backfitting and part 52 issue finality provisions.

The NRC is also making conforming changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 to reflect the addition of part 53. These changes do not meet the definition of "backfitting" in § 50.109 or § 70.76, "Backfitting," because the changes do not modify or add to the systems, structures, components, or design of a facility or to the procedures or organization required to operate a facility under part 50 or 70. These changes do not meet the definition of "backfitting" in § 72.62, "Backfitting," because the changes do not add, eliminate, or modify the SSCs of an independent spent fuel storage installation (ISFSI) or the procedures or organization required to operate an ISFSI. These changes do not inextricably affect activities regulated under parts 50, 52, 70, or 72. Therefore, the changes to parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 do not constitute backfitting under parts 50, 70, or 72 or affect the issue finality of an approval under part 52.

The NRC is issuing nine final guidance documents that provide guidance on the methods acceptable to the NRC for complying with aspects of this final rule. Further, as discussed in the guidance documents, applicants and licensees are not required to comply with the positions set forth in the guidance. Therefore, the final guidance documents do not constitute backfitting under part 50 or affect the issue finality of any approval issued under part 52.

X. Cumulative Effects of Regulation

The NRC seeks to minimize any potential negative consequences resulting from the cumulative effects of regulation (CER). The CER describes the challenges that licensees, or other impacted entities such as State partners, may face while implementing new regulatory positions, programs, or requirements (e.g., rules, generic

letters, backfits, inspections). The CER is an organizational effectiveness challenge that may result from a licensee or impacted entity implementing a number of complex regulatory actions, programs, or requirements within limited available resources.

The goals of the NRC's CER effort were met throughout the development of this final rule. The NRC engaged with external stakeholders at public meetings and solicited public comments on the proposed rule and associated draft guidance documents. The NRC also held numerous public meetings prior to publication of the proposed rule and published numerous versions of preliminary proposed rule language. Although the use of part 53 is voluntary, the NRC included in the proposed rule a request for feedback related to CER. Specifically, the NRC requested feedback on the implementation and potential unintended consequences of the proposed rule. The NRC received two comment submissions in response to these CER questions, but no comments required a change to the rule.

XI. 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).

XII. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment, and, therefore, an EIS is not required. The basis of this determination reads as follows: the implementation of the final rule will not have a significant impact on

the environment. The final rulemaking has requirements that are administrative in application, matters of procedure, or provide an equivalent level of safety as existing requirements; therefore, there will be similar environmental impacts from the implementation of the part 53 regulations as there are for existing requirements.

The NRC requested the views of States on the draft environmental assessment on the proposed rule. The NRC received three comment submissions from States (two comment submissions from the State of New York and one comment submission from the State of Utah), one of which commented on the draft environmental assessment. The NRC received three additional comment submissions related to the draft environmental assessment in the proposed rule. The NRC addressed the comments from the States, along with the other comments on the proposed rule, as discussed in Section VI, “Public Comment Analysis.” None of these comments resulted in changes to the environmental assessment.

The determination of this environmental assessment is that there will be no significant environmental impacts to the public from this action. The environmental assessment and finding of no significant impact are available as indicated under the “Availability of Documents” section.

XIII. Paperwork Reduction Act

This final rule contains new and amended collections of information that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collections of information were approved by the Office of Management and Budget, approval numbers 3150-0274 (part 53), 3150-0146 (part 26), 3150-0271 (part 50), 3150-0002 (part 73), 3150-0278 (NRC Forms 361, 361A, 361N, and 361S), 3150-0104 (NRC Forms 366, 366A, and 366B), 3150-0277 (NRC Form 396), 3150-0276 (NRC Form 398), and 3150-0272 (NRC Forms 893 and 894). The changes to parts 2, 10, 11, 19, 20, 21, 25, 30, 40, 51, 70, 72, 74, 75, 95, 140, 150, 170, and 171 do not contain any new or

amended collections of information subject to the Paperwork Reduction Act of 1995. Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150-0062 (part 11), 3150–0044 (part 19), 3150–0014 (part 20), 3150–0035 (part 21), 3150–0046 (part 25), 3150–0017 (part 30), 3150–0020 (part 40), 3150–0021 (part 51), 3150–0009 (part 70), 3150–0132 (part 72), 3150–0123 (part 74), 3150–0055 (part 75), 3150–0047 (part 95), 3150–0039 (part 140), and 3150–0032 (part 150).

The burden to the public for these information collections is estimated to average 2,257 hours per response for part 53, 9 hours per response for part 26, 4,383 hours per response for part 50, 1,502 hours per response for part 73, and 2 hours per response for NRC Forms 893 and 894, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Other identified information collections (NRC Forms 361, 366, 396, and 398) are not estimated to impose burden during the next 3 years.

The information collection is being conducted to evaluate applications for, issue, and regulate operations under part 53 licenses and exercise its oversight functions in an effective and efficient manner to ensure protection of public health and safety, the promotion of the common defense and security, and the protection of the environment. Information will be used by the NRC to make decisions regarding applications and license amendments, assess licensee compliance with part 53, and take corrective actions as needed. Responses to this collection of information are mandatory for licensees choosing to comply with part 53. Confidential and proprietary information submitted to the NRC is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b).

You may submit comments on any aspect of these information collections, including suggestions for reducing the burden, by the following methods:

- **Federal rulemaking website:** Go to https://www.regulations.gov and search for Docket ID NRC-2019-0062.
- **Mail comments to:** FOIA, Library, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T-6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to the OMB reviewer at OMB Office of Information and Regulatory Affairs (3150-0274), Attention: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503.

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.

XIV. Executive Orders

The following are E.O.s that are related to this final rulemaking.

A. Executive Order 12866: Regulatory Planning and Review (as amended by Executive Order 14215: Ensuring Accountability for All Agencies)

This action is a significant regulatory action under section 3(f) of E.O. 12866 and therefore was submitted to OMB for review.

B. Executive Order 14154: Unleashing American Energy

NRC has examined this final rule 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 a deregulatory action as defined by E.O. 14192. An E.O. 14192 deregulatory action is defined as “an action that has been finalized and has total costs

less than zero.” The final rule and associated guidance will result in net cost savings to the industry and the NRC of $152 million using a 7-percent discount rate and $203 million using a 3-percent discount rate, over the 66-year analysis period. The annualized costs are approximately $1.17 million per year at a 7 percent discount rate, and $1.37 million per year at a 3 percent discount rate. The annualized cost savings are approximately $11.9 million per year at a 7 percent discount rate, and $8.46 million per year at a 3 percent discount rate. Therefore, the net cost savings are estimated at $10.7 million per year at a 7 percent discount rate and $7.09 million per year at a 3 percent discount rate. Accordingly, this final rule has total costs less than zero, and therefore is an E.O. 14192 deregulatory action. Details on the estimated costs of this final rule can be found in Section VIII of this document, “Regulatory Analysis.”

D. Executive Order 14270: Zero-Based Regulatory Budgeting to Unleash American Energy

E.O. 14270, “Zero-Based Regulatory Budgeting to Unleash American Energy,” requires the NRC to insert a conditional sunset date into all new or amended NRC regulations provided the regulations are (1) promulgated under the AEA, the Energy Reorganization Act of 1974, as amended, or the NWPA; (2) not statutorily required; and (3) not part of the NRC’s permitting regime. The NRC determined that the regulatory changes in this rule are statutorily required to comply with NEIMA, necessary for the reasonable assurance of adequate protection of public health and safety, and part of the NRC’s regulatory permitting scheme authorized by the AEA. Therefore, the NRC views this rulemaking to be outside the scope of E.O. 14270 and did not insert conditional sunset dates for the regulatory changes in this final rule.

XV. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Information and Regulatory Affairs in the Office of Management and Budget has found that it does not meet the criteria at 5 U.S.C. 804(2).

XVI. Criminal Penalties

This final rule includes federal regulations that will be enforceable by criminal penalty, as authorized by Section 223 of the AEA. Therefore, per E.O. 14294, these regulations constitute "criminal regulatory offenses."

For the purposes of Section 223 of the AEA, the NRC is issuing this final rule that will add a new 10 CFR part 53 and amend 10 CFR parts 19, 20, 21, 25, 26, 30, 40, 50, 70, 72, 73, 74, 95, and 140 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the regulations in these parts will be subject to criminal enforcement, other than those listed in § 19.40(b), § 20.2402(b), § 21.62(b), § 25.39(b), § 26.825(b), § 30.64(b), § 40.82(b), § 50.111(b), § 53.9010(b), § 70.92(b), § 72.86(b), § 73.81(b), § 74.84(b), § 95.63(b), or § 140.89(b). Criminal penalties as they apply to regulations in part 53 are discussed in § 53.9010.

XVII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC will revise its regulations by adding a risk-informed, technology-inclusive regulatory framework for commercial advanced nuclear reactors. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVIII. Availability of Guidance

As discussed in section II, Background, of this document, the NRC's development of part 53 built upon activities such as those described in SECY-19-0117. Because a number of those activities are ongoing to support new reactor applications under the existing regulatory framework of 10 CFR parts 50 and 52, the NRC staff identified in its response to SRM-SECY-20-0032 that the timing of guidance document development to support the part 53 rulemaking was a key risk and uncertainty to publishing the final part 53 rule. To mitigate this risk, the NRC engaged external stakeholders to ensure a common prioritization of the development of these guidance documents and to work diligently on those that would be needed to support this rulemaking, forthcoming applications, or broader efforts such as the Advanced Reactor Demonstration Program being sponsored by the DOE. The NRC also recognizes that guidance development to support part 53 and advanced reactors will continue as the industry and NRC learn lessons from licensing reviews and operating experience.

The NRC is issuing nine guidance documents for the implementation of the requirements in this rulemaking. The guidance is available in ADAMS under the Accession Numbers as indicated under the "Availability of Documents" section in this document.

- RG 5.81, Revision 2, "Target Set Identification and Development for Nuclear Power Reactors" (nonpublic)

This regulatory guide (RG) was issued in draft form as Draft Regulatory Guide (DG)-5071 with the proposed rulemaking on Alternative Physical Security Requirements for Advanced Reactors (RIN 3150-AK19; Docket ID NRC-2017-0227) on August 9, 2024. (89 FR 65226). In addition, some sections from DG-5072, "Guidance for Alternative Physical Security Requirements for Small Modular Reactors and Non-Light-Water Reactors," which was also issued with the same rulemaking, have been incorporated into RG 5.97, "Guidance for Technology-Inclusive Requirements for

Physical Protection of Licensed Activities at Commercial Nuclear Plants." The changes to these guidance documents are a result of the NRC's resolution of public comments on the 10 CFR part 53 proposed rule that requested the NRC address comments made on the proposed Alternative Physical Security Requirements for Advanced Reactors rule. As a result, the NRC addressed the public comments received on those draft guidance documents that were incorporated into the guidance documents for this final rulemaking. Those comment responses can be found in "Comment Response Document for the Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Volume II.

- RG 1.254, Revision 0, "Technology-Inclusive Identification of Licensing Events for Commercial Nuclear Plants"

This RG describes an acceptable approach for identifying licensing events that can be used to inform the design basis, licensing basis, and content of applications for commercial nuclear plants, including large LWRs and non-LWRs. It applies to nuclear power reactor designers, applicants, and licensees of commercial nuclear plants applying for permits, licenses, certifications, and approvals under parts 50, 52, and 53. In this RG, the term "licensing events" is used in a generic sense to refer to collections of designated event categories such as, but not limited to AOOs, DBAs, DBEs, and postulated accidents. Specifically, this RG provides an acceptable approach for: (1) conducting a comprehensive and systematic search for initiating events; (2) using a systematic process to delineate a comprehensive set of event sequences; (3) grouping initiating events and event sequences into designated licensing event categories; and (4) providing assurance that the set of licensing events is complete.

- RG 5.95, Revision 0, "Access Authorization Program for Commercial Nuclear Plants"

This RG describes a method that the staff considers acceptable to comply with requirements in § 73.120, “Access authorization program for commercial nuclear plants,” related to an AA program. This document provides guidance and is one NRC-approved method (not the only method) for meeting regulatory requirements for part 53. The language in § 73.120 provides flexibility through availability of the use of an alternate approach, commensurate with risk and consequence to public health and safety, for part 53 applicants who demonstrate compliance with § 73.100(a)(1)(i).

- RG 5.96, Revision 0, “Establishing Cybersecurity Programs for Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

This RG describes an approach the NRC staff deems acceptable for complying with the Commission’s regulations for establishing, implementing, and maintaining a cybersecurity program at commercial nuclear plants licensed under part 53. This guidance provides an approach for meeting the requirements of § 73.110, “Technology-inclusive requirements for protection of digital computer and communication systems and networks.”

- RG 5.97, Revision 0, “Guidance for Technology-Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants”

This RG describes methods and approaches that the NRC staff considers acceptable for meeting the physical security requirements of 10 CFR part 53 and 10 CFR 73.100.

- RG 5.99, Revision 0, “Fatigue Management for Nuclear Power Plant Personnel at Commercial Nuclear Plants Licensed Under 10 CFR Part 53”

This RG describes methods that the NRC staff considers acceptable for addressing certain aspects of FFD programs established at commercial nuclear facilities licensed under part 53. This guidance, in conjunction with the existing RG 5.73, “Fatigue Management for Nuclear Plant Personnel,” provides comprehensive guidance regarding

acceptable methods for the development and implementation of licensee fatigue management programs.

The NRC is issuing the following interim staff guidance (ISG) documents for the implementation of NRC staff review of applications under the requirements in this rulemaking:

- DRO-ISG-2023-01, “Operator Licensing Programs”

This ISG provides guidance for the review of tailored operator licensing programs that are submitted for review consistent with the technical requirements of § 53.730(g). This guidance primarily addresses the review of operator licensing examination processes to facilitate the ability of reviewers to assess whether a proposed approach to the testing of licensed operators and trainees reflects sound assessment testing practices that are suitable for the screening of competent licensed operators. Additionally, this ISG provides further review guidance in other areas such as licensed operator continuing training and proficiency programs.

- DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53”

This ISG provides guidance for the review of customized facility operator staffing plans that are submitted for review consistent with the technical requirements of § 53.730(f). This ISG is structured as a companion document to the existing NUREG-1791 and adapts the existing HFE-based methodologies of that document for use in the evaluation of staffing plans that will be submitted within the context of part 53 facilities. Additionally, this ISG provides further guidance to address other staffing-related considerations, such as provisions for engineering expertise.

- DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans”

This ISG applies to the HFE review of applications for OLs, COLs, DCs, and standard design approvals for commercial nuclear plants submitted under part 53. The purpose of this ISG is to facilitate NRC understanding of an acceptable method for developing a scalable (i.e., application-specific) plan for the review of these applications for compliance with applicable HFE requirements. The ISG describes a process and provides implementation guidance for the NRC to tailor HFE review plans to each application to achieve an effective and efficient review.

The NRC has identified future guidance activities that need to be completed after this final rule is published to support advanced reactor applications and NRC reviews. This includes issuance of revisions or part 53-related companions to already available guidance documents after the final part 53 rule is published.

XIX. 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.

Document	**ADAMS Accession No. / Web link / *Federal Register* Citation**
Final Rule Documents	
Federal Register Notice, “Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” dated March, 2026	ML26042A232
“Environmental Assessment for the Final Rule—Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” dated March, 2026	ML26042A231

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
"Regulatory Analysis for the Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," March, 2026	ML26042A230
"Comment Response Document for the Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Volume I, dated March, 2026	ML26042A229
"Comment Response Document for the Final Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," Volume II, dated March, 2026	ML26042A228
Information Collection Documents	
Supporting Statement for Information Collection Analysis – 10 CFR Part 53	ML25230A038
Supporting Statement for Information Collection Analysis – 10 CFR Part 26	ML25230A037
Supporting Statement for Information Collection Analysis – 10 CFR Part 50	ML25232A004
Supporting Statement for Information Collection Analysis – 10 CFR Part 73	ML25230A039
Supporting Statement for Information Collection Analysis – NRC Form 361S	ML25230A034
Supporting Statement for Information Collection Analysis – NRC Form 366	ML25230A035
Supporting Statement for Information Collection Analysis – NRC Form 396	ML25245A175
Supporting Statement for Information Collection Analysis – NRC Form 398	ML25245A176
Supporting Statement for Information Collection Analysis – NRC Form 893 and 894	ML25230A036
Final Rule – Part 26 Burden Tables for Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors	ML25282A045

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
Final Rule – Part 50 Burden Tables for Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors	ML25282A044
Final Rule – Part 53 Burden Tables for Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors	ML25282A046
Final Rule – Part 73 Burden Tables for Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors	ML25282A043
NRC Form 361S, “Part 53 Plant Event Notification Worksheet”	ML25230A030
NRC Form 366, “Licensee Event Report (LER)”	ML25230A031
NRC Form 366A, “Licensee Event Report (LER) Continuation Sheet”	ML25230A032
NRC Form 366B, “Licensee Event Report (LER) (Failure Continuation)”	ML25231A040
NRC Form 396, “Certification of Medical Examination by Facility Licensee”	ML25245A149
NRC Form 398, “Personnel Qualification Statement—Licensee”	ML25245A173
NRC Form 893, “Single Positive Test Form, 10 CFR Part 26, Subpart M FFD Program”	ML25230A033
NRC Form 894, “Annual Reporting Form, 10 CFR Part 26, Subpart M FFD Program”	ML25231A039
Regulatory Guidance Documents	
RG 1.254, “Technology-Inclusive Identification Of Licensing Events For Commercial Nuclear Plants,” dated March, 2026	ML25232A005
RG 5.81, “Target Set Identification and Development for Nuclear Power Reactors,” Revision 2, (non-public) dated March, 2026	ML24229A186
RG 5.95, “Access Authorization Program for Commercial Nuclear Plants,” dated March, 2026	ML25232A007

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
RG 5.96, “Establishing Cybersecurity Programs For Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” dated March, 2026	ML25232A008
RG 5.97, “Guidance for Technology-Inclusive Requirements for Physical Protection of Licensed Activities at Commercial Nuclear Plants,” dated March, 2026	ML25232A009
RG 5.99, “Fatigue Management For Nuclear Power Plant Personnel At Commercial Nuclear Plants Licensed Under 10 CFR Part 53,” dated March, 2026	ML25232A010
ISG Documents	
DRO-ISG-2023-01, “Operator Licensing Programs,” dated March, 2026	ML25232A011
DRO-ISG-2023-02, “Interim Staff Guidance Augmenting NUREG-1791, ‘Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10 CFR 50.54(m),’ for Licensing Commercial Nuclear Plants under 10 CFR Part 53,” dated March, 2026	ML25232A023
DRO-ISG-2023-03, “Development of Scalable Human Factors Engineering Review Plans,” dated March, 2026	ML25232A022
Other References	
American National Standards Institute (ANSI)/American Nuclear Society (ANS)-3.4-2013, “Medical Certification And Monitoring Of Personnel Requiring Operator Licenses For Nuclear Power Plants”	https://webstore.ansi.org/Standards/ANSI/ansians2013
ASME/ANS RA-S-1.4-2021, “Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants”	https://www.asme.org/codes-standards/find-codes-standards/probabilistic-risk-assessment-standard-for-advanced-non-light-water-reactor-nuclear-power-plants/2021/pdf

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
ASCE/SEI 43-19, “Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities”	https://doi.org/10.1061/9780784415405
EO 12866, “Regulatory Planning and Review,” dated September 30, 1993	58 FR 190
EO 14154, “Unleashing American Energy,” dated January 20, 2025	90 FR 8353
EO 14192, “Unleashing Prosperity Through Deregulation,” dated February 6, 2025	90 FR 9065
EO 14270, “Zero-Based Regulatory Budgeting to Unleash American Energy,” dated April 15, 2025	90 FR 15643
EO 14300, “Ordering the Reform of the Nuclear Regulatory Commission,” dated May 29, 2025	90 FR 22587
Federal Register notice—Final policy statement, “Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement,” dated August 16, 1995	60 FR 42622
Federal Register notice—Final rule, “Consideration of Aircraft Impacts for New Nuclear Power Reactors,” dated June 12, 2009	74 FR 28112
Federal Register notice—Final rule, “Fitness for Duty Programs,” dated March 31, 2008	73 FR 16966
Federal Register notice—Final rule, “Licenses, Certifications, and Approvals for Nuclear Power Plants,” dated August 28, 2007	72 FR 49352
Federal Register notice—Final rule, “Station Blackout,” dated June 21, 1988	53 FR 23203
Federal Register notice—Final rule, “Technical Specifications,” dated July 19,1995	60 FR 36953
Federal Register notice—Guidance, “Mandatory Guidelines for Federal Workplace Drug Testing Programs – Oral/Fluid,” dated October 25, 2019	84 FR 57554

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
Federal Register notice—Policy Statement, “Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants,” dated August 8, 1985	50 FR 32138
Federal Register notice—Policy Statement, “Safety Goals for the Operation of Nuclear Power Plants; Policy Statement; Correction and Republication,” dated August 21, 1986	51 FR 30028
Federal Register notice—Policy Statement, “Tribal Policy Statement,” dated January 9, 2017	82 FR 2402
Federal Register notice—Policy Statement, “Policy Statement on the Regulation of Advanced Reactors,” dated October 14, 2008	73 FR 60612
Federal Register notice—Policy Statement, “Final Safety Culture Policy Statement,” dated June 14, 2011	76 FR 34773
Federal Register notice—Proposed rule, “Regulatory Improvements for Production and Utilization Facilities Transitioning to Decommissioning,” dated March 3, 2022	87 FR 12254
Federal Register notice—Proposed rule, “Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” dated October 31, 2024	89 FR 86918
Federal Register notice—Proposed rule; extension of comment period, “Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors,” dated November 22, 2024	89 FR 92609
Federal Register notice—Public meeting, “Reporting Requirements for Nonemergency Events at Nuclear Power Plants,” dated November 29, 2021	86 FR 67669
International Commission on Radiological Protection (ICRP), Publication 2 “Permissible dose for internal radiation,” dated 1960	https://www.icrp.org/publication.asp?id=icrp%20publication%202

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
ICRP, Publication 26 “Recommendations of the ICRP,” dated 1977	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2026
ICRP, Publication 30 “Limits for Intakes of Radionuclides by Workers,” dated 1979	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2030%20(Index)
Letter to Chairman Hanson, NRC, “Final Letter on Draft 10 CFR Part 53 Rulemaking Language,” dated November 22, 2022	ML22319A104
Letter to Chairman Hanson, NRC, “Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language,” dated August 2, 2022	ML22196A292
Letter to Chairman Hanson, NRC, “Preliminary Proposed Rule Language For 10 CFR Part 53, Regulation of Advanced Nuclear Reactors, Interim Report,” dated May 30, 2021	ML21140A354
Letter to Chairman Hanson, NRC, “Preliminary Rule Language For 10 CFR Part 53, Subpart F, ‘Requirements for Operations,’ Interim Report,” dated February 17, 2022	ML22040A361
Letter to Chairman Rempe, ACRS, “Response to the Advisory Committee on Reactor Safeguards, ‘Fourth Interim Letter on 10 CFR Part 53 Rulemaking Language,’” dated September 30, 2022	ML22249A073
Letter to Chairman Rempe, ACRS, “Response to the Advisory Committee on Reactor Safeguards Letter on Preliminary Rule Language for 10 CFR Part 53, Subpart F, ‘Requirements for Operations,’ Interim Report,” dated March 30, 2022	ML22063A012
Letter to Chairman Sunseri, ACRS, “Part 53, Licensing and Regulation of Advanced Nuclear Reactors,” dated November 24, 2020	ML20311A006
Letter to Chairman Svinicki, NRC, “10 CFR Part 53, Licensing and Regulation of Advanced Nuclear Reactors,” dated October 21, 2020	ML20295A647

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
National Library of Medicine, National Institutes of Health, Workshop Summary, "The Evolution of Telehealth: Where Have We Been and Where Are We Going?," dated November 2012	https://www.ncbi.nlm.nih.gov/books/NBK207141/
NEI 18-04, Rev. 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactors," dated August 2019	ML19241A472
NEI 22-05, Rev. 0, "Technology Inclusive Risk Informed Change Evaluation (TIRICE)," dated January 2024	ML24032A237
Nuclear Innovation Alliance (NIA), "Clarifying 'Major Portions' of a Reactor Design in Support of a Standard Design Approval," dated April 2017	https://www.nuclearinnovationalliance.org/clarifying-major-portions-reactor-design-support-standard-design-approval
NRC, "Advanced Reactor Vision and Strategy: Safely Achieving Effective and Efficient Non-Light Water Reactor Mission Readiness," dated December 2016	ML16356A670
NRC, "A Regulatory Review Roadmap for Non-Light Water Reactors," dated December 2017	ML17312B567
NRC, "Manufacturing License ML-1 for Production of Up to Eight Floating Nuclear Plants," dated September 30, 1982	ML20070J215
NRC, "Report to Congress: Advanced Reactor Licensing," dated August 2012	ML12158A398 (cover letter) ML12153A014 (report)
NRC, "Risk-Informed and Performance-Based Human-System Considerations for Advanced Reactors," dated March 2021	ML21069A003
NRC Form 890, "Single Positive Test Form"	ML25044A086
NRC Form 891, "Annual Reporting for Drug and Alcohol Tests"	ML26016A656
NRC Form 892, "Annual Fatigue Reporting Form"	ML22013B250

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
NRC Public Meeting Summary, “Public Meeting to Discuss the Part 53 Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors Rulemaking - Proposed Rule” (November 19, 20, and 21, 2024), dated January 14, 2025	ML25014A024
NRC Public Meeting Summary, “Public Meeting to Discuss the Part 53 Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors Rulemaking - Proposed Rule” (January 8, 2025), dated January 24, 2025	ML25042A010
NUREG-0880, “Safety Goals for Nuclear Power Plant Operation,” dated May 1983	ML071770230
NUREG/CR-2601, “Technology, Safety and Costs of Decommissioning Reference Light Water Reactors Following Postulated Accidents” dated November 1982	ML14023A046 (package)
NUREG-1530, Revision 1, “Reassessment of NRC’s Dollar Per Person-Rem Conversion Factor Policy, Final Report,” dated February 2022	ML22053A025
NUREG-1860, Volumes 1 and 2, “Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing,” dated December 2007	ML080440170 ML080440215
NUREG/BR-0058, Revision 5, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” dated April 2017	ML17100A480
NUREG/CR-5884, “Revised Analyses of Decommissioning for the Reference Pressurized Water Reactor Power Station,” dated November 1995	ML14008A187
NUREG/CR-6187, Volume 1, “Revised Analyses of Decommissioning for the Reference Boiling Water Reactor Power Station,” dated July 1996	ML14008A186

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
PNNL, Technical Letter Report, “The Use of Electronic Communications to Perform Determinations of Fitness,” dated August 2017	ML18081A607
Pre-decisional DG, “Technology-Inclusive, Risk-Informed, and Performance-Based Methodology for Seismic Design of Commercial Nuclear Plants,” dated October 3, 2022	ML22276A149
Research Information Letter 2021-04, “Feasibility Study on a Potential Consequence-Based Seismic Design Approach for Nuclear Facilities,” dated April 2021	ML21113A066
RG 1.110, Revision 1, “Cost-Benefit Analysis for Radwaste Systems for Light-Water-Cooled Nuclear Power Reactors,” dated October 2013	ML13241A052
RG 1.134, Revision 4, “Medical Assessment Of Licensed Operators Or Applicants For Operator Licenses At Nuclear Power Plants,” dated September 2014	ML14189A385
RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,” Revision 3, dated January 2018	ML17317A256
RG 1.208, “A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,” dated March 2007	ML070310619
RG 1.232, “Guidance for Developing Principal Design Criteria for Non-Light-Water Reactors,” Revision 0, dated April 2018	ML17325A611

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
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
RG 1.247, “Acceptability of Probabilistic Risk Assessment Results for Non-Light-Water Reactor Risk-Informed Activities,” issued March 2022 for trial use	ML21235A008
RG 5.71, “Cybersecurity Programs for Nuclear Power Reactors,” Revision 1, dated February 3, 2023	ML22258A204
RG 5.73, “Fatigue Management for Nuclear Power Plant Personnel,” dated March 20, 2009	ML083450028
SECY-18-0096, “Functional Containment Performance Criteria For Non-Light-Water-Reactors,” dated September 28, 2018	ML18115A157
SECY-19-0117, “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 December 2019	ML18311A264 (package)
SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062,’” dated April 13, 2020	ML19340A056
SECY-20-0070, “(Redacted) Technical Evaluation of the Security Bounding Time Concept for Operating Nuclear Power Plants,” dated November 8, 2021	ML20126G265 (package)
SECY-24-0049, “Proposed Rule: Reporting Requirements for Nonemergency Events at Nuclear Power Plants (RIN 3150-AK71; NRC-2020-0036),” dated June 10, 2024	ML23318A479

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
SECY-93-092, “Issues Pertaining to the Advanced Reactor (PRISM, MHTGR, and PIUS) and CANDU 3 Designs and their Relationship to Current Regulatory Requirements,” dated April 8, 1993	ML040210725
SRM-SECY-10-0121, “Modifying the Risk-Informed Regulatory Guidance for New Reactors,” dated March 2, 2011	ML110610166
SRM-SECY-17-0100, “Security Baseline Inspection Program Assessment Results and Recommendations for Program Efficiencies,” dated October 8, 2018	ML18283A072
SRM-SECY-20-0032, “Rulemaking Plan on ‘Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN-3150-AK31; NRC-2019-0062),’” dated October 2, 2020	ML20276A293
SRM-SECY-20-0045, “Population Related Siting Considerations for Advanced Reactors,” dated July 30, 2022	ML22194A885
SRM-SECY-98-144, “Staff Requirements—SECY-98-144—White Paper on Risk-Informed and Performance-Based Regulations,” dated February 24, 1999	ML003753593
SECY-23-0021, “Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31),” March 1, 2023	ML21162A095
SECY-23-0021, Enclosure 1, “Draft Federal Register Notification”	ML21162A102
SECY-23-0021, Enclosure 2, “Draft Environmental Assessment for the Proposed Rule—Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors”	ML21162A104
SECY-23-0021, Enclosure 3, “Draft Regulatory Analysis for the Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors”	ML21165A112

Document	ADAMS Accession No. / Web link / *Federal Register* Citation
SECY-23-0021, Enclosure 4, "Alternative Approaches Considered for Selected Topics During the Development of 10 CFR Part 53"	ML22244A001
SECY-23-0021, Enclosure 5, "Estimated Resources for The Risk-Informed, Technology-Inclusive Regulatory Framework For Advanced Reactors Rulemaking"	ML22304A099 (non-public)
Staff Requirements - SECY-23-0021, "Proposed Rule: Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors (RIN 3150-AK31)," March 4, 2024	ML24064A047 (package)

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-2019-0062. 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-2019-0062); 2) click the "Subscribe" link; and 3) enter an email address and click on the "Subscribe" link.

List of Subjects

10 CFR Part 1

Flags, Organization and functions (Government Agencies), Seals and insignia.

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 10

Administrative practice and procedure, Classified information, Government employees, Security measures.

10 CFR Part 11

Hazardous materials transportation, Investigations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Special nuclear material.

10 CFR Part 19

Criminal penalties, Environmental protection, Nuclear Energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 21

Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 25

Classified information, Criminal penalties, Investigations, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 26

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Appeals, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power plants and reactors, Privacy, Protection of information, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 30

Byproduct material, Criminal penalties, Fusion, Government contracts, Intergovernmental relations, Isotopes, Nuclear energy, Nuclear materials, Penalties, Radiation protection, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 40

Criminal penalties, Exports, Government contracts, Hazardous materials transportation, Hazardous waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Source material, Uranium, Whistleblowing.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 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 70

Classified information, Criminal penalties, Emergency medical services, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material, Whistleblowing.

10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

10 CFR Part 73

Criminal penalties, Exports, Hazardous materials transportation, Imports, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 74

Accounting, Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear energy, Nuclear materials, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Special nuclear material.

10 CFR Part 75

Criminal penalties, Intergovernmental relations, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Security measures, Treaties.

10 CFR Part 95

Classified information, Criminal penalties, Penalties, Reporting and recordkeeping requirements, Security measures.

10 CFR Part 140

Insurance, Intergovernmental relations, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements.

10 CFR Part 150

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Security measures, Source material, Special nuclear material.

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

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 adopting the following amendments to 10 CFR

parts 1, 2, 10, 11, 19, 20, 21, 25, 26, 30, 40, 50, 51, 70, 72, 73, 74, 75, 95, 140, 150, 170, and 171 and adding 10 CFR part 53:

PART 1—STATEMENT OF ORGANIZATION AND GENERAL INFORMATION

1. The authority citation for part 1 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 23, 25, 29, 161, 191 (42 U.S.C. 2033, 2035, 2039, 2201, 2241); Energy Reorganization Act of 1974, secs. 201, 203, 204, 205, 209 (42 U.S.C. 5841, 5843, 5844, 5845, 5849); Administrative Procedure Act (5 U.S.C. 552, 553); Reorganization Plan No. 1 of 1980, 5 U.S.C. Appendix (Reorganization Plans).

§ 1.43 [Amended]

2. In § 1.43, in paragraph (a)(2) add the number “53,” in sequential order.

PART 2—AGENCY RULES OF PRACTICE AND PROCEDURE

3. 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).

§ 2.1 [Amended]

4. In § 2.1, in paragraph (e) remove the phrase “part 52” and add in its place the phrase “part 52 or part 53”.

5. In § 2.4, revise the definitions for “*Contested proceeding*” and “*Facility*” to read as follows:

§ 2.4 Definitions.

* * * * *

Contested proceeding means—

(1) A proceeding in which there is a controversy between the NRC staff and the applicant for a license or permit concerning the issuance of the license or permit or any of the terms or conditions thereof;

(2) A proceeding in which the NRC is imposing a civil penalty or other enforcement action, and the subject of the civil penalty or enforcement action is an applicant for or holder of a license or permit, or is or was an applicant for or holder of a license or permit, or is or was an applicant for a standard design certification under part 52 or part 53 of this chapter; and

(3) A proceeding in which a petition for leave to intervene in opposition to an application for a license or permit has been granted or is pending before the Commission.

* * * * *

Facility means a production facility or a utilization facility as defined in §§ 50.2 and 53.020 of this chapter.

* * * * *

§ 2.100 [Amended]

6. In § 2.100, remove the phrase “subpart E of part 52” and add in its place the phrase “subpart E of part 52 or subpart H of part 53”.

7. In § 2.101, revise paragraphs (a)(3)(i), (a)(5), (a)(9) introductory text, and (a)(9)(i) to read as follows:

§ 2.101 Filing of application.

(a)* * *

(3)* * *

(i) Submit to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, such additional copies as the regulations in part 50, subpart A of part 51, and part 53 of this chapter require;

* * * * *

(5) An applicant for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this chapter, and is of the type specified in § 50.21(b)(2) or (b)(3); or § 50.22; or part 53, as applicable, of this chapter, or is a testing facility, may submit the information required of applicants by part 50, part 52, or part 53 of this chapter in two parts. One part shall be accompanied by the information required by § 50.30(f) of this chapter, § 52.80(b) of this chapter, or § 53.1100(f) of this chapter, as applicable. The other part shall include any information required by § 50.34(a) and, if applicable, § 50.34a of this chapter; or §§ 52.79 and 52.80(a) of this chapter; or §§ 53.1109, 53.1306, 53.1309, and 53.1312 of this chapter; or §§ 53.1109, 53.1413, 53.1416, and 53.1419 of this chapter, as applicable. One part may precede or follow other parts by no longer than 6 months. If it is determined that either of the parts as described above is incomplete and not acceptable for processing, the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will inform the applicant of this determination and the respects in which the document is deficient. Such a determination of completeness will generally be made within a period of 30 days. Whichever part is filed first shall also include the fee required by § 50.30(e) or § 53.1100(e) and § 170.21 of this chapter and the information required by §§ 50.33, 50.34(a)(1), and 52.79(a)(1) of this chapter; or §§ 53.1109, 53.1309, and 53.1416 of this chapter, as applicable, and § 50.37 or § 53.1115, as applicable, of this chapter. The Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, will accept for docketing an application for a construction permit under part 50 or part 53 of this chapter or a combined license under part 52 or part 53 of this chapter for a production or utilization facility which is subject to § 51.20(b) of this

chapter, and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53, as applicable, of this chapter or is a testing facility where one part of the application as described above is complete and conforms to the requirements of part 50 of this chapter. The additional parts will be docketed upon a determination by the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as appropriate, that it is complete.

* * * * *

(9) An applicant for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (b)(3), or § 50.22, or part 53 of this chapter, an applicant for or holder of an early site permit under part 52 or part 53 of this chapter, or an applicant for a combined license under part 52 or part 53 of this chapter, who seeks to conduct the activities authorized under § 50.10(d) or § 53.1130 of this chapter may submit a complete application under paragraphs (a)(1) through (a)(4) of this section, which includes the information required by § 50.10(d) or § 53.1130 of this chapter. Alternatively, the applicant (other than an applicant for or holder of an early site permit) may submit its application in two parts:

(i) Part one must include the information required by § 50.33(a) through (f) or § 53.1109(a) through (e) and § 53.1306 of this chapter, and the information required by § 50.10(d)(2) and (d)(3) or § 53.1130(a)(2) and (a)(3) of this chapter, as applicable.

* * * * *

8. In § 2.104, revise paragraph (a) to read as follows:

§ 2.104 Notice of hearing.

(a) In the case of an application on which a hearing is required by the Act or this chapter, or in which the Commission finds that a hearing is required in the public interest, the Secretary will issue a notice of hearing to be published in the *Federal Register*. The notice must be published at least 15 days, and in the case of an

application concerning a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or 50.22, or subpart H of part 53 of this chapter, as applicable, or a testing facility, at least 30 days, before the date set for hearing in the notice.[1] In addition, in the case of an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.22 or subpart H of part 53 of this chapter, as applicable, or a testing facility, the notice must be issued as soon as practicable after the NRC has docketed the application. If the Commission decides, under § 2.101(a)(2), to determine the acceptability of the application based on its technical adequacy as well as completeness, the notice must be issued as soon as practicable after the application has been tendered.

* * * * *

---

[1] If the notice of hearing concerning an application for a limited work authorization, construction permit, early site permit, or combined license for a facility of the type described in § 50.21(b) or § 50.22, or subpart H of part 53 of this chapter, as applicable, or a testing facility, does not specify the time and place of initial hearing, a subsequent notice will be published in the *Federal Register* which will provide at least 30-day notice of the time and place of that hearing. After this notice is given, the presiding officer may reschedule the commencement of the initial hearing for a later date or reconvene a recessed hearing without again providing at least 30-day notice.

9. In § 2.105, revise paragraph (a) introductory text and paragraphs (a)(4), (a)(10), (a)(12), (a)(13), (b)(3) introductory text, (b)(3)(i), (ii), and (iv) to read as follows:

§ 2.105 Notice of proposed action.

(a) If a hearing is not required by the Act or this chapter, and if the Commission has not found that a hearing is in the public interest, it will, before acting thereon, publish in the *Federal Register*, as applicable, or on the NRC's website, https://www.nrc.gov, or both, at the Commission's discretion, either a notice of intended operation under § 52.103(a) or § 53.1452(a) of this chapter, as applicable, and a proposed finding that

inspections, tests, analyses, and acceptance criteria for a combined license under subpart C of part 52 or under subpart H of part 53 of this chapter, have been or will be met, or a notice of proposed action with respect to an application for:

* * * * *

(4) An amendment to an operating license, combined license, or manufacturing license for a facility licensed under § 50.21(b) or § 50.22 or under subpart H of part 53 of this chapter, as applicable, or for a testing facility, as follows:

(i) If the Commission determines under § 50.58 or § 53.1515 of this chapter that the amendment involves no significant hazards consideration, though it will provide notice of opportunity for a hearing pursuant to this section, it may make the amendment immediately effective and grant a hearing thereafter; or

(ii) If the Commission determines under §§ 50.58 and 50.91 or § 53.1515 of this chapter, as applicable, that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing pursuant to § 2.106 (if a hearing is requested, it will be held after issuance of the amendment);

* * * * *

(10) In the case of an application for an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter, or a testing facility, a notice of opportunity for hearing shall be issued as soon as practicable after the application has been docketed; or

* * * * *

(12) An amendment to an early site permit issued under subpart A of part 52, or under subpart H of part 53 of this chapter, as follows:

(i) If the early site permit does not provide authority to conduct the activities allowed under § 50.10(e)(1) or § 53.1130(b)(1) of this chapter, the amendment will

involve no significant hazards consideration, and though the NRC will provide notice of opportunity for a hearing under this section, it may make the amendment immediately effective and grant a hearing thereafter; and

(ii) If the early site permit provides authority to conduct the activities allowed under § 50.10(e)(1) or § 53.1130(b)(1) of this chapter and the Commission determines under §§ 50.58 and 50.91 or § 53.1515 of this chapter that an emergency situation exists or that exigent circumstances exist and that the amendment involves no significant hazards consideration, it will provide notice of opportunity for a hearing under § 2.106 of this chapter (if a hearing is requested, which will be held after issuance of the amendment).

(13) A manufacturing license under subpart F of part 52 or subpart H of part 53 of this chapter.

(b) * * *

(3) For a notice of intended operation under § 52.103(a) or § 53.1452(a) of this chapter, the following information:

(i) The identification of the NRC action as making the finding required under § 52.103(g) or § 53.1452(g) of this chapter;

(ii) The manner in which the licensee notifications under § 52.99(c) or § 53.1449(c), of this chapter which are required to be made available by § 52.99(e)(2) or § 53.1449(e)(2), of this chapter may be obtained and examined;

* * * * *

(iv) Any conditions, limitations, or restrictions to be placed on the license in connection with the finding under § 52.103(g) or § 53.1452(g) of this chapter, and the expiration date or circumstances (if any) under which the conditions, limitations or restrictions will no longer apply.

* * * * *

10. In § 2.106, revise paragraphs (a)(2), (a)(3), and (b)(2) introductory text to read as follows:

§ 2.106 Notice of issuance.

(a) * * *

(2) An amendment of a license for a facility of the type described in § 50.21(b) or § 50.22, or part 53 of this chapter, as applicable, or a testing facility, whether or not a notice of proposed action has been previously published; and

(3) The finding under § 52.103(g) or § 53.1452(g) of this chapter.

(b) * * *

(2) In the case of a finding under § 52.103(g) or § 53.1452(g) of this chapter:

* * * * *

11. In § 2.109, revise paragraphs (b), (c), and (d) to read as follows:

§ 2.109 Effect of timely renewal application.

* * * * *

(b) If the licensee of a nuclear power plant licensed under § 50.21(b) or § 50.22 or under subpart H of part 53 of this chapter files a sufficient application for renewal of either an operating license or a combined license at least 5 years before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

(c) If the holder of an early site permit licensed under subpart A of part 52 or under subpart H of part 53 of this chapter, as applicable, files a sufficient application for renewal under § 52.29 or § 53.1173 of this chapter, as applicable, at least 12 months before the expiration of the existing early site permit, the existing permit will not be deemed to have expired until the application has been finally determined.

(d) If the licensee of a manufacturing license under subpart F of part 52, or under subpart H of part 53 of this chapter files a sufficient application for renewal under

§ 52.177 or § 53.1295 of this chapter at least 12 months before the expiration of the existing license, the existing license will not be deemed to have expired until the application has been finally determined.

* * * * *

12. In § 2.110, revise paragraphs (a)(1) and (b) to read as follows:

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

(a)(1) A submittal for a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter shall be subject to §§ 2.101(a) and 2.390 to the same extent as if it were an application for a permit or license.

* * * * *

(b) Upon initiation of review by the NRC staff of a submittal for an early review of site suitability issues under appendix Q to part 50 of this chapter, or for a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter, the Director, Office of Nuclear Reactor Regulation, shall publish in the *Federal Register* a notice of receipt of the submittal, inviting comments from interested persons within 60 days of publication or other time as may be specified, for consideration by the NRC staff and ACRS in their review.

* * * * *

13. In § 2.202, revise paragraph (e) to read as follows:

§ 2.202 Orders.

*** * * * ***

(e)(1) If the order involves the modification of a part 50 or a part 53 license and is a backfit, the requirements of § 50.109 or § 53.1590 of this chapter, as applicable, shall be followed, unless the licensee has consented to the action required.

(2) If the order involves the modification of combined license under subpart C of part 52, or subpart H of part 53 of this chapter, the requirements of § 52.98 or § 53.1443 of this chapter, as applicable, shall be followed unless the licensee has consented to the action required.

(3) If the order involves a change to an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter, the requirements of § 52.39 or § 53.1188 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

(4) If the order involves a change to a standard design certification rule referenced by that plant's application, the requirements, if any, in the referenced design certification rule with respect to changes must be followed, or, in the absence of these requirements, the requirements of § 52.63 or § 53.1263 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to follow the action required.

(5) If the order involves a change to a standard design approval referenced by that plant's application, the requirements of § 52.145 or § 53.1221 of this chapter, as applicable, must be followed unless the applicant or licensee has consented to follow the action required.

(6) If the order involves a modification of a manufacturing license under subpart F of part 52 or under subpart H of part 53 of this chapter, the requirements of § 52.171 or § 53.1288 of this chapter, as applicable, must be followed, unless the applicant or licensee has consented to the action required.

14. In § 2.309, revise paragraphs (a), (f)(1)(i), (f)(1)(vi) and (vii), (g), (h)(2), (i)(2), and (j) to read as follows:

§ 2.309 Hearing requests, petitions to intervene, requirements for standing, and contentions.

(a) *General requirements*. Any person whose interest may be affected by a proceeding and who desires to participate as a party must file a written request for hearing and a specification of the contentions which the person seeks to have litigated in the hearing. In a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable, the Commission, acting as the presiding officer, will grant the request if it determines that the requestor has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section. For all other proceedings, except as provided in paragraph (e) of this section, the Commission, presiding officer, or the Atomic Safety and Licensing Board designated to rule on the request for hearing and/or petition for leave to intervene, will grant the request/petition if it determines that the requestor/petitioner has standing under the provisions of paragraph (d) of this section and has proposed at least one admissible contention that meets the requirements of paragraph (f) of this section. In ruling on the request for hearing/petition to intervene submitted by petitioners seeking to intervene in the proceeding on the HLW repository, the Commission, the presiding officer, or the Atomic Safety and Licensing Board shall also consider any failure of the petitioner to participate as a potential party in the pre-license application phase under subpart J of this part in addition to the factors in paragraph (d) of this section. If a request for hearing or petition to intervene is filed in response to any notice of hearing or opportunity for hearing, the applicant/licensee shall be deemed to be a party.

* * * * *

(f) * * *

(1) * * *

(i) Provide a specific statement of the issue of law or fact to be raised or controverted, provided further, that the issue of law or fact to be raised in a request for hearing under § 52.103(b) or § 53.1452(b) of this chapter, as applicable, must be

directed at demonstrating that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety;

* * * * *

(vi) In a proceeding other than one under § 52.103 or § 53.1452 of this chapter provide sufficient information to show that a genuine dispute exists with the applicant/licensee on a material issue of law or fact. This information must include references to specific portions of the application (including the applicant's environmental report and safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner's belief; and

(vii) In a proceeding under § 52.103(b) or § 53.1452(b) of this chapter, as applicable, the information must be sufficient, and include supporting information showing, prima facie, that one or more of the acceptance criteria in the combined license have not been, or will not be met, and that the specific operational consequences of nonconformance would be contrary to providing reasonable assurance of adequate protection of the public health and safety. This information must include the specific portion of the report required by § 52.99(c) or § 53.1449(c) of this chapter, as applicable, which the requestor believes is inaccurate, incorrect, and/or incomplete (i.e., fails to contain the necessary information required by § 52.99(c) or § 53.1449(c) of this chapter, as applicable). If the requestor identifies a specific portion of the report under § 52.99(c) or § 53.1449(c) of this chapter, as applicable, as incomplete and the requestor contends that the incomplete portion prevents the requestor from making the necessary *prima*

facie showing, then the requestor must explain why this deficiency prevents the requestor from making the *prima facie* showing.

* * * * *

(g) *Selection of hearing procedures*. A request for hearing and/or petition for leave to intervene may, except in a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable, also address the selection of hearing procedures, taking into account the provisions of § 2.310. If a request/petition relies upon § 2.310(d), the request/petition must demonstrate, by reference to the contention and the bases provided and the specific procedures in subpart G of this part, that resolution of the contention necessitates resolution of material issues of fact which may be best determined through the use of the identified procedures.

(h) * * *

(2) If the proceeding pertains to a production or utilization facility (as defined in § 50.2 or § 53.020 of this chapter) located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, no further demonstration of standing is required. If the production or utilization facility is not located within the boundaries of the State, local governmental body, or Federally-recognized Indian Tribe seeking to participate as a party, the State, local governmental body, or Federally-recognized Indian Tribe also must demonstrate standing.

* * * * *

(i) * * *

(2) Except in a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable, the participant who filed the hearing request, intervention petition, or motion for leave to file new or amended contentions after the deadline may file a reply to any answer. The reply must be filed within 7 days after service of that answer.

* * * * *

(j) * * *

(1) In all proceedings other than a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable, the presiding officer shall issue a decision on each request for hearing or petition to intervene within 45 days of the conclusion of the initial pre-hearing conference or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies under paragraph (i) of this section. With respect to a request to admit amended or new contentions, the presiding officer shall issue a decision on each such request within 45 days of the conclusion of any pre-hearing conference that may be conducted regarding the proposed amended or new contentions or, if no pre-hearing conference is conducted, within 45 days after the filing of answers and replies, if any. In the event the presiding officer cannot issue a decision within 45 days, the presiding officer shall issue a notice advising the Commission and the parties, and the notice shall include the expected date of when the decision will issue.

(2) The Commission, acting as the presiding officer, shall expeditiously grant or deny the request for hearing in a proceeding under § 52.103 or § 53.1452 of this chapter, as applicable. The Commission's decision may not be the subject of any appeal under § 2.311.

15. Amend § 2.310 by:

a. In paragraphs (a) and (h) introductory text, removing the cross-reference "parts 30, 32 through 36, 39, 40, 50, 52, 54, 55, 61, 70 and 72 of this chapter" and adding, in its place, the cross reference "parts 30, 32 through 36, 39, 40, 50, 52, 53, 54, 55, 61, 70 and 72 of this chapter"; and

b. Revising paragraphs (i) and (j).

The revisions read as follows:

§ 2.310 Selection of hearing procedures.

* * * * *

(i) In design certification rulemaking proceedings under part 52 or part 53 of this chapter, any informal hearing held under § 52.51 or § 53.1242 of this chapter, as applicable, must be conducted under the procedures of subpart O of this part.

(j) Proceedings on a Commission finding under § 52.103(c) and (g) or § 53.1452(c) and (g) of this chapter, as applicable, shall be conducted in accordance with the procedures designated by the Commission in each proceeding.

* * * * *

16. In § 2.329, revise paragraph (a) to read as follows:

§ 2.329 Prehearing conference.

(a) *Necessity for prehearing conference; timing*. The Commission or the presiding officer may, and in the case of a proceeding on an application for a construction permit or an operating license for a facility of a type described in § 50.21(b) or § 50.22, or part 53 of this chapter, or a testing facility, must direct the parties or their counsel to appear at a specified time and place for a conference or conferences before trial. A prehearing conference in a proceeding involving a construction permit or operating license for a facility of a type described in § 50.21(b) or § 50.22 or part 53 of this chapter must be held within sixty (60) days after discovery has been completed or any other time specified by the Commission or the presiding officer.

* * * * *

17. In § 2.339, revise paragraph (d) to read as follows:

§ 2.339 Expedited decision-making procedure.

* * * * *

(d) The provisions of this section do not apply to an initial decision directing the issuance of a limited work authorization under 10 CFR 50.10 or 10 CFR 53.1130; an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter;

a construction permit or construction authorization under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or under subpart H of part 53 of this chapter; or a manufacturing license under subpart F of part 52 or under subpart H of part 53.

18. In § 2.340, revise paragraphs (b), (c), (d), (f), (i), and (j) to read as follows:

§ 2.340 Initial decision in certain contested proceedings; immediate effectiveness of initial decisions; issuance of authorizations, permits and licenses.

* * * * *

(b) *Initial decision—combined license under 10 CFR part 52 or part 53.*

(1) Matters in controversy; presiding officer consideration of matters not put in controversy by parties. In any initial decision in a contested proceeding on an application for a combined license under part 52 or part 53 of this chapter (including an amendment to or renewal of combined license), the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties and any matter designated by the Commission to be decided by the presiding officer. The presiding officer shall also make findings of fact and conclusions of law on any matter not put into controversy by the parties, but only to the extent that the presiding officer determines that a serious safety, environmental, or common defense and security matter exists, and the Commission approves of an examination of and decision on the matter upon its referral by the presiding officer under, inter alia, the provisions of §§ 2.323 and 2.341.

(2) Presiding officer initial decision and issuance of permit or license.

(i) In a contested proceeding for the initial issuance or renewal of a combined license under part 52 or part 53 of this chapter, or the amendment of a combined license where the NRC has not made a determination of no significant hazards consideration, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate after making the requisite findings, shall issue, deny, or appropriately condition the

permit or license in accordance with the presiding officer's initial decision once that decision becomes effective.

(ii) In a contested proceeding for the amendment of a combined license under part 52 or part 53 of this chapter where the NRC has made a determination of no significant hazards consideration, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate (appropriate official), after making the requisite findings and complying with any applicable provisions of § 2.1202(a) or § 2.1403(a), may issue the amendment before the presiding officer's initial decision becomes effective. Once the presiding officer's initial decision becomes effective, the appropriate official shall take action with respect to that amendment in accordance with the initial decision. If the presiding officer's initial decision becomes effective before the appropriate official issues the amendment, then the appropriate official, after making the requisite findings, shall issue, deny, or appropriately condition the amendment in accordance with the presiding officer's initial decision.

(c) *Initial decision on findings under 10 CFR 52.103 or 10 CFR 53.1452 with respect to acceptance criteria in nuclear power reactor combined licenses*. In any initial decision under § 52.103(g) or § 53.1452(g) of this chapter with respect to whether acceptance criteria have been or will be met, the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties, and any matter designated by the Commission to be decided by the presiding officer. Matters not put into controversy by the parties but identified by the presiding officer as matters requiring further examination, shall be referred to the Commission for its determination; the Commission may, in its discretion, treat any of these referred matters as a request for action under § 2.206 and process the matter in accordance with § 52.103(f) or § 53.1452(f) of this chapter.

(d) *Initial decision – manufacturing license under 10 CFR part 52 or part 53.*

(1) Matters in controversy; presiding officer consideration of matters not put in controversy by parties. In any initial decision in a contested proceeding on an application for a manufacturing license under subpart C of part 52 or subpart H of part 53 of this chapter (including an amendment to or renewal of a manufacturing license), the presiding officer shall make findings of fact and conclusions of law on the matters put into controversy by the parties and any matter designated by the Commission to be decided by the presiding officer. The presiding officer also shall make findings of fact and conclusions of law on any matter not put into controversy by the parties, but only to the extent that the presiding officer determines that a serious safety, environmental, or common defense and security matter exists, and the Commission approves of an examination of and decision on the matter upon its referral by the presiding officer under, inter alia, the provisions of §§ 2.323 and 2.341.

(2) Presiding officer initial decision and issuance of permit or license.

(i) In a contested proceeding for the initial issuance or renewal of a manufacturing license under subpart C of part 52 or subpart H of part 53 of this chapter, or the amendment of a manufacturing license, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, after making the requisite findings, shall issue, deny, or appropriately condition the permit or license in accordance with the presiding officer's initial decision once that decision becomes effective.

(ii) In a contested proceeding for the initial issuance or renewal of a manufacturing license under subpart C of part 52 or subpart H of part 53 of this chapter, or the amendment of a manufacturing license, the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate (appropriate official), may issue the license, permit, or license amendment in accordance with § 2.1202(a) or § 2.1403(a) before the presiding officer's initial decision becomes effective. If, however, the presiding officer's initial decision becomes effective before the license, permit, or license amendment is

issued under § 2.1202 or § 2.1403, then the Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall issue, deny, or appropriately condition the license, permit, or license amendment in accordance with the presiding officer's initial decision.

* * * * *

(f) *Immediate effectiveness of certain presiding officer decisions*. A presiding officer's initial decision directing the issuance or amendment of a limited work authorization under § 50.10 or § 53.1130 of this chapter; an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter; a construction permit or construction authorization under part 50 or part 53 of this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or subpart H or part 53 of this chapter; a manufacturing license under subpart F of part 52 or subpart H of part 53 of this chapter; a renewed license under part 53 or part 54 of this chapter; or a license under part 72 of this chapter to store spent fuel in an independent spent fuel storage facility (ISFSI) or a monitored retrievable storage installation (MRS); an initial decision directing issuance of a license under part 61 of this chapter; or an initial decision under § 52.103(g) or § 53.1452(g) of this chapter that acceptance criteria in a combined license have been met, is immediately effective upon issuance unless the presiding officer finds that good cause has been shown by a party why the initial decision should not become immediately effective.

* * * * *

(i) *Issuance of authorizations, permits, and licenses—production and utilization facilities*. The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall issue a limited work authorization under § 50.10 or § 53.1130 of this chapter; an early site permit under subpart A of part 52 or subpart H of part 53 of this chapter; a construction permit or construction authorization under part 50 or part 53 of

this chapter; an operating license under part 50 or part 53 of this chapter; a combined license under subpart C of part 52 or part 53 of this chapter; or a manufacturing license under subpart F of part 52 or part 53 of this chapter within 10 days from the date of issuance of the initial decision:

(1) If the Commission or the Director has made all findings necessary for issuance of the authorization, permit or license, not within the scope of the initial decision of the presiding officer; and

(2) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

(j) *Issuance of finding on acceptance criteria under 10 CFR 52.103 or 10 CFR 53.1452*. The Commission or the Director, Office of Nuclear Reactor Regulation, as appropriate, shall make the finding under § 52.103(g) or § 53.1452(g) of this chapter, that acceptance criteria in a combined license are met within 10 days from the date of the presiding officer's initial decision:

(1) If the Commission or the Director is otherwise able to make the finding under § 52.103(g) or § 53.1452(g) of this chapter, that the prescribed acceptance criteria are met for those acceptance criteria not within the scope of the initial decision of the presiding officer;

(2) If the presiding officer's initial decision—with respect to contentions that the prescribed acceptance criteria have not been met—finds that those acceptance criteria have been met, and the Commission or the Director thereafter is able to make the finding that those acceptance criteria are met;

(3) If the presiding officer's initial decision—with respect to contentions that the prescribed acceptance criteria will not be met—finds that those acceptance criteria will

be met, and the Commission or the Director thereafter is able to make the finding that those acceptance criteria are met; and

(4) Notwithstanding the pendency of a petition for reconsideration under § 2.345, a petition for review under § 2.341, or a motion for stay under § 2.342, or the filing of a petition under § 2.206.

* * * * *

§ 2.341 [Amended]

19. In § 2.341(a)(1), remove the phrase "§ 52.103(c)" and add in its place the phrase "§ 52.103(c) or § 53.1452(c)".

§ 2.400 [Amended]

20. In § 2.400, remove the phrase "parts 50 or 52" and add in its place the phrase "part 50 or part 52, or § 53.1470".

21. In § 2.401, revise the section heading and paragraph (a) to read as follows:

§ 2.401 Notice of hearing on construction permit or combined license applications pursuant to appendix N of 10 CFR part 50, part 52, or part 53.

(a) In the case of applications under appendix N of part 50 or § 53.1470 of this chapter for construction permits for nuclear power reactors of the type described in § 50.22 or part 53 of this chapter, or applications under appendix N of part 52 or § 53.1470 of this chapter for combined licenses, the Secretary will issue notices of hearing pursuant to § 2.104.

* * * * *

22. In § 2.402, revise paragraph (a) to read as follows:

§ 2.402 Separate hearings on separate issues; consolidation of proceedings.

(a) In the case of applications under appendix N of part 50 or § 53.1470 of this chapter for construction permits for nuclear power reactors of a type described in 10 CFR 50.22 or part 53, or applications pursuant to appendix N of part 52 or § 53.1470 of

this chapter for combined licenses, the Commission or the presiding officer may order separate hearings on particular phases of the proceeding, such as matters related to the acceptability of the design of the reactor in the context of the site parameters postulated for the design or environmental matters.

* * * * *

§ 2.403 [Amended]

23. In § 2.403, remove the phrase “appendix N of part 50” and add in its place the phrase “appendix N to part 50 or § 53.1470”.

§ 2.404 [Amended]

24. In § 2.404, remove the phrase “appendix N of part 50” and add in its place the phrase “appendix N to part 50 or § 53.1470”.

§ 2.405 [Amended]

25. In § 2.405, remove the phrase “part 52” and add in its place the phrase “part 52 or part 53”.

§ 2.406 [Amended]

26. In § 2.406, remove the phrase “appendices N of parts 50 or 52” and add in its place the phrase “appendix N to part 50 or part 52 or § 53.1470”.

§ 2.500 [Amended]

27. In § 2.500, remove the phrase “subpart F of part 52” and add in its place the phrase “subpart F of part 52 or subpart H of part 53”.

28. In § 2.501, revise the section heading and paragraph (a) introductory text to read as follows:

§ 2.501 Notice of hearing on application under 10 CFR parts 52 or 53 for a license to manufacture nuclear power reactors.

(a) In the case of an application under subpart F of part 52 or subpart H of part 53 of this chapter for a license to manufacture nuclear power reactors of the type

described in § 50.22 or part 53 of this chapter to be operated at sites not identified in the license application, the Secretary will issue a notice of hearing to be published in the *Federal Register* at least 30 days before the date set for hearing in the notice.[1] The notice shall be issued as soon as practicable after the application has been docketed. The notice will state:

* * * * *

[1] The thirty-day (30) requirement of this paragraph is not applicable to a notice of the time and place of hearing published by the presiding officer after notice of hearing described in this section has been published.

29. In § 2.643, revise paragraph (b) to read as follows:

§ 2.643 Acceptance and docketing of application for limited work authorization.

* * * * *

(b) The Director will accept for docketing part one of an application for a construction permit for a utilization facility which is subject to § 51.20(b) of this chapter and is of the type specified in § 50.21(b)(2) or (3) or § 50.22 or part 53 of this chapter or an application for a combined license where part one of the application as described in § 2.101(a)(9) is complete. Part one will not be considered complete unless it contains the information required by § 50.10(d)(3) or § 53.1130(a)(3) of this chapter. Upon assignment of a docket number, the procedures in § 2.101(a)(3) and (4) relating to formal docketing and the submission and distribution of additional copies of the application must be followed.

* * * * *

§ 2.645 [Amended]

30. In § 2.645, in paragraph (a), remove the phrase “§ 50.33(a) through (f) of this chapter” and add in its place the phrase “§ 50.33(a) through (f), § 53.1109, and § 53.1306(a) or § 53.1413 of this chapter, as applicable,”.

§ 2.649 [Amended]

31. In § 2.649, remove the phrase “10 CFR 50.10(d)” and add in its place the phrase “10 CFR 50.10(d) or 10 CFR 53.1130(a)”.

§ 2.800 [Amended]

32. In § 2.800, remove the phrase “subpart B of part 52” and add in its place the phrase “subpart B of part 52 or subpart H of part 53”.

§ 2.801 [Amended]

33. In § 2.801, remove the phrase “subpart B of part 52” and add in its place the phrase “subpart B of part 52 or subpart H of part 53”.

§ 2.813 [Amended]

34. In § 2.813(a), remove the phrase “parts 50, 52, and 100” and add in its place the phrase “parts 50, 52, 53, and 100”.

§ 2.1103 [Amended]

35. In § 2.1103, remove the phrase “part 50 of this chapter” and add in its place the phrase “part 50 or part 53 of this chapter”.

§ 2.1200 [Amended]

36. In § 2.1200, remove the phrase “parts 30, 32 through 36, 39, 40, 50, 52, 54, 55, 61, 70, and 72 of this chapter,” and add in its place “parts 30, 32 through 36, 39, 40, 50, 52, 53, 54, 55, 61, 70, and 72 of this chapter,”.

37. In § 2.1202, revise paragraphs (a)(1) through (3) and (a)(6) to read as follows:

§ 2.1202 Authority and role of NRC staff.

(a) * * *

(1) An application to construct and/or operate a production or utilization facility (including an application for a limited work authorization under § 50.10 or § 53.1130 of this chapter, or an application for a combined license under subpart C of 10 CFR part 52, or under subpart H of 10 CFR part 53;

(2) An application for an early site permit under subpart A of 10 CFR part 52 or under subpart H of 10 CFR part 53;

(3) An application for a manufacturing license under subpart F of 10 CFR part 52 or under subpart H of 10 CFR part 53;

* * * * *

(6) Production or utilization facility licensing actions that involve significant hazards considerations as defined in § 50.92 or § 53.1520 of this chapter.

* * * * *

§ 2.1301 [Amended]

38. In § 2.1301(b), remove “part 50 and part 52” and add in its place “parts 50, 52, and 53”.

§ 2.1403 [Amended]

39. In § 2.1403(a)(3), remove the phrase “10 CFR 50.92” and add in its place the phrase “10 CFR 50.92 or 10 CFR 53.1520”.

§ 2.1500 [Amended]

40. In § 2.1500, remove the phrase “subpart B of part 52” and add in its place the phrase “subpart B of part 52 or under subpart H of part 53”.

§ 2.1502 [Amended]

41. In § 2.1502, in paragraph (a), remove the phrase “§ 52.51(b)" and add in its place the phrase “§ 52.51(b) or § 53.1242(b)(2)”; and in paragraph (b)(1), wherever it may appear, remove the phrase “§ 52.51(a)” and add in its place the phrase “§ 52.51(a) or § 53.1242(b)”.

PART 10—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO RESTRICTED DATA OR NATIONAL SECURITY INFORMATION OR AN EMPLOYMENT CLEARANCE

42. The authority citation for part 10 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161 (42 U.S.C. 2165, 2201); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); E.O. 10450, 18 FR 2489, 3 CFR, 1949-1953 Comp., p. 936, as amended; E.O. 10865, 25 FR 1583, 3 CFR, 1959-1963 Comp., p. 398, as amended; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391.

§ 10.1 [Amended]

43. In § 10.1, in paragraph (a)(3) remove the phrase “under part 52” and add in its place the phrase “under part 52 or part 53”.

§ 10.2 [Amended]

44. In § 10.2, in paragraph (b), wherever it may appear, remove the phrase “under part 52” and add in its place the phrase “under part 52 or part 53”.

PART 11—CRITERIA AND PROCEDURES FOR DETERMINING ELIGIBILITY FOR ACCESS TO OR CONTROL OVER SPECIAL NUCLEAR MATERIAL

45. The authority citation for part 11 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 223 (42 U.S.C. 2201, 2273); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note.

Section 11.15(e) also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

§ 11.7 [Amended]

46. In § 11.7, in the introductory text, add the number “53,” in sequential order.

PART 19—NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

47. The authority citation for part 19 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 211, 401 (42 U.S.C. 5841, 5851, 5891); 44 U.S.C. 3504 note.

48. In § 19.2, revise paragraph (a) to read as follows:

§ 19.2 Scope.

(a) * * *

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under part 50, part 52, or part 53 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, 53, and 54 of this chapter;

(3) All applicants for and holders of a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter; and

(4) All applicants for a standard design certification under subpart B of part 52 or under subpart H of part 53 of this chapter, and those (former) applicants whose designs have been certified under that subpart.

49. In § 19.3, revise the definitions for "*License*" and "*Regulated entities*" to read as follows:

§ 19.3 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, 53, or 54 of this chapter.

* * * * *

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an

applicant for or holder of a standard design approval under subpart E of part 52 or under subpart H of part 53 of this chapter or a standard design certification under subpart B of part 52 or under subpart H of part 53 of this chapter.

* * * * *

§ 19.11 [Amended]

50. In § 19.11, in paragraph (a) introductory text, paragraph (b) introductory text, and paragraph (e)(1), wherever it may appear, remove the phrase “of part 52” and add in its place the phrase “of part 52 or under subpart H of part 53".

§ 19.14 [Amended]

51. In § 19.14, in paragraph (a), wherever it may appear, remove the phrase “of part 52” and add in its place the phrase “of part 52 or under subpart H of part 53".

§ 19.20 [Amended]

52. In § 19.20, add the number “53,” in sequential order.

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

53. The authority citation for part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

§ 20.1002 [Amended]

54. In § 20.1002, add the number “53,” in sequential order.

55. In § 20.1003, revise the definition for “*License*” to read as follows:

§ 20.1003 Definitions.

* * * * *

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 53, 60, 61, 63, 70, or 72 of this chapter.

* * * * *

§ 20.1101 [Amended]

56. In § 20.1101, in paragraph (d), remove the phrase “subject to § 50.34a” and add in its place the phrase “subject to § 50.34a or § 53.260 of this chapter”.

§ 20.1401 [Amended]

57. In § 20.1401, in paragraph (a), add the number “53,” in sequential order; and in paragraphs (a) and (c) remove the phrase “in accordance with § 50.83” and add in its place the phrase “in accordance with § 50.83 or § 53.1080”.

58. In § 20.1403, revise paragraph (d) introductory text to read as follows:

§ 20.1403 Criteria for license termination under restricted conditions.

* * * * *

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with § 30.36(d), § 40.42(d), § 50.82 (a) and (b), subpart G of part 53, § 70.38(d), or § 72.54 of this chapter, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

* * * * *

59. In § 20.1404, revise paragraph (a)(4) introductory text to read as follows:

§ 20.1404 Alternate criteria for license termination.

(a) * * *

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with § 30.36(d), § 40.42(d), § 50.82 (a) and (b), subpart G of part 53, § 70.38(d), or § 72.54 of

this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

* * * * *

§ 20.1406 [Amended]

60. In § 20.1406, in paragraphs (a) and (b), wherever it may appear, remove the phrase “under part 52” and add in its place the phrase “under part 52 or part 53”.

61. In § 20.1501, revise paragraph (b) to read as follows:

§ 20.1501 General.

* * * * *

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with § 30.35(g), § 40.36(f), § 50.75(g), subpart G of part 53, § 70.25(g), or § 72.30(d) of this chapter, as applicable.

* * * * *

§ 20.1905 [Amended]

62. In § 20.1905, in paragraph (g) introductory text, remove the phrase “Parts 50 or 52” and add in its place the phrase “part 50, part 52, or part 53”.

63. In § 20.2004, revise paragraph (b)(1) to read as follows:

§ 20.2004 Treatment or disposal by incineration.

* * * * *

(b)(1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been

radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under part 50 or part 53 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 or § 53.425(c) of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under § 50.34, § 50.34a, or under subpart H of part 53 of this chapter associated with this incineration pursuant to § 50.71 or § 53.1620 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 or § 53.1565 of this chapter with respect to such changes to the facility or procedures.

* * * * *

64. In § 20.2201, revise paragraphs (a)(2)(i), (b)(2)(i), and (c) to read as follows:

§ 20.2201 Reports of theft or loss of licensed material.

(a) * * *

(2) * * *

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center under § 50.72 or § 53.1630 of this chapter, and

* * * * *

(b) * * *

(2) * * *

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported under the procedures described in § 50.73(b), (c), (d), (e), and (g) or § 53.1640(b), (c), (d), and (e) of this chapter and must include the information required in paragraph (b)(1) of this section, and

* * * * *

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to § 30.55(c), § 37.57, § 37.81, § 40.64(c), § 50.72, § 50.73, § 53.1630, § 53.1640, § 70.52, § 73.27(b), § 73.67(e)(3)(vii), § 73.67(g)(3)(iii), § 73.1205, or § 150.19(c) of this chapter.

* * * * *

§ 20.2202 [Amended]

65. In § 20.2202, in paragraph (d)(1), remove the phrase “10 CFR 50.72” and add in its place the phrase “§ 50.72 or § 53.1630 of this chapter;”.

66. In § 20.2203, revise paragraph (c) to read as follows:

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

* * * * *

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported under the procedures described in § 50.73(b), (c), (d), (e), and (g) or § 53.1640(b), (c), (d), and (e) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported under § 50.73 or § 53.1640 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

* * * * *

§ 20.2206 [Amended]

67. In § 20.2206, in paragraph (a)(1), remove the phrase “or § 50.22” and add in its place the phrase “, § 50.22, or part 53”.

PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

68. The authority citation for part 21 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 81, 103, 104, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2111, 2133, 2134, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

69. In § 21.2, revise paragraphs (a)(2) through (a)(4), (b), and (c) to read as follows:

§ 21.2 Scope.

(a) * * *

(1) * * *

(2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation under part 50, part 52, or part 53 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or part 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 53, 60, 61, 63, 70, 71, or 72 of this chapter;

(3) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 or part 53 of this chapter; or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 or part 53 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;

(4) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for or holding a standard design approval under part 52 or part 53 of this chapter; or supplying basic components with respect to a standard design approval under part 52 or part 53 of this chapter;

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 or § 53.1333 of this chapter or a combined license under part 52 or part 53 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) or § 53.1452(g) of this chapter), or to manufacture a facility under part 52 or part 53 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) or § 53.605 of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50, part 52, or part 53 of this chapter, evaluation of potential defects and appropriate reporting of defects under § 50.72, § 50.73, § 53.1630, § 53.1640, or §§ 73.1200 and 73.1205 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

* * * * *

70. In § 21.3, revise the definitions for "*Basic component*", "*Commercial grade item*", "*Critical characteristics*", "*Dedicating entity*", "*Dedication*", "*Defect*", and "*Substantial safety hazard*" to read as follows:

§ 21.3 Definitions.

* * * * *

Basic component. (1)(i) When applied to nuclear power plants licensed under part 53 of this chapter, basic component means a safety-related structure, system, or component (SSC), or part thereof, and when applied to nuclear power plants licensed under part 50 or part 52 of this chapter, basic component means an SSC, or part thereof, that affects its safety function necessary to assure:

(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 which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications and approvals under part 53 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a safety-related SSC, or part thereof. When applied to standard design certifications under subpart B of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for an SSC, or part thereof, that affects its safety function necessary to assure:

(i) The integrity of the reactor coolant pressure boundary;

(ii) The capability to shut down the reactor and maintain it in a safe-shutdown condition; or

(iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 or part 53 of this chapter, whether these services are performed by the component supplier or others.

Commercial grade item. (1) When applied to nuclear power plants licensed under 10 CFR part 50 or 10 CFR part 53, commercial grade item means an SSC, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

(i) Not subject to design or specification requirements that are unique to those facilities or activities;

(ii) Used in applications other than those facilities or activities; and

(iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

* * * * *

Critical characteristics. When applied to nuclear power plants licensed under part 50, part 52, or part 53 of this chapter, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedicating entity. When applied to nuclear power plants licensed under part 50, part 52, or part 53 of this chapter, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, under § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Dedication. (1) When applied to nuclear power plants licensed pursuant to 10 CFR part 30, 40, 50, 53, or 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical

characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted under the applicable provisions of 10 CFR part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in this section;

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50, part 52, or part 53 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50, part 52, or part 53 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

* * * * *

Substantial safety hazard means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under part 30, 40, 50, 52, 53, 60, 61, 63, 70, 71, or 72 of this chapter.

* * * * *

§ 21.21 [Amended]

71. In § 21.21,

a. In paragraphs (a)(3) and (a)(3)(i), remove the phrase “under part 52” and add in its place the phrase “under part 52 or part 53”; and

b. In paragraphs (d)(1)(i) and (ii) add “53,” in sequential order.

§ 21.51 [Amended]

72. In § 21.51, in paragraphs (a)(4) and (5) remove the phrase “of part 52” and add in its place the phrase “of part 52 or under subpart H of part 53”.

§ 21.61 [Amended]

73. In § 21.61, in paragraph (b) remove the phrase “under part 52” wherever it may appear and add in its place the phrase “under part 52 or part 53”.

PART 25—ACCESS AUTHORIZATION

74. The authority citation for part 25 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, 25 FR 1583, as amended, 3 CFR, 1959-1963 Comp., p. 398; 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. Section 25.17(f) and Appendix A also issued under 31 U.S.C. 9701; 42 U.S.C. 2214.

75. In § 25.5, revise the definition for "*License*" to read as follows:

§ 25.5 Definitions.

* * * * *

License means a license issued pursuant to 10 CFR part 50, 52, 53, 60, 63, 70, or 72.

* * * * *

§ 25.17 [Amended]

76. In § 25.17, in paragraph (a), add the number "53," in sequential order.

§ 25.35 [Amended]

77. In § 25.35, in paragraph (a), wherever it may appear, remove the phrase "under part 52" and add in its place the phrase "under part 52 or part 53".

PART 26—FITNESS FOR DUTY PROGRAMS

78. The authority citation for part 26 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 103, 104, 107, 161, 223, 234, 1701 (42 U.S.C. 2073, 2133, 2134, 2137, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

79. In § 26.3, revise paragraph (d) and add paragraph (f) to read as follows:

§ 26.3 Scope.

* * * * *

(d) Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in paragraphs (a) through (c) and (f) of this section rely on those C/V FFD programs or program elements to meet the requirements of this part, shall comply with the requirements of this part.

* * * * *

(f) No later than the start of construction activities, licensees and other entities that have applied for or have been issued a license under part 53 of this chapter, other than a manufacturing license (ML), must implement the requirements in subpart M of this part or all the requirements of this part except subparts K and M. Holders of an ML under part 53 of this chapter must implement the requirements in subpart M or all the requirements of this part except subparts K and M, before commencing activities that assemble a manufactured reactor.

80. In § 26.4, revise paragraphs (a) introductory text, (a)(1), (a)(4), (b), (c), (e) introductory, (e)(4), (f), (g) introductory text, and (h) to read as follows:

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subparts K and M of this part, and those persons who are granted unescorted access to either nuclear power reactor protected areas or remote facilities where safety-significant systems or components may be operated within the design basis of a licensed commercial nuclear plant, by the licensees and other entities in § 26.3(f) and perform the following duties must be subject to an FFD program that satisfies the requirements in subpart M of this part, unless the licensee or other entity subjects these individuals to an FFD program that satisfies all of the requirements of this part except for those requirements in subparts K and M:

(1) For persons who are granted unescorted access by the licensees in § 26.3(a) and, as applicable, (c), operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety; for those persons who are granted unescorted access by the licensees and other entities in § 26.3(f), operating or directing of the operation of

systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;

* * * * *

(4) For persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c), performing maintenance or onsite directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; for those persons who are granted unescorted access to nuclear power reactor protected areas by the licensees and other entities in § 26.3(f), performing maintenance or directing of the maintenance of SSCs that a risk-informed evaluation process has shown to be significant to public health and safety; and

* * * * *

(b) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and who do not perform the duties described in paragraph (a) of this section shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M of this part. All persons who are granted unescorted access to a facility licensed under part 53 of this chapter, and who do not perform or direct the performance of the duties described in § 26.4(a), must be subject to the requirements in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

(c) All persons who are required by a licensee in § 26.3(a) and, as applicable, (c) to physically report to the licensee’s Technical Support Center or Emergency Operations Facility by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209

and subparts K and M of this part. Also, for licensees or other entities in § 26.3(f), all persons without unescorted access to the facility who make decisions and/or direct actions regarding plant safety and security, and all persons who participate remotely in emergency response activities or physically report to the Technical Support Center or Emergency Operations Facility (or an equivalent facility), must be subject to an FFD program that satisfies all of the requirements described in subpart M of this part, unless the licensee or other entity implements an FFD program that satisfies all of the requirements of this part, except §§ 26.205 through 26.209 and subparts K and M.

* * * * *

(e) When construction activities, as defined in § 26.5, begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to have the following types of access or perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and for any individual whose duties for the licensees and other entities in § 26.3(f) require him or her to have the following types of access, perform construction activities as defined in § 26.5, or perform the following activities must be subject to an FFD program as described in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M:

* * * * *

(4) Witnesses or determines inspections, tests, and analyses certification required under part 52 or part 53 of this chapter;

* * * * *

(f) Any individual who is constructing or directing the construction of safety- or security-related SSCs shall be subject to an FFD program that meets the requirements of subpart K, or, if applicable, subpart M of this part, unless the licensee or other entity

subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I, K, and M of this part.

(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a) through (c), and, as applicable, (d) and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I, K, and M of this part, and, at the licensee's or other entity's discretion, subpart C of this part. All personnel whose duties require them to have the following types of access or perform the following activities at facilities licensed under part 53 of this chapter must be subject to the requirements in subpart M or an FFD program that satisfies all of the requirements of this part, except subparts I, K, and M, and, at the licensee's or other entity's discretion, subpart C of this part:

* * * * *

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to §§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, E through H, and M of this part.

* * * * *

81. Amend § 26.5 by:

a. Adding the definitions for "*Biological marker*", "*Change", and "*"*Consortium/Third party administrator (C/TPA)*";

b. Revising the definitions for "*Constructing or construction activities"* and "*Contractor/vendor (C/V)";*

c. Adding the definition of "*Illicit substance"*;

d. Revising the definition of "*Other entity"*;

e. Adding the definition of "*Reduction in FFD program effectiveness"*;

f. Revising the definitions of "*Reviewing official"*, "*Safety-related structures, systems, and components (SSCs)"*, and "*Security-related SSCs"*;

g. Adding the definition of "*Special nuclear material"*; and

h. Revising the definition of "*Unit outage"*.

The additions and revisions read as follows:

§ 26.5 Definitions.

* * * * *

Biological marker means, for a part 53 licensee implementing subpart M of this part, an endogenous substance that is used to validate that the biological specimen collected for testing was produced by the donor.

* * * * *

Change as used in § 26.603(e) means an action that results in a modification of, addition to, or removal from the licensee's or other entity's FFD program.

* * * * *

Consortium/Third-party administrator (C/TPA) means a contractor/vendor that provides or coordinates one or more FFD program elements for a group of licensees or other entities, such as administering a collective random testing pool and random testing selections under § 26.607(b)(2)(vi), that otherwise could not be independently implemented by those licensees or other entities. A C/TPA also could provide access to, for example, the services of medical review officers, substance abuse experts, employee assistance programs, and HHS-certified laboratories under contract to perform drug testing.

Constructing or construction activities means, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated. These tasks include

fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete. For a licensee or other entity described in § 26.3(f), construction is defined in § 53.020 of this chapter.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c) and (f), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c) and (f), either by contract, purchase order, oral agreement, or other arrangement.

* * * * *

Illicit substance means a substance that causes impairment and possible addiction but is not an illegal drug as defined in this section.

* * * * *

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under § 26.3(a) through (c) and (f) but is not licensed by the NRC.

* * * * *

Reduction in FFD program effectiveness means, for a part 53 licensee or other entity implementing subpart M of this part, a change or series of changes to an element of the FFD program that reduces or eliminates the licensee's ability to satisfy or maintain site-specific FFD program performance when compared to historical site-specific performance, the licensee's fleet-level program performance, or industry performance.

* * * * *

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c) and (f), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness,

as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization.

Safety-related structures, systems, and components (SSCs) means, for part 50 or part 52 licensees and other entities described in § 26.3(a) through (d), those SSCs that are relied on to remain functional during and following design-basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in § 50.34(a)(1) of this chapter. For part 53 licensees and other entities described in § 26.3(d) and (f), safety-related has the same meaning as that in § 53.020 of this chapter.

Security-related SSCs means, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in § 26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in § 26.3(c)(1) and (c)(2), respectively, or a licensee or other entity described in § 26.3(d) or (f).

* * * * *

Special nuclear material (SNM) has the same meaning as that in § 70.4 of this chapter.

* * * * *

Unit outage means, for the purposes of this part, for electricity-generation units, that the reactor unit is disconnected from the electrical grid. *Unit outage* means, for the purposes of this part, for non-electricity-generation units, that the reactor unit is

disconnected from the loads to which its output is supplied under normal operating conditions.

* * * * *

82. In § 26.8, revise paragraph (b) to read as follows:

§ 26.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 26.9, 26.27, 26.29, 26.31, 26.33, 26.35, 26.37, 26.39, 26.41, 26.53, 26.55, 26.57, 26.59, 26.61, 26.63, 26.65, 26.67, 26.69, 26.75, 26.77, 26.85, 26.87, 26.89, 26.91, 26.93, 26.95, 26.97, 26.99, 26.101, 26.103, 26.107, 26.109, 26.111, 26.113, 26.115, 26.117, 26.119, 26.125, 26.127, 26.129, 26.135, 26.137, 26.139, 26.153, 26.157, 26.159, 26.163, 26.165, 26.167, 26.168, 26.169, 26.183, 26.185, 26.187, 26.189, 26.202, 26.203, 26.205, 26.207, 26.211, 26.401, 26.403, 26.405, 26.406, 26.407, 26.411, 26.413, 26.415, 26.417, 26.603, 26.605, 26.606, 26.607, 26.608, 26.609, 26.611, 26.613, 26.617, 26.619, 26.711, 26.713, 26.715, 26.717, 26.719, and 26.821.

83. Revise § 26.21 to read as follows:

§ 26.21 Fitness-for-duty program.

The licensees and other entities specified in § 26.3(a) through (c) and (f) (for those licensees and other entities that do not implement the requirements in subparts M and K of this part) shall establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. The individuals specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and, if necessary, § 26.4(j) shall be subject to these FFD programs. Licensees and other entities may rely on the FFD program or program elements of a

C/V, as defined in § 26.5, if the C/V's FFD program or program elements satisfy the applicable requirements of this part.

84. In § 26.35, revise paragraph (c)(3) to read as follows:

§ 26.35 Employee assistance programs.

* * * * *

(c) * * *

(3) If a licensee or other entity receives a report from EAP personnel under paragraph (c)(2) of this section, the licensee or other entity must ensure that the requirements of §§ 26.69(d) and 26.77(b), or the procedures and actions required by § 26.606(b)(2)(vii) are implemented, as applicable.

85. Revise § 26.51 to read as follows:

§ 26.51 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this subpart. Certain requirements in this subpart also apply to the individuals specified in § 26.4(h). The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

§ 26.53 [Amended]

86. In § 26.53, in paragraph (e), wherever it may appear, remove the phrase "§ 26.3(a) through (c)" and add in its place the phrase "§ 26.3(a) through (c) and (f)"; and in paragraphs (g), (h), and (i), wherever it may appear, remove the phrase "(c) and (d)" and add in its place the phrase "(c), (d), and (f)".

§ 26.63 [Amended]

87. In § 26.63, in paragraph (d) remove the phrase "§ 26.3(a) through (d)" and add in its place the phrase "§ 26.3(a) through (d) and (f)".

88. Revise § 26.73 to read as follows:

§ 26.73 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals specified in § 26.4(a) through (d) and (g). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to satisfy the requirements of this subpart. The regulations in this subpart also apply to the individuals specified in § 26.4(h) and (j), as appropriate. The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605(b).

89. Revise § 26.81 to read as follows:

§ 26.81 Purpose and applicability.

This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g). At the discretion of a licensee or other entity in § 26.3(c), specimen collections and alcohol tests must be conducted either under this subpart for the individuals specified in § 26.4(e) and (f) or the licensee or other entity may rely on specimen collections and alcohol tests conducted under the requirements of 49 CFR part 40 for the individuals specified in § 26.4(e) and (f). The requirements of this subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR part 40, as permitted in this paragraph and under §§ 26.4(j) and 26.31(b)(2) and subpart K. The requirements in this subpart apply to the FFD programs of licensees and other entities identified in § 26.3(f) that elect not to implement the requirements in subpart M for the categories of individuals in § 26.4 and those licensees and other entities that elect to implement the requirements in § 26.605.

90. In § 26.97, revise paragraph (a) introductory text and paragraph (b) introductory text to read as follows:

§ 26.97 Collecting oral fluid specimens for alcohol and drug testing.

(a) The collector, with the assistance of a virtual collection monitor as permitted under § 26.607(g)(2) if applicable, shall perform the oral fluid specimen collection consistent with the device manufacturer’s instructions. The collector shall:

* * * * *

(b) If all steps in paragraph (a) of this section could not be completed successfully (e.g., the device breaks, the device is dropped on the floor, the device fails to activate), the collector, with the assistance of a virtual collection monitor as permitted under § 26.607(g)(2) if applicable, shall:

* * * * *

91. Revise § 26.201 to read as follows:

§ 26.201 Applicability.

(a) The requirements in this subpart, with the exception of § 26.202, apply to the licensees and other entities identified in § 26.3(a); if applicable, (c), (d), and (f), for licensees and other entities not implementing the requirements in subparts K and M. For the licensees and other entities to whom the requirements in this subpart, with the exception of § 26.202, apply, the requirements in §§ 26.203 and 26.211 apply to the individuals identified in § 26.4(a) through (c). In addition, the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).

(b) The requirements in this subpart, with the exception of § 26.203, apply to the licensees or other entities identified in § 26.3(f) implementing this subpart under § 26.605. For these licensees and other entities, the requirements in §§ 26.202 and 26.211 apply to the individuals identified in § 26.4(a) through (c) and any person licensed to operate under 10 CFR part 53; and the requirements in §§ 26.205 through 26.209 apply to the individuals identified in § 26.4(a).

92. Add new § 26.202 to read as follows:

§ 26.202 General provisions for facilities licensed under part 53.

(a) *Policy*. Licensees must establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and incorporate it into the written policy required in § 26.606(a).

(b) *Procedures*. In addition to the procedures required in § 26.606(b), licensees must develop, implement, and maintain procedures that—

(1) Describe the process to be followed when any individual identified in § 26.4(a) through (c) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must—

(i) Describe the individual's and licensee's rights and responsibilities related to self-declaration;

(ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and

(iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under § 26.211(a)(2);

(2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a);

(3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and

(4) Describe the disciplinary actions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions.

(c) *Training and assessments*. Licensees must include the following KAs in the content of the training and trainee assessments required in § 26.608:

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and

(2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

(d) *Recordkeeping*. Licensees must retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of work hours for individuals who are subject to the work hour controls in § 26.205;

(2) For licensees implementing the requirements of § 26.205(d)(3), records of shift schedules and shift cycles, or, for licensees implementing the requirements of § 26.205(d)(7), records of shift schedules and records showing the beginning and end times and dates of all averaging periods, of individuals who are subject to the work hour controls in § 26.205;

(3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers;

(4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and

(5) The documentation of fatigue assessments that is required in § 26.211(g).

(e) *Reporting*. Licensees must include the following information in a standard format in the annual FFD program performance report required under § 26.617(b)(2):

(1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived one or more of the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) and (d)(7) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee must report—

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), and (d)(7) was waived for individuals not working on outage activities;

(ii) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (iii), (d)(2)(i) and (ii), (d)(3)(i) through (v), (d)(4) and (d)(5)(i), and (d)(7) was waived for individuals working on outage activities; and

(iii) A summary that shows the distribution of waiver use among the individuals applicable within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals who received only one waiver during the reporting period, the number of individuals who received a total of two waivers during the reporting period).

(2) A summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

(f) *Audits*. Licensees must audit the management of worker fatigue under § 26.615.

93. In § 26.205, revise paragraphs (d)(7)(iii) and (d)(8) to read as follows:

§ 26.205 Work hours.

* * * * *

(d) * * *

(7) * * *

(iii) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the work hour counting system in § 26.205(d)(7)(ii) the licensee is using.

(8) Each licensee shall state, in its FFD policy and procedures required by either § 26.27 and § 26.203(a) and (b) or § 26.202(a) and (b) and § 26.606, the requirements with which the licensee is complying: the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7).

* * * * *

94. In § 26.207, revise paragraph (a)(1)(ii) to read as follows:

§ 26.207 Waivers and exceptions.

(a) * * *

(1) * * *

(ii) A supervisor assesses the individual face-to-face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. The supervisor performing the assessment shall be trained as required by either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608 and shall be qualified to direct the work to be performed by the individual. If there is no supervisor on site who is qualified to direct the work, the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work. For licensees and other entities in § 26.3(f), the assessment may be performed remotely using electronic communications. In such instances, the assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained under the requirements of either § 26.29 and § 26.203(c) or § 26.202(c) and § 26.608.

* * * * *

95. In § 26.211, revise paragraphs (a)(1) and (3) and paragraph (b) introductory text to read as follows:

§ 26.211 Fatigue assessments.

(a) * * *

(1) For-cause. In addition to any other test or determination of fitness that may be required under §§ 26.31(c), 26.77, 26.607(b), and 26.619, a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties, except if the condition is observed during an individual's break period. If the observed condition is impaired alertness with no other behaviors or physical conditions creating a reasonable suspicion of possible substance abuse, then the licensee need only conduct a fatigue assessment. If the licensee has reason to believe that the observed condition is not due to fatigue, the licensee need not conduct a fatigue assessment;

* * * * *

(3) Post-event. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in § 26.31(c) or post-event tests in § 26.607(b)(4). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and

* * * * *

(b) Only supervisors and FFD program personnel who are trained under either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608 may conduct a fatigue assessment. The fatigue assessment must be conducted face-to-face with the individual whose alertness may be impaired. For licensees and other entities in § 26.3(f), a fatigue assessment may be performed remotely using electronic communications. In such instances, the fatigue assessment must be supported by someone who is present in-person with the individual whose alertness may be impaired, and that supporting person must be trained in accordance with the requirements of either §§ 26.29 and 26.203(c) or §§ 26.202(c) and 26.608.

* * * * *

96. Add Subpart M—Fitness-for-Duty Programs for Facilities Licensed Under 10 CFR Part 53 and §§ 26.601 through 26.619 to read as follows:

Subpart M—Fitness-for-Duty Programs for Facilities Licensed Under 10 CFR Part 53

Sec.
§ 26.601 Applicability.
§ 26.603 General provisions.
§ 26.605 FFD program requirements.
§ 26.606 Written policy and procedures.
§ 26.607 Drug and alcohol testing.
§ 26.608 FFD program training.
§ 26.609 Behavioral observation.
§ 26.610 Sanctions.
§ 26.611 Protection of information.
§ 26.613 Appeals process.
§ 26.615 Audits.
§ 26.617 Recordkeeping, reporting, and FFD program performance.
§ 26.619 Suitability and fitness determinations.

§ 26.601 Applicability.

(a) A licensee or other entity in § 26.3(f), at its discretion, may establish, implement, and maintain a fitness-for-duty (FFD) program that satisfies the requirements of this subpart for those categories of individuals in § 26.4, as applicable, and any person licensed to operate under 10 CFR part 53. If a licensee or other entity in § 26.3(f) does not elect to implement an FFD program that satisfies the requirements of this subpart, then those categories of individuals in § 26.4, as applicable, and any person licensed to operate under 10 CFR part 53 must be subject to an FFD program that satisfies all part 26 requirements, except for those requirements in subparts K and M.

(b) A licensee or other entity in § 26.3(f) that elects to implement an FFD program that satisfies the requirements of this subpart, and that demonstrates compliance with § 73.100(a)(1)(i) of this chapter, must establish, implement, and maintain an FFD program under § 26.605(a) or (b).

(c) A licensee or other entity in § 26.3(f) that elects to implement an FFD program that satisfies the requirements of this subpart and does not demonstrate compliance with § 73.100(a)(1)(i) of this chapter must establish, implement, and maintain an FFD program under § 26.605(a) and (b).

§ 26.603 General provisions.

(a) *FFD program description*. An applicant's description of the FFD program in its Final Safety Analysis Report, required by subpart H of part 53 of this chapter, must include—

(1) Whether the applicant demonstrates compliance with § 73.100(a)(1)(i) of this chapter;

(2) A statement whether the FFD program will be implemented pursuant to § 26.605(a), 26.605(b), or 26.605(a) and (b), or will satisfy all part 26 requirements, except for the requirements in subparts K and M;

(3) A discussion of the applicability of the FFD program to those individuals described in § 26.4 and how the program will be implemented offsite at a U.S. Nuclear Regulatory Commission (NRC)-licensed facility authorized to assemble or test a manufactured reactor, if applicable; and

(4) A description of the drug and alcohol testing and fitness determination process to be implemented through the licensee's or other entity's procedures, including the collection and testing facilities to be used, biological specimens to be collected and tested, and sanctions to be imposed for FFD policy violations.

(b) *FFD program implementation and availability*. For the licensees and other entities in § 26.3(f), other than the holder of a manufacturing license (ML), the FFD program must be maintained until the NRC's docketing of the license holder's certifications described in § 53.1070 of this chapter. For holders of an ML, the FFD program must be maintained until expiration of the ML.

(c) [Reserved]

(d) [Reserved]

(e) *FFD program change control.*

(1) The licensee or other entity may make changes to its FFD program under this subpart if—

(i) The licensee or other entity performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the FFD program; or

(ii) The change was necessitated or justified by a change to part 26, laboratory processes or procedures, or guidance issued by the U.S. Department of Health and Human Services (HHS) or NRC, as implemented by the licensee or other entity though its procedures.

(2) A licensee or other entity desiring to make a change that decreases FFD program effectiveness must implement a mitigating strategy so the FFD program, as revised, will continue to satisfy the performance objectives in § 26.23 and not result in a reduction in FFD program effectiveness.

(3) Except for phencyclidine, and notwithstanding § 26.603(e)(1)(ii), the change control process may not be used to reduce the minimum panel of drugs to be tested in § 26.607(c)(1).

(4) The licensee must retain a record of each change made under this section for a period of at least 5 years from the date the change was implemented and summarize this change in its annual FFD performance report required by § 26.617(b)(2) or § 26.717, as applicable.

§ 26.605 FFD program requirements.

(a)(1) The licensee or other entity must establish, implement, and maintain an FFD program under this paragraph before the start of—

(i) Construction activities as defined in § 26.5;

(ii) Activities performed under an ML that authorizes the assembly, non-operational testing, or both of a manufactured reactor; or

(iii) Activities described in paragraphs (a)(1)(i) and (ii) of this section.

(2) An FFD program under this paragraph must—

(i) Apply to those individuals described in § 26.4, as applicable; and,

(ii) Implement the following requirements and subparts:

(A) § 26.23, Performance objectives;

(B) § 26.35, Employee assistance programs

(1) For licensees and other entities who demonstrate compliance with § 73.100(a)(1)(i) of this chapter, § 26.35 must be implemented before the earliest occurrence of the following, as applicable: the loading of fuel onsite into a reactor vessel; receiving a fueled manufactured reactor; or individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety;

(2) For licensees and other entities that do not demonstrate compliance with § 73.100(a)(1)(i) of this chapter, § 26.35 must be implemented before the start of activities performed under an ML that allows the assembly, non-operational testing, or both, of a manufactured reactor.

(C) § 26.603, General provisions;

(D) § 26.606, Written policy and procedures;

(E) § 26.607, Drug and alcohol testing;

(F) § 26.608, FFD program training;

(G) § 26.609, Behavioral observation;

(H) § 26.610, Sanctions;

(I) § 26.611, Protection of information;

(J) § 26.613, Appeals process;

(K) § 26.615, Audits;

(L) § 26.617, Recordkeeping, reporting, and FFD program performance;

(M) § 26.619, Suitability and fitness determinations;

(N) Subpart A—Administrative Provisions;

(O) Subpart I—Managing Fatigue, in the case of holders of an ML that allows the assembly, non-operational testing, or both of a manufactured reactor; and

(P) Subpart O—Inspections, Violations, and Penalties.

(b)(1) Except for a licensee or other entity that demonstrates compliance with § 73.100(a)(1)(i) of this chapter and elects to implement an FFD program that satisfies the requirements of this paragraph (b), for which its FFD program must be established, implemented, and maintained no later than the start of construction activities, as defined in § 26.5, and except for holders of manufacturing licenses if they possess a separate license to load fuel into a manufactured reactor, for which its FFD program under this paragraph (b) must be established, implemented, and maintained no later than the start of the loading of fuel into the reactor, the licensee or other entity must establish, implement, and maintain an FFD program under this paragraph before the earliest occurrence of the following, as applicable:

(i) The loading of fuel onsite into a reactor vessel;

(ii) Receiving a fueled manufactured reactor; and

(iii) Individuals subject to part 26 operate, test, perform maintenance of, or direct the maintenance or surveillance of security-related equipment or equipment that a risk-informed evaluation process has shown to be significant to public health and safety.

(2) An FFD program under this paragraph must—

(i) Apply to those individuals described in § 26.4, as applicable; and

(ii) Implements the following requirements and subparts:

(A) § 26.23, Performance objectives;

(B) § 26.35, Employee assistance programs;

(C) § 26.603, General provisions;

(D) § 26.606, Written policy and procedures;

(E) § 26.607, Drug and alcohol testing;

(F) § 26.608, FFD program training;

(G) § 26.609, Behavioral observation;

(H) § 26.611, Protection of information;

(I) § 26.613, Appeals process;

(J) § 26.615, Audits;

(K) Subpart A—Administrative Provisions;

(L) Subpart C—Granting and Maintaining Authorization;

(M) Subpart D—Management Actions and Sanctions to be Imposed;

(N) Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness, unless using the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* (the HHS Guidelines) for Medical Review Officer (MRO) evaluation of drug test results, and determining fitness;

(O) Subpart I—Managing Fatigue;

(P) Subpart N—Recordkeeping and Reporting Requirements; and

(Q) Subpart O—Inspections, Violations, and Penalties.

§ 26.606 Written policy and procedures.

(a) Licensees and other entities that implement an FFD program under this subpart must ensure that—

(1) A written FFD policy statement is provided to each individual who is subject to the program before the individual is subject to drug and alcohol testing.

(2) The FFD policy statement describes the performance objectives in § 26.23.

(3) The FFD policy statement describes the minimum days off requirements in § 26.205(d)(3) or maximum average work hours requirements in § 26.205(d)(7).

(4) The FFD policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy, including those elements described in § 26.606(b), part 26-required sanctions, and required medical/clinical treatment and follow-up testing for FFD policy violations.

(5) The FFD policy statement describes the individual’s responsibilities to report for work in a physiological and psychological condition that enables the safe and competent performance of assigned duties and responsibilities and inform a licensee- or other entity-designated representative when the individual determines that this cannot be accomplished.

(6) The FFD policy statement must prohibit the consumption of alcohol, at a minimum, within an abstinence period of 5 hours preceding the individual's arrival at the licensee's or other entity's facility.

(7) The FFD policy statement must convey that abstinence from alcohol for the 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty.

(b) Licensees and other entities must establish, implement, and maintain written procedures that address the following topics:

(1) For the drug and alcohol testing program under this subpart,

(i) The methods and techniques to collect and test for drugs and alcohol and for the shipping and temporary storage of biological specimens used for drug testing at HHS-certified laboratories,

(ii) The urine specimen volumes, techniques for split specimen collections, and the acceptability of a urine specimen as described in § 26.111 or as described in the HHS Guidelines,

(iii) Protecting the privacy of an individual who provides a specimen, protecting the integrity of the specimen, and ensuring that the test results are valid and attributable to the correct individual, and

(iv) If the licensee or other entity elects to use the HHS Guidelines, the name of the specific HHS Guideline and revision being implemented by the licensee or other entity and a description of the specific sections in the guideline that are being implemented in the procedure, including specimen collections, drug testing, and evaluation of test results.

(2) The immediate and follow-up actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program:

(i) Have been involved in the use, sale, or possession of illegal substances, illegal drugs, or illicit substances;

(ii) Are impaired by any illegal substances, illegal drugs, or illicit substances or the consumption of alcohol as determined by behavioral observation or a test that measures blood alcohol concentration;

(iii) Attempted to subvert the testing process by adulterating or diluting specimens (*in vivo* or *in vitro*), substituting specimens, or by any other means;

(iv) Refused to provide a specimen for analysis or follow instructions provided by FFD program personnel;

(v) Had legal action taken relating to drug or alcohol use;

(vi) Demonstrated character or actions indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, special nuclear material (SNM), or sensitive information; or

(vii) Have a condition or have taken actions that pose or have posed an immediate hazard to themselves or others, as notified by EAP personnel under § 26.35(c)(2).

(3) The process, including the duties and responsibilities of FFD program personnel, to be followed if an individual's behavior or condition raises a concern regarding the possible use, sale, or possession of illegal drugs on- or offsite; the possible use or possession of alcohol on the NRC-licensed facility; impairment from any cause that in any way could adversely affect the individual's ability to safely and competently perform the individual's duties; or the receipt of credible information indicating that the individual cannot be trusted or relied on to perform those duties and responsibilities making the individual subject to this part.

(4) Operation and oversight of any onsite or offsite collection facility.

(5) The fatigue management requirements in §§ 26.202(b) and either 26.205(d)(3) or (d)(7).

(6) Measures to prevent subversion of drug and alcohol tests conducted onsite and offsite.

§ 26.607 Drug and alcohol testing.

Licensees and other entities must perform drug and alcohol testing that complies with the following requirements—

(a) *Split specimens.* Split specimen collections of oral fluid or urine must be used for the test conditions described in paragraph (b) of this section. Testing of the split specimen (specimen B) requires the donor's permission unless ordered by the MRO to resolve an invalid test result obtained for specimen A.

(b) *Test conditions.* Individuals identified in § 26.4 must be subject to drug and alcohol testing under the following conditions:

(1) *Pre-access*. A pre-access test must be conducted for drugs and alcohol before performing or directing the conduct of roles and responsibilities making the individual subject to this subpart or being granted unescorted access to the protected areas of the NRC-licensed facility. A pre-access test must have been conducted no more than 14 days before the individual is granted unescorted access.

(2) *Random*. Random testing for drugs and alcohol must—

(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected;

(ii) Require individuals who are selected for random testing to report to the onsite collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program procedure;

(iii) Ensure that all individuals in the population that is subject to random testing on a given day have an equal probability of being selected and tested;

(iv) Ensure that an individual completing a test is immediately eligible for another random test; and

(v) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program at the NRC-licensed site.

(vi) If the number of individuals subject to random testing at an NRC-licensed site is such that paragraph (b)(2)(v) of this section cannot be implemented without predictable outcomes, the licensee must use a consortium/third-party administrator to manage the random testing pool and make selections for testing throughout the year.

(3) *For-cause*. For-cause drug and alcohol tests must be conducted onsite in response to an individual's observed behavior or physical condition indicating possible substance abuse, as defined in § 26.5. A for-cause drug test, alcohol test, or both, must

be conducted onsite after receiving credible information either that an individual is engaging in substance abuse or in response to a portal area screening test result under paragraph (j) of this section.

(4) *Post-event*. A post-event test for drugs and alcohol must be conducted—

(i) As soon as practical after an event involving a human error that was committed by an individual specified in § 26.4, where the human error may have caused or contributed to the event. This test must be conducted onsite unless the individual requires offsite medical care. The licensee or other entity must test the individual(s) who committed or directed the error and need not test individuals who were affected by the event and whose actions likely did not cause or contribute to the event. The licensee or other entity must describe in its procedures what constitutes a human error.

(ii) Within 4 hours of an event unless immediate medical intervention precludes the conduct of the test on the individual(s) who caused or contributed to the accident(s), if the event results in—

(A) An illness or personal injury to any individual which results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury, as diagnosed by a licensee- or other entity-designated physician or other licensed health care professional, even if the illness or injury does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or

(B) Damage to any safety- or security-related structures, systems, and components; and

(5) *Follow-up*. An individual subject to part 26 who has violated the FFD policy for substance use or abuse, or the sale, use, or possession of illegal drugs must be subject to a follow-up series of tests for drugs, alcohol, or both to verify an individual's continued abstinence from substance abuse.

(c) *Urine and oral fluid specimens.*

(1) All urine or oral fluid specimens must be tested for the substances listed in § 26.31(d)(1), except as allowed by § 26.603(e)(3). All urine specimens must be subject to validity testing as specified in either this part or the HHS Guidelines. All oral fluid specimens may be subject to validity testing, including a biological marker, as specified in either this part or the HHS Guidelines.

(2) For the use of urine as the biological specimen to be tested, the following requirements must be implemented—

(i) § 26.115, Collecting a urine specimen under direct observation;

(ii) § 26.119, Determining “shy” bladder; and

(iii) § 26.163, Cutoff levels for drugs and drug metabolites.

(3) For alcohol testing onsite, the following requirements must be implemented—

(i) § 26.91, Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use;

(ii) § 26.93, Preparing for alcohol testing;

(iii) § 26.95, Conducting an initial test for alcohol using a breath specimen;

(iv) § 26.97, Collecting oral fluid specimens for alcohol and drug testing;

(v) § 26.99, Determining the need for a confirmatory test for alcohol;

(vi) § 26.101, Conducting a confirmatory test for alcohol; and,

(vii) § 26.103, Determining a confirmed positive test result for alcohol.

(4) For all test conditions in § 26.607(b) and for MRO-directed tests under § 26.185, drug testing must be performed at an HHS-certified laboratory for the specific biological specimen to be tested. Only HHS-certified laboratory test results from urine and oral fluid specimens may be used for the issuance of a part 26-required sanction. The licensee or other entity must establish and maintain a contract with a primary and a back-up HHS-certified laboratory (with a different Certifying Scientist) for the

specimen(s) to be tested. These contracts must stipulate that the laboratories are subject to inspection or audit by the licensee or other entity and that records and documents must be provided and/or able to be photocopied and removed from the premises to support the inspection or audit.

(d) *Privacy and integrity*. The specimen collection and drug and alcohol testing procedures of FFD programs must protect the donor's privacy and the integrity of the specimen and implement quality controls to ensure that test results are valid and attributable to the correct individual.

(e) *Offsite collection facilities.* At the licensee's or other entity's discretion, except for those specimens that must be collected onsite under paragraphs (b)(3) and (b)(4) of this section, specimen collections and alcohol testing may be conducted at a local hospital or other facility licensed to conduct specimen collections and perform alcohol testing and audited by the State or a State-designated entity. The licensee or other entity must audit these facilities, if used, before their initial use and then on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part or the HHS Guidelines for urine and oral fluid.

(f) *Initial testing*. A licensee or other entity subject to this subpart performing an initial test must use an immunoassay, or an alternative technology as specified in the HHS Guidelines for the specific biological specimen that is to be tested. Specimens that yield positive, positive and dilute, adulterated, substituted, or invalid initial validity or drug test results or discrepant biological markers must be subject to confirmatory testing by an HHS-certified laboratory, certified for that biological specimen, except for invalid specimens that cannot be tested.

(g) *Oral fluid testing.*

(1) If the licensee or other entity elects to use oral fluid for drug or alcohol testing, the collection, packaging, temporary storage, and shipment of an oral fluid specimen to

an HHS-certified laboratory for drug testing, or the collection of an oral fluid specimen for alcohol testing must be performed in accordance with licensee- or other entity-established procedures based either on the requirements in this part or the procedures in HHS Guidelines identified by the licensee or other entity in § 26.606(b)(1)(iv). The oral fluid device must not expire before the date of the collection of the specimen for testing. The drugs, drug metabolites, initial and confirmatory testing cutoffs, and biological markers, if applicable, must be those established by the HHS Guidelines for oral fluid testing and the alcohol cutoffs in this part or, if not established by the HHS Guidelines or this part for the panel of drugs and drug metabolites to be tested, as determined and documented by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(2) The virtual collection of oral fluid specimens for drug and alcohol testing is only permitted for sites that must use a C/TPA to implement random testing under § 26.607(b)(2)(vi). For a licensee or other entity to utilize a virtual oral fluid specimen collection process, the following must apply or should be considered, as applicable:

(i) The specimen collector completing the virtual collection must meet the requirements in § 26.85, “Collector qualifications and responsibilities.”

(ii) The oral fluid specimen collection process must be completed as described under § 26.97, “Collecting oral fluid specimens for alcohol and drug testing,” and § 26.99, “Determining the need for a confirmatory test for alcohol.”

(iii) An individual other than the donor (i.e., a virtual collection monitor) may be needed in the location where the specimen collection is to be performed to assist the virtual collector in completing activities, performing observations, or both.

(iv) If a virtual collection monitor is used to assist the specimen collector in completing an oral fluid specimen collection, then the virtual specimen collector must explain the collection process to the monitor and provide instruction to the monitor on required activities to be performed during the collection process. The monitor’s name

must be recorded on the Federal custody and control form (Federal CCF) for drug testing specimens, or an analogous document for alcohol testing.

(v) Video teleconference communication method(s) must provide sufficient visual and aural clarity to complete the process and ensure that a donor is not able to subvert the testing process.

(vi) Collection kit materials must be maintained in a secure fashion until the virtual collector initiates the virtual collection process with the donor.

(vii) The licensee or other entity's written FFD procedures must describe in detail the virtual collection process and when and how it is to be implemented.

(viii) The virtual collection procedure must address problem collections, such as the video teleconference becomes inoperable during the collection process or the donor is unable to provide an oral fluid specimen of sufficient quantity to complete the specimen collection process for drug or alcohol testing.

(ix) The virtual collection procedure must include steps to collect a breath specimen using an evidential breath testing device (EBT) if the oral fluid specimen test result under § 26.99(b) requires a confirmatory testing for alcohol under § 26.101. At a minimum, a donor with an oral fluid specimen test result requiring confirmatory testing for alcohol must be removed from duty pending additional testing.

(h) [Reserved]

(i) *Hair testing*. The testing of hair specimens may only be used to inform a licensee's or other entity's determination of whether the individual is trustworthy and reliable under the test condition in § 26.607(b)(1) to supplement the information gained from a pre-access test using oral fluid or urine as the test specimen and must be conducted at an HHS-certified laboratory certified to test hair specimens.

(1) If used, this process must be described in the licensee's or other entity's FFD policy and described in detail in its procedure. The panel of drugs and drug metabolites

to be evaluated must only include those listed as Schedule I or II of section 202 of the Controlled Substances Act [21 U.S.C. 812]. The collection, packaging, and temporary storage of a hair specimen and shipment of the specimen to an HHS-certified laboratory must be conducted in accordance with the HHS Guidelines. The licensee- or other entity-designated FFD program personnel must conduct the collection, packaging, temporary storage, shipping, and custody and control of the specimen.

(2) Before the licensee or other entity begins to conduct hair testing, the initial and confirmatory testing cutoffs must be the cutoffs established by the HHS Guidelines for hair testing or, if not established by the HHS Guidelines or this part, as determined by a forensic toxicologist review conducted pursuant to § 26.31(d)(1)(i)(D).

(3) Confirmed positive test results must be considered potentially disqualifying FFD information until proven otherwise by a review under § 26.613. Sanctions under this subpart must not be issued for any FFD policy violation involving a drug test using a hair specimen unless the licensee or other entity determines that the individual has attempted to subvert the testing process, as defined in § 26.5, for the hair test.

(j) *Portal area screening*. A non-invasive testing instrument may be used to screen individuals for drugs, drug metabolites, and alcohol before the individuals' entry into or exit from a protected or vital area.

(1) The instrument must be operated in accordance with the manufacturer's specifications. If screening detects the presence of any drug, drug metabolite, or alcohol at or above the instrument set point, the individual screened by the instrument must be subject to for-cause testing under § 26.607(b)(3).

(2) Annually, the licensee or other entity must verify the accuracy of the portal area screening test for each substance with any positive results. If at least 85 percent of the positive portal area screening test results for a substance in the past 12 months do not subsequently confirm positive on for-cause testing performed under paragraph (j)(1)

of this section, the licensee or other entity cannot continue to use the screening test for the particular substance until such time as corrective actions have been implemented to improve the testing accuracy.

(3) A part 26 sanction may not be issued to an individual based solely on a portal area screening instrument detection that drugs or alcohol exceed the instrument's established setpoint.

(k) *Blood testing*. The testing of blood specimens may only be conducted under the order of the licensee- or other entity-designated MRO for a valid medical reason as confirmed by the MRO pursuant to § 26.31(d)(5). This specimen must be subject to testing by a laboratory that satisfies quality control requirements that are comparable to those required for certification by the HHS.

(l) *Federal custody and control form*. For the collection and packaging of urine, oral fluid, and hair specimens for drug testing, the licensee or other entity must use a Federal CCF.

(m) *Medical Review Officer.* Licensees or other entities must—

(1) Require their designated MRO to review positive, positive and dilute, adulterated, substituted, and invalid confirmatory drug and validity test results to determine whether the donor has violated the FFD policy. The review must be completed before reporting the results to the individual designated by the licensee or other entity to assess authorization or perform the suitability and fitness determinations required under § 26.619, or, if required, that are described in subpart H of this part.

(2) Require their MRO to satisfy the requirements in § 26.183 and, prior to conducting any activities under this part, attend and pass a medical- or clinical-based training session to improve his/her knowledge of MRO duties and responsibilities, drug and alcohol testing processes and procedures, and evaluation of drug testing results. This training session must be conducted by a nationally recognized MRO training and

certification organization that has been assessed by the licensee's or other entity's FFD program personnel to include the technical elements an MRO must implement under § 26.185. An MRO who performed the duties and responsibilities in §§ 26.185 and 26.187 for at least 3 continuous years in the last 10 years prior to being hired or contracted by the licensee or other entity satisfies the requirements in this paragraph (m)(2).

(3) Require their MRO to attend a medical- or clinical-based training session at least every 5 years to improve his/her knowledge of changes in drug and alcohol testing processes and procedures and evaluation of drug testing results.

(4) Require their MRO to determine whether a biological specimen is positive, positive and dilute, adulterated, substituted, or invalid by implementing the requirements in § 26.185 or the HHS Guidelines through the licensee's or other entity's procedures.

(i) If § 26.185 or the HHS Guidelines, as used by the licensee or other entity in its procedures, are insufficient to make this determination, then guidance issued by a State agency in the State in which the NRC-licensed facility is located, Federal agencies, or nationally recognized MRO training and certification organizations may be used to inform an MRO determination.

(ii) An MRO need not review alcohol test results, including positive confirmatory alcohol test results determined by an EBT under § 26.607(c)(3)(vi) and (vii).

(5) Require their MRO to determine and approve the use of oral fluid or urine as an alternative biological specimen when the donor cannot provide a specimen for testing. This determination and the retest must be documented and completed as soon as reasonably practicable.

(6) Require the MRO to review all specimen test results associated with drug-related FFD policy violations. This review includes split specimens and all specimens taken to resolve a discrepant condition, such as a possible subversion attempt,

impairment without a known cause, or a donor-requested or MRO-directed re-test. To resolve a discrepant condition, the MRO is authorized to test a specimen for a biological marker, adulterants, or additional drugs.

(n) *Limitations of screening and testing*. Specimens collected under NRC regulations may only be designated or approved for screening and testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses, screens, and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes. No biological specimens may be passively sampled and analyzed in a manner different than described in this subpart.

(o) *Specimen collectors.* All onsite specimen collections, except a collection by a portal area screening instrument in § 26.607(j), must be conducted by licensee- or other entity-designated and -trained personnel.

§ 26.608 FFD program training.

(a) *FFD program training.*

(1) Individuals must be trained in the FFD policy and procedure, including fatigue management, and their FFD program responsibilities. Individuals who collect specimens for testing must also be trained in specimen collector duties and responsibilities, including, at a minimum, specimen collection, custody and control, identification and response to subversion attempts, and privacy. For licensees and other entities of commercial nuclear plants, the FFD program training program must use a systems approach to training as defined in § 53.725 of this chapter and described in § 53.830 of this chapter for those individuals in § 26.4.

(2) FFD program training must include training on the behavioral observation program. The behavioral observation program training must include the detection of physiological behaviors or conditions that may indicate—

(i) Possible use, sale, or possession of illegal drugs or illicit drugs, or substance abuse on- or offsite;

(ii) Use or possession of alcohol onsite or use while on duty offsite;

(iii) Impairment from fatigue or any cause that, if left unattended, could result in inattentiveness or human errors; and

(iv) Any individual's inability to safely and competently perform assigned duties and responsibilities or act in a trustworthy and reliable manner while having access to protected areas, SNM, or sensitive information.

(3) Training must explain that an individual's FFD policy violation will—

(i) Subject the individual to an FFD program-required sanction designed to preclude recurrence of an FFD policy violation;

(ii) Contribute to the licensee's or other entity's assessment of whether the individual can be trusted and relied upon to safely and competently perform the assigned duties and responsibilities making the individual subject to this subpart;

(iii) Be used to inform the licensee's or other entity's insider mitigation and access authorization programs under § 73.55, § 73.56, § 73.100 or § 73.120 of this chapter; and

(iv) Be used to inform other NRC licensees and other entities subject to part 26 when FFD program information is requested to support authorization determinations under subpart C of part 26; § 73.56; or § 73.120 of this chapter.

(b) *Training and assessments*. Training and a trainee assessment must be conducted before pre-access testing, and FFD program refresher training and trainee assessments must be conducted on a nominal 24-month frequency, or more frequently

where the need is indicated. Indications of the need for more frequent training include, but are not limited to, an individual's failure to properly implement FFD program procedures and the frequency, nature, or severity of problems discovered through audits or the administration of the program.

(c) *Training program review*. The licensee or other entity must periodically evaluate its FFD training program and revise it as appropriate to reflect industry experience as well as applicable changes to the regulations in this part, the HHS Guidelines, if used, and specimen collection and testing processes implemented by the licensee or other entity.

§ 26.609 Behavioral observation.

(a) Licensees and other entities must ensure that the individuals who are subject to this subpart are subject to behavioral observation and that behavioral observation is performed by all individuals subject to this subpart.

(b) Licensees and other entities must require all individuals subject to the FFD program to report to the licensee- or other entity-designated representative any onsite or offsite behaviors or activities by individuals subject to this part that may constitute an unreasonable risk to the safety or security of the NRC-licensed facility or SNM or may cause harm to others. This reporting must include any information relating to character or reputation of the individual indicating that the individual cannot be trusted or relied upon to perform those duties and responsibilities or maintain access to NRC-licensed facilities, SNM, or sensitive information that makes them subject to part 26.

(c) Behavioral observation must be performed visually, in-person, and, when necessary, remotely by live video and audible streaming and capture, to observe the behavior of individuals in the workforce subject to the requirements in this subpart.

(d) Not withstanding § 26.609(c), for a reactor facility where individual task loading does not allow for the effective conduct of behavior observation in addition to

assigned operational tasks, the licensee or other entity must implement a live video and audible streaming and capture system to conduct behavioral observation of persons licensed to operate under 10 CFR part 53 who manipulate the controls of any commercial nuclear plant licensed under 10 CFR part 53.

§ 26.610 Sanctions.

(a) Licensees and other entities that implement an FFD program under this subpart must establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4 from being assigned to perform or direct those duties and responsibilities or maintaining authorization making them subject to this subpart.

(b) The severity of the sanction must escalate with the number of occurrences and severity of the FFD policy violation. The sanction must be long enough to act as a deterrent and, if the individual is retained as a licensee employee or contractor/vendor, facilitate the individual to complete counseling or treatment. The sanctions must include an immediate unfavorable termination of the individual's authorization as follows:

(1) A minimum 14-day denial of access for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result,

(2) A minimum 3-year denial of access for a second violation of the FFD policy involving a confirmed positive drug or alcohol test result,

(3) A minimum 5-year denial of access for any individual who is determined to have been involved in the sale, use, or possession of illegal drugs or the consumption of alcohol within a protected area of any facility licensed under part 53 of this chapter or within a transporter's facility or vehicle used in the conveyance of formula quantities of strategic SNM while the individual is subject to this subpart, and

(4) A permanent denial of access for a third violation of the FFD policy involving a confirmed positive drug or alcohol test result or a subversion attempt of any drug or alcohol test or screening process.

§ 26.611 Protection of information.

(a) Licensees and other entities that collect personal information about an individual for the purpose of complying with this subpart must establish and maintain a system of files and procedures to prevent unauthorized disclosure.

(b) Licensees and other entities must obtain a signed consent that documents the individual's acceptance of being subject to the FFD program and authorizes the disclosure of the personal information collected and maintained under this subpart, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.613. This signed and dated consent must be obtained before making the individual subject to the FFD program.

§ 26.613 Appeals process.

Licensees and other entities that implement an FFD program under this subpart must establish and implement procedures for the review of a determination that an individual in § 26.4 has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy and a schedule for the completion of the review.

§ 26.615 Audits.

(a) Licensees and other entities that implement an FFD program under this subpart must audit their programs at a frequency that ensures the continuing effectiveness of their FFD program, FFD program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity. Corrective actions must be taken as soon as reasonably practicable to resolve any problems identified in an audit and preclude recurrence.

(b) The subject matter, scope, and frequency of audits must be revised as necessary to improve or maintain program performance based on annual FFD program

performance data reviews performed under § 26.617(d) and unsatisfactory performance or programmatic weaknesses identified under § 26.617(b)(3) and (e).

(c) Licensees and other entities may conduct joint audits or accept audits of C/Vs so long as the audit addresses the relevant services of the C/Vs.

(d) Licensees and other entities must audit HHS-certified laboratories unless the licensee's or other entity's panel of drugs and drug metabolites to be tested is equivalent to the panel by which the laboratory is certified by HHS or is subject to the standards and procedures for drug testing and evaluation used by the laboratory under the HHS Guidelines. Licensees and other entities must audit any hospital or other facility licensed by the State (or State-designated entity) if used to conduct specimen collections and perform alcohol testing under this part on a biennial basis to confirm that the facility procedures are comparable to those described in subpart E of this part, for urine and oral fluid.

§ 26.617 Recordkeeping, reporting, and FFD program performance.

(a) Licensees and other entities that implement FFD programs under this subpart must ensure that records pertaining to the administration of their program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. Records pertaining to the administration of the FFD program and FFD performance data required by § 26.717 must be retained until license termination.

(b) Licensees and other entities must make the following reports:

(1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by

individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of § 73.1200 of this chapter;

(2) Annual FFD program performance data under § 26.717(b) for each FFD program subject to this subpart. Licensees and other entities must submit FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year and must use unexpired NRC-provided forms for the electronic submission of FFD information to the NRC; and

(3) Reports on drug and alcohol testing errors within 30 days of completing an investigation of any testing errors or unsatisfactory performance, discovered at an HHS-certified laboratory or through the processing of appeals under § 26.613, or errors or matters that could adversely reflect on the integrity of the random selection or random testing process. The reports must describe the incident and any corrective actions taken or planned.

(c) Licensees and other entities subject to this subpart must describe in sufficient detail to support an authorization determination, an individual's FFD policy violation (while protecting privacy information under § 26.611) and FFD program weakness to NRC, licensees, and other entities subject to part 26 when requested to support authorization determinations under subpart C of part 26 or § 73.120 of this chapter, as applicable, or to support licensee or other entity performance monitoring.

(d) Licensees and other entities must analyze FFD program performance data at least annually and take appropriate actions to correct any identified program weakness.

(e) Licensees and other entities must document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program, but may not track or trend drug and alcohol test results in a manner that would permit the identification of any individuals.

§ 26.619 Suitability and fitness determinations.

Licensees and other entities that implement FFD programs under this subpart must develop, implement, and maintain procedures for evaluating whether to assign individuals to perform or direct those duties and responsibilities making them subject to this subpart. A suitability or fitness determination conducted for cause must be performed face-to-face. A suitability or fitness determination conducted for cause may be performed remotely using electronic communications that provide sufficient visual and aural clarity to complete the assessment. A fitness determination may be supported by someone who is present in-person with the individual being assessed only during for-cause drug and alcohol testing determinations under § 26.607(b)(3) and fatigue assessments performed under § 26.211(a)(1). The supporting person must be trained in accordance with the requirements of either § 26.29 or § 26.608.

97. Revise § 26.709 to read as follows:

§ 26.709 Applicability.

(a) The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(a) through (d), except for FFD programs that are implemented under subpart K of this part.

(b) The requirements in this subpart apply to the FFD programs of licensees and other entities specified in § 26.3(f) that elect not to implement the requirements in subpart M or elect to implement the requirements in § 26.605(b).

§ 26.711 [Amended]

98. In § 26.711, in paragraphs (c) and (d), remove the phrase “(c) and (d),” and add in its place the phrase “(c), (d), and (f),”.

§ 26.825 [Amended]

99. In § 26.825, in paragraph (b) add “26.601,” in sequential order.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

100. The authority citation for part 30 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 81, 161, 181, 182, 183, 184, 186, 187, 223, 234, 274 (42 U.S.C. 2014, 2111, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

101. In § 30.4, revise the definition for "*Utilization facility"* to read as follows:

§ 30.4 Definitions.

* * * * *

Utilization facility means a utilization facility as defined in the regulations contained in part 50 or part 53 of this chapter;

102. In § 30.50, revise paragraph (c)(3) to read as follows:

§ 30.50 Reporting requirements.

* * * * *

(c) * * *

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72 or § 53.1630 of this chapter. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72 of this chapter.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

103. The authority citation for part 40 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 62, 63, 64, 65, 69, 81, 83, 84, 122, 161, 181, 182, 183, 184, 186, 187, 193, 223, 234, 274, 275 (42 U.S.C. 2092, 2093, 2094, 2095, 2099, 2111, 2113, 2114, 2152, 2201, 2231, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2022); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Uranium Mill Tailings Radiation Control Act of 1978, sec. 104 (42 U.S.C. 7914); 44 U.S.C. 3504 note.

104. In § 40.60, revise paragraph (c)(3) to read as follows:

§ 40.60 Reporting requirements.

* * * * *

(c) * * *

(3) The provisions of § 40.60 do not apply to licensees subject to the notification requirements in § 50.72 or § 53.1630 of this chapter. They do apply to those part 50 licensees possessing material licensed under part 40 of this chapter who are not subject to the notification requirements in § 50.72 of this chapter.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

105. The authority citation for part 50 is revised 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.

106. In § 50.47, revise paragraphs (a)(1) and (e) to read as follows:

§ 50.47 Emergency plans.

(a)(1)(i) Except as provided in paragraph (d) of this section, no initial operating license for a nuclear power reactor will be issued under this part or under part 53 of this chapter unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. No finding under this section is necessary for issuance of a renewed nuclear power reactor operating license.

(ii) No initial combined license under part 52 or part 53 of this chapter will be issued unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological

emergency. No finding under this section is necessary for issuance of a renewed combined license.

(iii) If an application for an early site permit under subpart A of part 52 of this chapter includes complete and integrated emergency plans under 10 CFR 52.17(b)(2)(ii) or an application for an early site permit under subpart H of part 53 of this chapter includes complete and integrated emergency plans under § 53.1146(b)(2)(ii) of this chapter, no early site permit will be issued unless a finding is made by the NRC that the emergency plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(iv) If an application for an early site permit proposes major features of the emergency plans under § 52.17(b)(2)(i) or 53.1146(b)(2)(i) of this chapter, no early site permit will be issued unless a finding is made by the NRC that the major features are acceptable in accordance with the applicable standards of either § 50.47 and appendix E to this part or the applicable requirements of § 50.160, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

(e) Notwithstanding the requirements of paragraph (b) of this section and the provisions of § 52.103 or § 53.1452 of this chapter, a holder of a combined license under part 52 or part 53 of this chapter, as applicable, that is complying with the requirements of § 50.47(b) and appendix E to this part may not load fuel or operate except as provided in accordance with appendix E to this part and § 50.54(gg), and a holder of a combined license under part 52 or part 53 of this chapter that is complying with the requirements of § 50.160 may not load fuel or operate except as provided in accordance with § 50.160(c)(2) and § 50.54(gg).

* * * * *

107. In § 50.54, revise paragraph (gg)(1) introductory text to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(gg)(1) Notwithstanding § 52.103 or § 53.1452 of this chapter, if following the conduct of the exercise required by paragraph IV.f.2.a of appendix E to this part or § 50.160(c)(2), as applicable, FEMA identifies one or more deficiencies in the state of offsite emergency preparedness, the holder of a combined license under 10 CFR part 52 or under 10 CFR part 53, as applicable*,* may operate at up to 5 percent of rated thermal power only if the Commission finds that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC will base this finding on its assessment of the applicant's onsite emergency plans against the pertinent standards in either § 50.47 and appendix E to this part, or § 50.160, as applicable. Review of the applicant's emergency plans will include the following standards with offsite aspects:

* * * * *

108. In § 50.160, revise paragraphs (b)(3) and (c)(2) to read as follows:

§ 50.160 Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities.

* * * * *

(b) * * *

(3) *Emergency planning zone*. For an applicant whose analysis required by § 50.33(g)(2) or § 53.1109(g)(2) of this chapter meets the criteria in § 50.33(g)(2)(i) or § 53.1109(g)(2)(i) of this chapter, as applicable, determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.

* * * * *

(c) * * *

(2) A holder of a combined license issued under part 52 or part 53 of this chapter before the Commission has made the finding under § 52.103(g) or § 53.1452(g) of this chapter, as applicable, 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 within 2 years before the scheduled date for initial loading of fuel (or, for a fueled manufactured reactor, within 2 years before the scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter).

109. In appendix B to part 50, revise the first paragraph in the Introduction section, the first paragraph of section III, and the first paragraph of section IV to read as follows:

Appendix B to Part 50—Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 or § 53.1309 of this chapter to include in its Preliminary Safety Analysis Report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required by the provisions of § 50.34 or § 53.1369 of this chapter to include, in its Final Safety Analysis Report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license is required by the provisions of § 52.79 or § 53.1416 of this chapter to include in its Final Safety Analysis Report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe

operation. For applications submitted after September 27, 2007, every applicant for an early site permit is required by the provisions of § 52.17 or § 53.1146 of this chapter to include in its Site Safety Analysis Report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval is required by the provisions of § 52.137 or § 53.1209 of this chapter to include in its Final Safety Analysis Report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a design certification is required by the provisions of § 52.47 or § 53.1239 of this chapter to include in its Final Safety Analysis Report a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license is required by the provisions of § 52.157 or § 53.1279 of this chapter to include in its Final Safety Analysis Report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components 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 structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

* * * * *

III. Design Control

Measures shall be established to assure that applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the license application, or the functional design criteria, as defined in § 53.020 of this chapter and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures shall also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.

* * * * *

IV. Procurement Document Control

Measures shall be established to assure that applicable regulatory requirements, design bases or functional design criteria, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this appendix.

* * * * *

110. In Appendix E to part 50:

a. Revise paragraph I.1;

b. Add paragraph I.7;

c. Revise the first paragraph of section III;

d. Revise and republish section IV; and

e. Revise section V.

The addition and revisions read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. Introduction

1. Each applicant for a construction permit is required by § 50.34(a) or § 53.1309(a)(4) of this chapter to include in the preliminary safety analysis report a discussion of preliminary plans for coping with emergencies. Each applicant for an operating license is required by § 50.34(b) 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.

* * * * *

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.

* * * * *

III. The Final Safety Analysis Report; Site Safety Analysis Report

The final safety analysis report or the site safety analysis report for an early site permit that includes complete and integrated emergency plans under § 52.17(b)(2)(ii) or § 53.1146(b)(2)(ii) of this chapter shall contain the plans for coping with emergencies. The plans shall be an expression of the overall concept of operation; they shall describe the essential elements of advance planning that have been considered and the provisions that have been made to cope with emergency situations. The plans shall incorporate information about the emergency response roles of supporting organizations

and offsite agencies. That information shall be sufficient to provide assurance of coordination among the supporting groups and with the licensee. The site safety analysis report for an early site permit which proposes major features must address the relevant provisions of 10 CFR 50.47 and 10 CFR part 50, appendix E, within the scope of emergency preparedness matters addressed in the major features.

* * * * *

IV. Content of Emergency Plans

1. The applicant's emergency plans shall contain, but not necessarily be limited to, information needed to demonstrate compliance with the elements in this section IV., i.e., organization for coping with radiological emergencies, assessment actions, activation of emergency organization, notification procedures, emergency facilities and equipment, training, maintaining emergency preparedness, recovery, and onsite protective actions during hostile action. In addition, the emergency response plans submitted by an applicant for a nuclear power reactor operating license under 10 CFR part 50 or 10 CFR part 53, or for an early site permit (as applicable) or combined license under 10 CFR part 52 or 10 CFR part 53, shall contain information needed to demonstrate compliance with the standards described in § 50.47(b), and they will be evaluated against those standards.

2. This nuclear power reactor license applicant shall also provide an analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, using the most recent U.S. Census Bureau data as of the date the applicant submits its application to the NRC.

3. Nuclear power reactor licensees shall use NRC approved evacuation time estimates (ETEs) and updates to the ETEs in the formulation of protective action recommendations and shall provide the ETEs and ETE updates to State and local governmental authorities for use in developing offsite 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 protective action recommendations and providing it to State and local governmental authorities for use in developing offsite protective action strategies.

5. During the years between decennial censuses, nuclear power reactor licensees shall estimate EPZ permanent resident population changes once a year, but no later than 365 days from the date of the previous estimate, using the most recent U.S. Census Bureau annual resident population estimate and State/local government population data, if available. These licensees shall maintain these estimates so that they are available for NRC inspection during the period between decennial censuses and shall submit these estimates to the NRC with any updated ETE analysis.

6. If at any time during the decennial period, the EPZ permanent resident population increases such that it causes the longest ETE value for the 2-mile zone or 5-mile zone, including all affected Emergency Response Planning Areas, or for the entire 10-mile EPZ to increase by 25 percent or 30 minutes, whichever is less, from the nuclear power reactor licensee’s currently NRC-approved or updated ETE, the licensee shall update the ETE analysis to reflect the impact of that population increase. The licensee shall submit the updated ETE analysis to the NRC under § 50.4 or § 53.040 of this chapter no later than 365 days after the licensee’s determination that the criteria for updating the ETE have been met and at least 180 days before using it to form protective action recommendations and providing it to State and local governmental authorities for use in developing offsite protective action strategies.

7. After an applicant for a combined license under part 52 or part 53 of this chapter receives its license, the licensee shall conduct at least one review of any changes in the population of its EPZ at least 365 days prior to its scheduled fuel load. The licensee shall estimate EPZ permanent resident population changes using the most recent U.S. Census Bureau annual resident population estimate and State/local government population data, if available. If the EPZ permanent resident population increases such that it causes the longest ETE value for the 2-mile zone or 5-mile zone, including all affected Emergency Response Planning Areas, or for the entire 10-mile EPZ, to increase by 25 percent or 30 minutes, whichever is less, from the licensee's currently approved ETE, the licensee shall update the ETE analysis to reflect the impact of that population increase. The licensee shall submit the updated ETE analysis to the NRC for review under § 50.4 or § 53.040 of this chapter no later than 365 days before the licensee's scheduled fuel load.

A. Organization

The organization for coping with radiological emergencies shall be described, including definition of authorities, responsibilities, and duties of individuals assigned to the licensee's emergency organization and the means for notification of such individuals in the event of an emergency. Specifically, the following shall be included:

1. A description of the normal plant operating organization.

2. A description of the onsite emergency response organization (ERO) with a detailed discussion of:

a. Authorities, responsibilities, and duties of the individual(s) who will take charge during an emergency;

b. Plant staff emergency assignments;

c. Authorities, responsibilities, and duties of an onsite emergency coordinator who shall be in charge of the exchange of information with offsite authorities responsible for coordinating and implementing offsite emergency measures.

3. A description, by position and function to be performed, of the licensee's headquarters personnel who will be sent to the plant site to augment the onsite emergency organization.

4. Identification, by position and function to be performed, of persons within the licensee organization who will be responsible for making offsite dose projections, and a description of how these projections will be made and the results transmitted to State and local authorities, NRC, and other appropriate governmental entities.

5. Identification, by position and function to be performed, of other employees of the licensee with special qualifications for coping with emergency conditions that may arise. Other persons with special qualifications, such as consultants, who are not employees of the licensee and who may be called upon for assistance for emergencies shall also be identified. The special qualifications of these persons shall be described.

6. A description of the local offsite services to be provided in support of the licensee's emergency organization.

7. Identification of, and a description of the assistance expected from, appropriate State, local, and Federal agencies with responsibilities for coping with emergencies, including hostile action at the site. For purposes of this appendix, "hostile action" is defined as an act directed toward a nuclear power plant or its personnel that includes the use of violent force to destroy equipment, take hostages, and/or intimidate the licensee to achieve an end. This includes attack by air, land, or water using guns, explosives, projectiles, vehicles, or other devices used to deliver destructive force.

8. Identification of the State and/or local officials responsible for planning for, ordering, and controlling appropriate protective actions, including evacuations when necessary.

9. For nuclear power reactor licensees, a detailed analysis demonstrating that on-shift personnel assigned emergency plan implementation functions are not assigned responsibilities that would prevent the timely performance of their assigned functions as specified in the emergency plan.

B. Assessment Actions

1. The means to be used for determining the magnitude of, and for continually assessing the impact of, the release of radioactive materials shall be described, including emergency action levels that are to be used as criteria for determining the need for notification and participation of local and State agencies, the Commission, and other Federal agencies, and the emergency action levels that are to be used for determining when and what type of protective measures should be considered within and outside the site boundary to protect health and safety. The emergency action levels shall be based on in-plant conditions and instrumentation in addition to onsite and offsite monitoring. For nuclear power reactor licensees, these action levels must include hostile action that may adversely affect the nuclear power plant. The initial emergency action levels shall be discussed and agreed on by the applicant or licensee and state and local governmental authorities, and approved by the NRC. Thereafter, emergency action levels shall be reviewed with the State and local governmental authorities on an annual basis.

2. A licensee desiring to change its entire emergency action level scheme shall submit an application for an amendment to its license and receive NRC approval before

implementing the change. Licensees shall follow the change process in § 50.54(q) or § 53.1565(d)(3) of this chapter for all other emergency action level changes.

C. Activation of Emergency Organization

1. The entire spectrum of emergency conditions that involve the alerting or activating of progressively larger segments of the total emergency organization shall be described. The communication steps to be taken to alert or activate emergency personnel under each class of emergency shall be described. Emergency action levels (based not only on onsite and offsite radiation monitoring information but also on readings from a number of sensors that indicate a potential emergency, such as the pressure in containment and the response of the Emergency Core Cooling System) for notification of offsite agencies shall be described. The existence, but not the details, of a message authentication scheme shall be noted for such agencies. The emergency classes defined shall include: (1) Notification of unusual events, (2) alert, (3) site area emergency, and (4) general emergency. These classes are further discussed in NUREG-0654/FEMA-REP-1.

2. Nuclear power reactor licensees shall establish and maintain the capability to assess, classify, and declare an emergency condition within 15 minutes after the availability of indications to plant operators that an emergency action level has been exceeded and shall promptly declare the emergency condition as soon as possible following identification of the appropriate emergency classification level. Licensees shall not construe these criteria as a grace period to attempt to restore plant conditions to avoid declaring an emergency action due to an emergency action level that has been exceeded. Licensees shall not construe these criteria as preventing implementation of response actions deemed by the licensee to be necessary to protect public health and safety provided that any delay in declaration does not deny the State and local

authorities the opportunity to implement measures necessary to protect the public health and safety.

D. Notification Procedures

1. Administrative and physical means for notifying local, State, and Federal officials and agencies and agreements reached with these officials and agencies for the prompt notification of the public and for public evacuation or other protective measures, should they become necessary, shall be described. This description shall include identification of the appropriate officials, by title and agency, of the State and local government agencies within the EPZs.

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 local broadcast stations 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 administrative and physical means have been established for alerting and providing prompt instructions to the public within the plume exposure

pathway EPZ. The design objective of the prompt public alert and notification system 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 public alert and notification system. The alerting and notification capability shall additionally include administrative and physical means for a backup method of public alerting and notification 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. The backup method 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. Emergency Facilities and Equipment

Adequate provisions shall be made and described for emergency facilities and equipment, including:

1. Equipment at the site for personnel monitoring;

2. Equipment for determining the magnitude of and for continuously assessing the impact of the release of radioactive materials to the environment;

3. Facilities and supplies at the site for decontamination of onsite individuals;

4. Facilities and medical supplies at the site for appropriate emergency first aid treatment;

5. Arrangements for medical service providers qualified to handle radiological emergencies onsite;

6. Arrangements for transportation of contaminated injured individuals from the site to specifically identified treatment facilities outside the site boundary;

7. Arrangements for treatment of individuals injured in support of licensed activities on the site at treatment facilities outside the site boundary;

8. a. (i) A licensee onsite technical support center and an emergency operations facility from which effective direction can be given and effective control can be exercised during an emergency;

(ii) For nuclear power reactor licensees, a licensee onsite operational support center;

b. For a nuclear power reactor licensee's emergency operations facility required by paragraph 8.a of this section, either a facility 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(s). 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:

(1) Space for members of an NRC site team and Federal, State, and local responders;

(2) Additional space for conducting briefings with emergency response personnel;

(3) Communication with other licensee and offsite emergency response facilities;

(4) Access to plant data and radiological information; and

(5) Access to copying equipment and office supplies;

c. For a nuclear power reactor licensee's emergency operations facility required by paragraph 8.a of this section, a facility having the following capabilities:

(1) The capability for obtaining and displaying plant data and radiological information for each reactor at a nuclear power reactor site and for each nuclear power reactor site that the facility serves;

(2) The capability to analyze plant technical information and provide technical briefings on event conditions and prognosis to licensee and offsite response organizations for each reactor at a nuclear power reactor site and for each nuclear power reactor site that the facility serves; and

(3) The capability to support response to events occurring simultaneously at more than one nuclear power reactor site if the emergency operations facility serves more than one site; and

d. For nuclear power reactor licensees, an alternative facility (or facilities) that would be accessible even if the site is under threat of or experiencing hostile action, to

function as a staging area for augmentation of emergency response staff and collectively having the following characteristics: the capability for communication with the emergency operations facility, control room, and plant security; the capability to perform offsite notifications; and the capability for engineering assessment activities, including damage control team planning and preparation, for use when onsite emergency facilities cannot be safely accessed during hostile action. The requirements in this paragraph 8.d must be implemented no later than December 23, 2014, with the exception of the capability for staging emergency response organization personnel at the alternative facility (or facilities) and the capability for communications with the emergency operations facility, control room, and plant security, which must be implemented no later than June 20, 2012.

e. A licensee shall not be subject to the requirements of paragraph 8.b of this section for an existing emergency operations facility approved as of December 23, 2011;

9. At least one onsite and one offsite communications system; each system shall have a backup power source. All communication plans shall have arrangements for emergencies, including titles and alternates for those in charge at both ends of the communication links and the primary and backup means of communication. Where consistent with the function of the governmental agency, these arrangements will include:

a. Provision for communications with contiguous State/local governments within the plume exposure pathway EPZ. Such communications shall be tested monthly.

b. Provision for communications with Federal emergency response organizations. Such communications systems shall be tested annually.

c. Provision for communications among the nuclear power reactor control room, the onsite technical support center, and the emergency operations facility; and among

the nuclear facility, the principal State and local emergency operations centers, and the field assessment teams. Such communications systems shall be tested annually.

d. Provisions for communications by the licensee with NRC Headquarters and the appropriate NRC Regional Office Operations Center from the nuclear power reactor control room, the onsite technical support center, and the emergency operations facility. Such communications shall be tested monthly.

F. Training

1. The program to provide for: (a) The training of employees and exercising, by periodic drills, of emergency plans to ensure that employees of the licensee are familiar with their specific emergency response duties, and (b) The participation in the training and drills by other persons whose assistance may be needed in the event of a radiological emergency shall be described. This shall include a description of specialized initial training and periodic retraining programs to be provided to each of the following categories of emergency personnel:

i. Directors and/or coordinators of the plant emergency organization;

ii. Personnel responsible for accident assessment, including control room shift personnel;

iii. Radiological monitoring teams;

iv. Fire control teams (fire brigades);

v. Repair and damage control teams;

vi. First aid and rescue teams;

vii. Medical support personnel;

viii. Licensee's headquarters support personnel;

ix. Security personnel.

In addition, a radiological orientation training program shall be made available to local services personnel; e.g., local emergency services/Civil Defense, local law enforcement personnel, local news media persons.

2. The plan shall describe provisions for the conduct of emergency preparedness exercises as follows: Exercises shall test the adequacy of timing and content of implementing procedures and methods, test emergency equipment and communications networks, test the public alert and notification system, and ensure that emergency organization personnel are familiar with their duties.[3]

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. Nuclear power reactor licensees shall submit exercise scenarios under § 50.4 or § 53.040 of this chapter at least 60 days before use in a full participation exercise required by this paragraph 2.a.

(i) For an operating license issued under part 50 or part 53 of this chapter, this exercise must be conducted within 2 years before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway EPZ and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than 1 year prior to issuance of an operating licensee for full power, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before issuance of an operating license for full power. This exercise need not have State or local government participation.

(ii) For a combined license issued under part 52 or part 53 of this chapter, this exercise must be conducted within 2 years of the scheduled date for initial loading of

fuel. If the first full participation exercise is conducted more than 1 year before the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted within 1 year before the scheduled date for initial loading of fuel. This exercise need not have State or local government participation. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

(iii) For a combined license issued under part 52 or part 53 of this chapter, if the applicant currently has an operating reactor at the site, an exercise, either full or partial participation,[5] shall be conducted for each subsequent reactor constructed on the site. This exercise may be incorporated in the exercise requirements of Sections IV.F.2.b. and c. in this appendix. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of this exercise for the new reactor, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

b. Each licensee at each site shall conduct a subsequent exercise of its onsite emergency plan every 2 years. Nuclear power reactor licensees shall submit exercise scenarios under § 50.4 or § 53.040 of this chapter at least 60 days before use in an exercise required by this paragraph 2.b. The exercise may be included in the full participation biennial exercise required by paragraph 2.c. of this section. In addition, the licensee shall take actions necessary to ensure that adequate emergency response capabilities are maintained during the interval between biennial exercises by conducting

drills, including at least one drill involving a combination of some of the principal functional areas of the licensee's onsite emergency response capabilities. The principal functional areas of emergency response include activities such as management and coordination of emergency response, accident assessment, event classification, notification of offsite authorities, assessment of the onsite and offsite impact of radiological releases, protective action recommendation development, protective action decision making, plant system repair and mitigative action implementation. During these drills, activation of all of the licensee's emergency response facilities (Technical Support Center (TSC), Operations Support Center (OSC), and the Emergency Operations Facility (EOF)) would not be necessary, licensees would have the opportunity to consider accident management strategies, supervised instruction would be permitted, operating staff in all participating facilities would have the opportunity to resolve problems (success paths) rather than have controllers intervene, and the drills may focus on the onsite exercise training objectives.

c. Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the radiological response plan. 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 2 years and shall, at least, partially participate in other offsite plan exercises in this period. If two different licensees each have licensed facilities located either on the same site or on adjacent, contiguous sites, and share most of the elements defining co-located licensees,[6] then each licensee shall:

(1) Conduct an exercise biennially of its onsite emergency plan;

(2) Participate quadrennially in an offsite biennial full or partial participation exercise;

(3) Conduct emergency preparedness activities and interactions in the years between its participation in the offsite full or partial participation exercise with offsite

authorities, to test and maintain interface among the affected State and local authorities and the licensee. Co-located licensees shall also participate in emergency preparedness activities and interaction with offsite authorities for the period between exercises;

(4) Conduct a hostile action exercise of its onsite emergency plan in each exercise cycle; and

(5) Participate in an offsite biennial full or partial participation hostile action exercise in alternating exercise cycles.

d. Each State with responsibility for nuclear power reactor emergency preparedness should fully participate in the ingestion pathway portion of exercises at least once every exercise cycle. In States with more than one nuclear power reactor plume exposure pathway EPZ, the State should rotate this participation from site to site. Each State with responsibility for nuclear power reactor emergency preparedness should fully participate in a hostile action exercise at least once every cycle. States with more than one nuclear power reactor plume exposure pathway EPZ should rotate this participation from site to site.

e. Licensees shall enable any State or local government located within the plume exposure pathway EPZ to participate in the licensee's drills when requested by such State or local government.

f. Remedial exercises will be required if the emergency plan is not satisfactorily tested during the biennial exercise, such that NRC, in consultation with FEMA, cannot (1) find reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency or (2) determine that the Emergency Response Organization (ERO) has maintained key skills specific to emergency response. The extent of State and local participation in remedial exercises must be sufficient to show that appropriate corrective measures have been taken regarding the elements of the plan not properly tested in the previous exercises.

g. All exercises, drills, and training that provide performance opportunities to develop, maintain, or demonstrate key skills must provide for formal critiques in order to identify weak or deficient areas that need correction. Any weaknesses or deficiencies that are identified in a critique of exercises, drills, or training must be corrected.

h. The participation of State and local governments in an emergency exercise is not required to the extent that the applicant has identified those governments as refusing to participate further in emergency planning activities, pursuant to § 50.47(c)(1). In such cases, an exercise shall be held with the applicant or licensee and such governmental entities as elect to participate in the emergency planning process.

i. Licensees shall use drill and exercise scenarios that provide reasonable assurance that anticipatory responses will not result from preconditioning of participants. Such scenarios for nuclear power reactor licensees must include a wide spectrum of radiological releases and events, including hostile action. Exercise and drill scenarios as appropriate must emphasize coordination among onsite and offsite response organizations.

j. (i) The exercises conducted under paragraph 2 of this section by nuclear power reactor licensees must provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to implement the principal functional areas of emergency response identified in paragraph 2.b of this section.

(ii) Each exercise must provide the opportunity for the ERO to demonstrate key skills specific to emergency response duties in the control room, TSC, OSC, EOF, and joint information center.

(iii) In each 8-calendar-year exercise cycle, nuclear power reactor licensees shall vary the content of scenarios during exercises conducted under paragraph 2 of this section to provide the opportunity for the ERO to demonstrate proficiency in the key skills necessary to respond to the following scenario elements:

(1) Hostile action directed at the plant site;

(2) No radiological release or an unplanned minimal radiological release that does not require public protective actions;

(3) An initial classification of, or rapid escalation to, a Site Area Emergency or General Emergency;

(4) Implementation of strategies, procedures, and guidance under § 50.155(b)(2) for applicants and licensees under parts 50 and 52 of this chapter; and

(5) Integration of offsite resources with onsite response.

(iv) The licensee shall maintain a record of exercises conducted during each 8-year exercise cycle that documents the content of scenarios used to comply with the requirements of section IV.F.2.j of this appendix.

(v) Each licensee shall conduct a hostile action exercise for each of its sites no later than December 31, 2015.

(vi) The first 8-year exercise cycle for a site will begin in the calendar year in which the first hostile action exercise is conducted. For a site licensed under 10 CFR part 52 or 10 CFR part 53 using 10 CFR 50.47 and this appendix, the first 8-year exercise cycle begins in the calendar year of the initial exercise required by section IV.F.2.a of this appendix.

G. Maintaining Emergency Preparedness

Provisions to be employed to ensure that the emergency plan, its implementing procedures, and emergency equipment and supplies are maintained up to date shall be described.

H. Recovery

Criteria to be used to determine when, following an accident, reentry of the facility would be appropriate or when operation could be resumed shall be described.

I. Onsite Protective Actions During Hostile Action

For nuclear power reactor licensees, a range of protective actions to protect onsite personnel during hostile action must be developed to ensure the continued ability of the licensee to safely shut down the reactor and perform the functions of the licensee's emergency plan.

V. Implementing Procedures

No less than 180 days before the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material, or the scheduled date for initial loading of fuel for a combined license under part 52 or part 53 of this chapter, the applicant's or licensee's detailed implementing procedures for its emergency plan shall be submitted to the Commission as specified in § 50.4 or § 53.040.

* * * * *

---

* * * * *

[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.

[6] Co-located licensees are two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements:

a. Plume exposure and ingestion emergency planning zones;

b. Offsite governmental authorities;

c. Offsite emergency response organizations;

d. Public notification system; and/or

e. Emergency facilities.

* * * * *

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

111. The authority citation for part 51 is revised 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.

112. In § 51.4, revise the definition for "*Construction*" to read as follows:

§ 51.4 Definitions.

* * * * *

Construction means:

(1)(i) For production and utilization facilities licensed under 10 CFR part 50 or 10 CFR part 52, the activities in 10 CFR 50.10(a)(1), and does not mean the activities in 10 CFR 50.10(a)(2).

(ii) For utilization facilities licensed under 10 CFR part 53, the activities in paragraph (1) of the definition of *construction* in 10 CFR 53.020, and does not mean the activities in paragraph (2) of the definition of *construction* in 10 CFR 53.020.

(2) For materials licenses, the activities in paragraph (2)(i) of this definition, and does not mean the activities in paragraph (2)(ii) of this definition.

(i) Taking any site-preparation activity at the site of a facility subject to the regulations in 10 CFR parts 30, 36, 40, and 70 that has a reasonable nexus to radiological health and safety or the common defense and security.

(ii) Construction does not include:

(A) The activities listed in 10 CFR 50.10(a)(2)(i)-(viii); or

(B) Taking any other action that has no reasonable nexus to radiological health and safety or the common defense and security.

* * * * *

113. In § 51.20, revise paragraphs (b)(1) and (2) to read as follows:

§ 51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements.

* * * * *

(b) * * *

(1) Issuance of a limited work authorization or a permit to construct a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 of this chapter, issuance of an early site permit under part 52 of this chapter, or issuance of a limited work authorization, construction permit, or early site permit under part 53 of this chapter.

(2) Issuance or renewal of a full power or design capacity license to operate a nuclear power reactor, testing facility, or fuel reprocessing plant under part 50 or part 53 of this chapter, or a combined license under part 52 or part 53 of this chapter.

* * * * *

114. In § 51.22, revise paragraphs (c)(3) introductory text, (c)(9) introductory text, (c)(12) introductory text, (c)(17), (c)(22), and (c)(23) to read as follows:

§ 51.22 Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review.

* * * * *

(c) * * *

(3) Amendments to parts 20, 30, 31, 32, 33, 34, 35, 37, 39, 40, 50, 51, 52, 53, 54, 60, 61, 63, 70, 71, 72, 73, 74, 81, and 100 of this chapter which relate to—

* * * * *

(9) Issuance of an amendment to a permit or license for a reactor under part 50, part 52, or part 53 of this chapter that changes a requirement or issuance of an exemption from a requirement, with respect to installation or use of a facility component located within the restricted area, as defined in part 20 of this chapter; or the issuance of an amendment to a permit or license for a reactor under part 50, part 52, or part 53 of this chapter that changes an inspection or a surveillance requirement; provided that:

* * * * *

(12) Issuance of an amendment to a license under parts 50, 52, 53, 60, 61, 63, 70, 72, or 75 of this chapter relating solely to safeguards matters (i.e., protection against sabotage or loss or diversion of special nuclear material) or issuance of an approval of a safeguards plan submitted under parts 50, 52, 53, 70, 72, and 73 of this chapter, provided that the amendment or approval does not involve any significant construction impacts. These amendments and approvals are confined to—

* * * * *

(17) Issuance of an amendment to a permit or license under part 30, part 40, part 50, part 52, part 53, or part 70 of this chapter which deletes any limiting condition of operation or monitoring requirement based on or applicable to any matter subject to the provisions of the Federal Water Pollution Control Act.

* * * * *

(22) Issuance of a standard design approval under part 52 or part 53 of this chapter.

(23) The Commission finding for a combined license under § 52.103(g) or § 53.1452(g) of this chapter.

* * * * *

§ 51.26 [Amended]

115. In § 51.26, in paragraph (d) remove the phrase “under part 52” and add in its place the phrase “under 10 CFR part 52 or part 53,”.

116. In § 51.30, revise paragraph (a) introductory text and paragraphs (d) and (e) to read as follows:

§ 51.30 Environmental assessment.

(a) An environmental assessment for proposed actions, other than those for a standard design certification under 10 CFR part 52 or part 53, or a manufacturing license under 10 CFR part 52 or part 53, shall identify the proposed action and include:

* * * * *

(d) An environmental assessment for a standard design certification under subpart B of part 52, or under subpart H of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the design certification. An environmental assessment for an amendment to a design certification will be limited to the consideration of whether the design change which is the subject of the proposed amendment renders a severe accident mitigation design alternative previously rejected in the earlier environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the

costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the design certification must be addressed.

(e) An environmental assessment for a manufacturing license under subpart F of part 52 of this chapter or under subpart H of part 53 of this chapter must identify the proposed action and will be limited to the consideration of the costs and benefits of severe accident mitigation design alternatives and the bases for not incorporating severe accident mitigation design alternatives in the manufacturing license. An environmental assessment for an amendment to a manufacturing license will be limited to consideration of whether the design change which is the subject of the proposed amendment either renders a severe accident mitigation design alternative previously rejected in an environmental assessment to become cost beneficial, or results in the identification of new severe accident mitigation design alternatives, in which case the costs and benefits of new severe accident mitigation design alternatives and the bases for not incorporating new severe accident mitigation design alternatives in the manufacturing license must be addressed. In either case, the environmental assessment will not address the environmental impacts associated with manufacturing the reactor under the manufacturing license.

§ 51.31 [Amended]

117. In § 51.31, in paragraph (a) remove the phrase “under part 52” and add in its place the phrase “under part 52 or part 53”.

§ 51.32 [Amended]

118. In § 51.32, in paragraphs (b)(1) and (3) remove the phrase “of part 52 of this chapter” and add in its place the phrase “of part 52 or subpart H of part 53 of this chapter”.

§ 51.49 [Amended]

119. In § 51.49, in paragraph (c) introductory text, remove the phrase “of part 52 of this chapter” and add in its place the phrase “of part 52 or under subpart H of part 53 of this chapter”.

§ 51.50 [Amended]

120. In § 51.50, wherever it may appear, remove the phrase “in accordance with § 50.36b of this chapter” and add in its place the phrase “in accordance with § 50.36b or § 53.1112 of this chapter”.

§ 51.53 [Amended]

121. In § 51.53, in paragraph (d) remove the phrase “under § 50.82 of this chapter” and add in its place the phrase “under § 50.82 or § 53.1080 of this chapter”.

§ 51.54 [Amended]

122. In § 51.54, in paragraph (a), remove the phrase “of part 52 of this chapter” and add in its place the phrase “of part 52 or under subpart H of part 53 of this chapter”.

§ 51.55 [Amended]

123. In § 51.55, in paragraph (a) remove the phrase “of part 52 of this chapter” and add in its place the phrase “of part 52 or under subpart H of part 53 of this chapter”.

124. In § 51.58, revise paragraph (b) to read as follows:

§ 51.58 Environmental report—number of copies; distribution.

* * * * *

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture, seeking approval of the final design of the nuclear power reactor under subpart F of part 52 or under subpart H of part 53 of this chapter, shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in § 50.3 or § 53.040 of this chapter. The applicant shall maintain the capability to generate additional copies of the environmental report or any supplement to the environmental report for subsequent

distribution to parties and Boards in the NRC proceeding; Federal, State, and local officials; and any affected Indian Tribes, in accordance with written instructions issued by the Director, Office of Nuclear Reactor Regulation.

125. In § 51.77, revise paragraph (a) introductory text to read as follows:

§ 51.77 Distribution of draft environmental impact statement.

(a) In addition to the distribution authorized by § 51.74, a copy of a draft environmental statement for a licensing action for a production or utilization facility, except an action authorizing issuance, amendment, or renewal of a license to manufacture a nuclear power reactor pursuant to 10 CFR part 52, subpart F or 10 CFR part 53, subparts H or I will also be distributed to:

* * * * *

§ 51.92 [Amended]

126. In § 51.92, in paragraph (b), remove the phrase “10 CFR part 52” and add in its place the phrase “10 CFR part 52 or part 53”.

§ 51.95 [Amended]

127. In § 51.95, in paragraph (c) introductory text remove the phrase “under 10 CFR parts 52 or 54” and add in its place the phrase “under 10 CFR part 52, part 53, or part 54”.

128. In § 51.101, revise paragraph (a)(2) to read as follows:

§ 51.101 Limitations on actions.

(a) * * *

(2) Any action concerning the proposal taken by an applicant which would—

(i) Have an adverse environmental impact, or

(ii) Limit the choice of reasonable alternatives that may be grounds for denial of the license. In the case of an application covered by § 30.32(f), § 40.31(f), § 50.10(c), § 53.1130, § 70.21(f), or § 72.16 and § 72.34 of this chapter, the provisions of this

paragraph will be applied in accordance with § 30.33(a)(5), § 40.32(e), § 50.10(c), § 53.1130, § 70.23(a)(7), or § 72.40(b) of this chapter, as appropriate.

* * * * *

§ 51.103 [Amended]

129. In § 51.103, in paragraph (a)(6) remove the phrase “under 10 CFR 50.10” and add in its place the phrase “under § 50.10 or § 53.1130 of this chapter”.

130. In § 51.105, revise paragraph (c)(1) to read as follows:

§ 51.105 Public hearings in proceedings for issuance of construction permits or early site permits; limited work authorizations.

* * * * *

(c)(1) In addition to complying with the applicable provisions of § 51.104, in any proceeding for the issuance of a construction permit for a nuclear power plant or an early site permit under part 52 or part 53 of this chapter, where the applicant requests a limited work authorization under § 50.10(d) or § 53.1130 of this chapter, the presiding officer will—

* * * * *

131. In § 51.107, revise paragraphs (a) introductory text, (b) introductory text, and (d)(1) to read as follows:

§ 51.107 Public hearings in proceedings for issuance of combined licenses; limited work authorizations.

(a) In addition to complying with the applicable requirements of § 51.104, in a proceeding for the issuance of a combined license for a nuclear power reactor under part 52 or part 53 of this chapter, the presiding officer will:

* * * * *

(b) If a combined license application references an early site permit, then the presiding officer in the combined license hearing must not admit any contention

proffered by any party on environmental issues that have been accorded finality under § 52.39 or § 53.1188 of this chapter, unless the contention:

* * * * *

(d)(1) In any proceeding for the issuance of a combined license where the applicant requests a limited work authorization under § 50.10(d) or § 53.1130(a) of this chapter, the presiding officer, in addition to complying with any applicable provision of § 51.104, will:

* * * * *

132. Revise § 51.108 to read as follows:

§ 51.108 Public hearings on Commission findings that inspections, tests, analyses, and acceptance criteria of combined licenses are met.

In any public hearing requested under § 52.103(b) or § 53.1452(b) of this chapter, the Commission will not admit any contentions on environmental issues, the adequacy of the environmental impact statement for the combined license issued under subpart C of part 52 or under subpart H of part 53 of this chapter, or the adequacy of any other environmental impact statement or environmental assessment referenced in the combined license application. The Commission will not make any environmental findings in connection with the finding under § 52.103(g) or § 53.1452(g) of this chapter.

133. Add new Part 53—Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants and new §§ 53.000 through 53.9010 to read as follows:

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

Sec.
§ 53.000 Purpose.
Subpart A—General Provisions
§ 53.015 Scope.
§ 53.020 Definitions.

§ 53.030 [Reserved]
§ 53.040 Written communications.
§ 53.050 Deliberate misconduct.
§ 53.060 Employee protection.
§ 53.070 Completeness and accuracy of information.
§ 53.080 Specific exemptions.
§ 53.090 Standards for review.
§ 53.100 Jurisdictional limits.
§ 53.110 Attacks and destructive acts.
§ 53.115 Rights related to special nuclear material.
§ 53.117 License suspension and rights of recapture.
§ 53.120 Information collection requirements: OMB approval.
Subpart B—Technology-Inclusive Safety Requirements
§ 53.210 Safety criteria for design-basis accidents.
§ 53.220 Safety criteria for licensing-basis events other than design-basis accidents.
§ 53.230 Safety functions.
§ 53.240 Licensing-basis events.
§ 53.250 Defense in depth.
§ 53.260 Normal operations.
§ 53.270 Protection of plant workers.
Subpart C—Design and Analysis Requirements
§ 53.400 Design features for licensing-basis events.
§ 53.410 Functional design criteria for design-basis accidents.
§ 53.415 Protection against external hazards.
§ 53.420 Functional design criteria for licensing-basis events other than design-basis accidents.
§ 53.425 Design features and functional design criteria for normal operations.
§ 53.430 Design features and functional design criteria for protection of plant workers.
§ 53.440 Design requirements.
§ 53.450 Analysis requirements.
§ 53.460 Safety categorization and treatments.
§ 53.470 [Reserved]
§ 53.480 Earthquake engineering.
Subpart D—Siting Requirements
§ 53.500 General siting and siting assessment.
§ 53.510 External hazards.
§ 53.520 Site characteristics.
§ 53.530 Population-related considerations.
§ 53.540 Siting interfaces.
Subpart E—Construction and Manufacturing Requirements
§ 53.600 Construction and manufacturing – scope and purpose.
§ 53.605 Reporting of defects and noncompliance.
§ 53.610 Construction.
§ 53.620 Manufacturing.
Subpart F—Requirements for Operation
§ 53.700 Operational objectives.
§ 53.710 Maintaining capabilities and availability of structures, systems, and components.
§ 53.715 Maintenance, repair, and inspection programs.
§ 53.720 Response to seismic events.

§ 53.725 General staffing, training, personnel qualifications, and human factors requirements.
§ 53.726 Communications.
§ 53.728 Completeness and accuracy of information.
§ 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.
§ 53.735 General exemptions.
§ 53.740 Facility licensee requirements – general.
§ 53.745 Operator license requirements.
§ 53.760 Operator licensing.
§ 53.765 Medical requirements.
§ 53.770 Incapacitation because of disability or illness.
§ 53.775 Applications for operators and senior operators.
§ 53.780 Training, examination, and proficiency program.
§ 53.785 Conditions of operator and senior operator licenses.
§ 53.790 Issuance, modification, and revocation of operator and senior operator licenses.
§ 53.795 Expiration and renewal of operator and senior operator licenses.
§ 53.800 Facility licensees for self-reliant-mitigation facilities.
§ 53.805 Facility licensee requirements related to generally licensed reactor operators.
§ 53.810 Generally licensed reactor operators.
§ 53.815 Generally licensed reactor operator training, examination, and proficiency programs.
§ 53.820 Cessation of individual applicability.
§ 53.830 Training and qualification of commercial nuclear personnel.
§ 53.845 Programs.
§ 53.850 Radiation protection.
§ 53.855 Emergency preparedness.
§ 53.860 Security programs.
§ 53.865 Quality assurance.
§ 53.870 Integrity assessment programs.
§ 53.875 Fire protection.
§ 53.880 Inservice inspection and inservice testing.
§ 53.910 Procedures and guidelines.
Subpart G—Decommissioning Requirements
§ 53.1000 Scope and purpose.
§ 53.1010 Financial assurance for decommissioning.
§ 53.1020 Cost estimates for decommissioning.
§ 53.1030 Annual adjustments to cost estimates for decommissioning.
§ 53.1040 Methods for providing financial assurance for decommissioning.
§ 53.1045 Limitations on the use of decommissioning trust funds.
§ 53.1050 NRC oversight.
§ 53.1060 Reporting and recordkeeping requirements.
§ 53.1070 Termination of license.
§ 53.1075 Program requirements during decommissioning.
§ 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.
Subpart H—Licenses, Certifications, and Approvals
§ 53.1100 Filing of application for licenses, certifications, or approvals; oath or affirmation.
§ 53.1101 Requirement for license.
§ 53.1103 Combining applications and licenses.

§ 53.1106 Elimination of repetition.
§ 53.1109 Contents of applications; general information.
§ 53.1112 Environmental conditions.
§ 53.1115 Agreement limiting access to classified information.
§ 53.1118 Ineligibility of certain applicants.
§ 53.1120 Exceptions and exemptions from licensing requirements.
§ 53.1121 Public inspection of applications.
§ 53.1124 Relationship between sections.
§ 53.1130 Limited work authorizations.
§ 53.1140 Early site permits.
§ 53.1144 Contents of applications for early site permits; general information.
§ 53.1146 Contents of applications for early site permits; technical information.
§ 53.1149 Review of applications.
§ 53.1155 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1158 Issuance of early site permit.
§ 53.1161 Extent of activities permitted.
§ 53.1164 Duration of permit.
§ 53.1167 Limited work authorization after issuance of early site permit.
§ 53.1170 Transfer of early site permit.
§ 53.1173 Application for renewal.
§ 53.1176 Criteria for renewal.
§ 53.1179 Duration of renewal.
§ 53.1182 Use of site for other purposes.
§ 53.1188 Finality of early site permit determinations.
§ 53.1200 Standard design approvals.
§ 53.1206 Contents of applications for standard design approvals; general information.
§ 53.1209 Contents of applications for standard design approvals; technical information.
§ 53.1210 Contents of applications for standard design approvals; other application content.
§ 53.1212 Standards for review of applications.
§ 53.1215 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1218 Staff approval of design.
§ 53.1221 Finality of standard design approvals; information requests.
§ 53.1230 Standard design certifications.
§ 53.1236 Contents of applications for standard design certifications; general information.
§ 53.1239 Contents of applications for standard design certifications; technical information.
§ 53.1241 Contents of applications for standard design certifications; other application content.
§ 53.1242 Review of applications.
§ 53.1245 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1248 Issuance of standard design certification.
§ 53.1251 Duration of certification.
§ 53.1254 Application for renewal.
§ 53.1257 Criteria for renewal.
§ 53.1260 Duration of renewal.
§ 53.1263 Finality of standard design certifications.
§ 53.1270 Manufacturing licenses.
§ 53.1276 Contents of applications for manufacturing licenses; general information.
§ 53.1279 Contents of applications for manufacturing licenses; technical information.

§ 53.1282 Contents of applications for manufacturing licenses; other application content.
§ 53.1285 Review of applications.
§ 53.1286 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1287 Issuance of manufacturing licenses.
§ 53.1288 Finality of manufacturing licenses.
§ 53.1291 Duration of manufacturing licenses.
§ 53.1293 Transfer of manufacturing licenses.
§ 53.1295 Renewal of manufacturing licenses.
§ 53.1300 Construction permits.
§ 53.1306 Contents of applications for construction permits; general information.
§ 53.1309 Contents of applications for construction permits; technical information.
§ 53.1312 Contents of applications for construction permits; other application content.
§ 53.1315 Review of applications.
§ 53.1318 Finality of referenced NRC approvals, permits, and certifications.
§ 53.1324 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1327 Authorization to conduct limited work authorization activities.
§ 53.1330 Exemptions, departures, and variances.
§ 53.1333 Issuance of construction permits.
§ 53.1336 Finality of construction permits.
§ 53.1342 Duration of construction permits.
§ 53.1345 Transfer of construction permits.
§ 53.1348 Termination of construction permits.
§ 53.1360 Operating licenses.
§ 53.1366 Contents of applications for operating licenses; general information.
§ 53.1369 Contents of applications for operating licenses; technical information.
§ 53.1372 Contents of applications for operating licenses; other application content.
§ 53.1375 Review of applications.
§ 53.1381 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1384 Exemptions, departures, and variances.
§ 53.1387 Issuance of operating licenses.
§ 53.1390 Backfitting of operating licenses.
§ 53.1396 Duration of operating licenses.
§ 53.1399 Transfer of an operating license.
§ 53.1402 Application for renewal.
§ 53.1405 Continuation of an operating license.
§ 53.1410 Combined licenses.
§ 53.1413 Contents of applications for combined licenses; general information.
§ 53.1416 Contents of applications for combined licenses; technical information.
§ 53.1419 Contents of applications for combined licenses; other application content.
§ 53.1422 Review of applications.
§ 53.1425 Finality of referenced NRC approvals.
§ 53.1431 Referral to the Advisory Committee on Reactor Safeguards.
§ 53.1434 Authorization to conduct limited work authorization activities.
§ 53.1437 Exemptions, departures, and variances.
§ 53.1440 Issuance of combined licenses.
§ 53.1443 Finality of combined licenses.
§ 53.1449 Inspection during construction.
§ 53.1452 Operation under a combined license.
§ 53.1455 Duration of combined license.
§ 53.1456 Transfer of a combined license.
§ 53.1458 Application for renewal.

§ 53.1461 Continuation of combined license.
§ 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.
Subpart I—Maintaining and Revising Licensing-Basis Information
§ 53.1500 Licensing-basis information.
§ 53.1502 Specific terms and conditions of licenses.
§ 53.1505 Changes to licensing-basis information requiring prior NRC approval.
§ 53.1510 Application for amendment of license.
§ 53.1515 Public notices; State consultation.
§ 53.1520 Issuance of amendment.
§ 53.1525 Revising certification information within a design certification rule.
§ 53.1530 Revising design information within a Final Safety Analysis Report associated with a manufacturing license.
§ 53.1535 Amendments during construction.
§ 53.1540 Updating licensing-basis information and determining the need for NRC approval.
§ 53.1545 Updating Final Safety Analysis Reports.
§ 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.
§ 53.1560 Updating program documents included in licensing-basis information.
§ 53.1565 Evaluating changes to programs included in licensing-basis information.
§ 53.1570 Transfer of licenses.
§ 53.1575 Termination of licenses.
§ 53.1580 Information requests.
§ 53.1585 Revocation, suspension, modification of licenses and approvals for cause.
§ 53.1590 Backfitting.
§ 53.1595 Renewal.
Subpart J—Reporting and Other Administrative Requirements
§ 53.1600 General information.
§ 53.1610 Unfettered access for inspections.
§ 53.1620 Maintenance of records, making of reports.
§ 53.1630 Immediate notification requirements for operating commercial nuclear plants.
§ 53.1640 Licensee event report system.
§ 53.1645 Reports of radiation exposure to members of the public.
§ 53.1650 Facility information and verification.
§ 53.1660 Financial requirements.
§ 53.1670 Financial qualifications.
§ 53.1680 [Reserved]
§ 53.1690 Licensee’s change of status; financial qualifications.
§ 53.1700 Creditor regulations.
§ 53.1710 Financial protection.
§ 53.1720 Insurance required to stabilize and decontaminate plant following an accident.
§ 53.1730 Financial protection requirements.
Subparts K and L [Reserved]
Subpart M—Enforcement
§ 53.9000 Violations.
§ 53.9010 Criminal penalties.

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.

§ 53.000 Purpose.

This part provides an optional, technology-inclusive, performance-based framework for the issuance, amendment, renewal, and termination of licenses, permits, certifications, and approvals for commercial nuclear plants licensed under section 103 of the Atomic Energy Act of 1954, as amended (the Act) (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974, as amended (88 Stat. 1242). Also, this part gives notice to all persons who knowingly provide to any holder of or applicant for an approval, certification, permit, or license, or to a contractor, subcontractor, or consultant of any of them, components, equipment, materials, or other goods or services that relate to the activities of a holder of or applicant for an approval, certification, permit, or license, subject to this part, that they may be individually subject to U.S. Nuclear Regulatory Commission enforcement action for violation of the provisions in § 53.050.

Subpart A—General Provisions

§ 53.015 Scope.

Subpart A provides general provisions applicable to all applicants and licensees subject to the rules of this part.

§ 53.020 Definitions.

As used in this part:

Anticipated event sequence means event sequences expected to occur one or more times during the life of a commercial nuclear plant. Anticipated event sequences take into account the expected response of all structures, systems, and components (SSCs) within the plant, regardless of safety classification.

Applicant means a person applying for a license, permit, or other form of Commission permission or approval under this part.

Certified fuel handler means, for a commercial nuclear plant, either—

(1) A non-licensed operator who has qualified in accordance with a fuel handler training program approved by the Commission; or

(2) A non-licensed operator who demonstrates compliance with the following criteria:

(i) Has qualified in accordance with a fuel handler training program that demonstrates compliance with the same requirements as training programs for non-licensed operators required by § 53.830, and

(ii) Is responsible for decisions on—

(A) Safe conduct of decommissioning activities,

(B) Safe handling and storage of spent fuel, and

(C) Appropriate response to plant emergencies.

Combined license (COL) means a combined construction permit (CP) and operating license (OL) with conditions for a commercial nuclear plant issued under this part.

Commercial nuclear plant means a facility consisting of one or more commercial nuclear reactors and associated co-located support facilities, including the collection of buildings, radionuclide sources, and SSCs for which a license, certification, or approval is being sought under this part, that is or will be used for producing power for commercial electric power or other commercial purposes. For the purposes of requirements in this part that reference requirements in part 50 of this chapter, a commercial nuclear plant is equivalent to a nuclear power plant.

Commercial nuclear reactor means an apparatus, other than an atomic weapon, designed or used to sustain nuclear fission. For the purposes of requirements in this part that reference requirements in 10 CFR part 50, a commercial nuclear reactor is equivalent to a nuclear reactor as defined in § 50.2 of this chapter.

Commission means the U.S. Nuclear Regulatory Commission (NRC) or its duly authorized representatives.

Construction means the activities in paragraph (1) below and does not mean the activities in paragraph (2) below.

(1) Activities constituting construction are those activities that 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—

(i) 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;

(ii) SSCs necessary to comply with 10 CFR part 73; or

(iii) Onsite emergency facilities necessary to comply with § 53.855.

(2) Construction does not include—

(i) Changes for temporary use of the land for public recreational purposes;

(ii) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(iii) Preparation of a site for construction of a facility, including clearing of the site, grading, installation of drainage, erosion, and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(iv) Erection of fences and other access control measures;

(v) Excavation;

(vi) Erection of support buildings (such as construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(vii) Building of service facilities (such as paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewage treatment facilities, and transmission lines);

(viii) Procurement or fabrication of components or portions of the proposed facility occurring at locations other than the final, in-place location at the facility; or

(ix) Manufacture of a nuclear power reactor under a manufacturing license (ML) under subpart H of this part to be installed at the proposed site and to be part of the proposed facility.

Custom combined license (custom COL) means a COL that does not reference a standard design approval, standard design certification, or manufacturing license.

Decommission or decommissioning means to remove a plant or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Defense in depth means inclusion of two or more independent and redundant layers of defense in the design of a facility and its operating procedures to compensate for uncertainties such that no single layer of defense, no matter how robust, is exclusively relied upon. Defense in depth includes, but is not limited to, the use of access controls, physical barriers, redundant and diverse safety functions, and emergency response measures.

Design-basis accidents (DBAs) means postulated event sequences that are used to set functional design criteria and performance objectives for the design of SR SSCs

through deterministic analyses. Design-basis accidents are a type of licensing-basis event and are based on the capabilities and reliabilities of SR SSCs needed to mitigate and prevent event sequences, respectively.

Design-basis external hazard level means the level of severity or intensity of an external hazard for which the SR SSCs are protected against or designed to withstand without losing their capability to perform their safety functions.

Design features means the active and passive SSCs and the inherent characteristics of those SSCs that contribute to limiting the total effective dose equivalent to individual members of the public during normal operations and prevent or mitigate the consequences of event sequences.

Early site permit (ESP) means a Commission approval, issued under subpart H of this part, for a site for one or more commercial nuclear plants. An early site permit is a partial construction permit.

Electric utility means any entity that generates or distributes electricity and that recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities, including generation or distribution subsidiaries, public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of “electric utility.”

Event sequence means a postulated initiating event defined for a set of initial plant conditions followed by system, safety function, and operator successes or failures, and terminating in a specified end state depending on the system, safety function, and operator successes and failures (e.g., prevention of release of radioactive material or release in one of the reactor-specific release categories). An event sequence may include many unique variations of events that are similar in terms of results or end states.

Exclusion area means that area surrounding the reactor, in which the reactor licensee has the authority to determine all activities including exclusion or removal of personnel and property from the area. This area may be traversed by a highway, railroad, or waterway, provided these are not so close to the facility as to interfere with normal operations of the facility and provided appropriate and effective arrangements are made to control traffic on the highway, railroad, or waterway, in case of emergency, to protect the public health and safety. Residence within the exclusion area must normally be prohibited. In any event, residents must be subject to ready removal in case of necessity. Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.

Fission product release means the amount and composition of radioactive material released to the environment, after accounting for any retention of radionuclides provided by reactor design features.

Fuel means special nuclear material (SNM) or source material, discrete elements that physically contain SNM or source material, and homogeneous mixtures that contain SNM or source material, intended to or used to create power in a commercial nuclear plant.

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.

License, when used in the context of a facility, means a limited work authorization, CP, OL, early site permit, COL, or ML under this part, or a renewed license issued by the Commission under this part. When used in the context of a license authorizing an individual to manipulate the controls of a facility, *license* means a license

issued by the Commission to perform the function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

Licensee means a person who is authorized to conduct activities under a license issued under this part by the Commission.

Licensing-basis events means a collection of event sequences considered in the design and licensing of the commercial nuclear plant. Licensing-basis events are unplanned events and include anticipated event sequences, unlikely event sequences, very unlikely event sequences, and DBAs.

Licensing-basis information means the information contained in regulations, orders, licenses, certifications, or approvals issued by the NRC for a commercial nuclear plant licensed under this part and that information submitted to the NRC by an applicant or licensee in a Safety Analysis Report, program description, or other licensing-related document required under this part.

Low-population zone means the area immediately surrounding the exclusion area which contains residents, the total number and density of which are such that there is a reasonable probability that appropriate protective measures could be taken on their behalf in the event of a serious accident. A permissible population density or total population within this zone is not included in this definition because the situation may vary from case to case. Whether a specific number of people can, for example, be evacuated from a specific area or instructed to take shelter on a timely basis, will depend on many factors such as location, number and size of highways, scope and extent of advance planning, and actual distribution of residents within the area.

Major decommissioning activity means, for a commercial nuclear plant, any activity that results in permanent removal of major radioactive components, permanently modifies the structure of the containment, if applicable, or results in dismantling

components for shipment containing greater than class C waste in accordance with § 61.55 of this chapter.

Major feature of the emergency plans means an aspect of those plans necessary to:

(1) Address in whole or part either one or more of the 16 standards in 10 CFR 50.47(b) or the requirements of 10 CFR 50.160(b), as applicable; or

(2) Describe the emergency planning zones as required in 10 CFR 53.1109(g).

Manufactured reactor means the essential portions of a nuclear reactor that are manufactured under an ML and subsequently transported and incorporated into a commercial nuclear plant under a COL or CP.

Manufacturing license means a license issued under this part that authorizes the manufacture of manufactured reactors but not its construction, installation, or operation.

Non-Safety-Related but Safety-Significant (NSRSS) SSCs means those SSCs which are not SR but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment.

Non-Safety-Significant SSCs means those SSCs that are not SR or NSRSS, are not relied on to achieve adequate defense in depth or to perform risk-significant functions, and do not warrant special treatment.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, government agency other than the Commission or the Department of Energy, except that the Department of Energy shall be considered a person to the extent that its facilities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974, any State or any political subdivision of, or any political entity within a State, any

foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Population center distance means the distance from the reactor to the nearest boundary of a densely populated center containing more than about 25,000 residents.

Programmatic controls means administrative measures that govern human action in implementing programs and operating, monitoring, and maintaining SSCs and equipment of a commercial nuclear plant. Programmatic controls considered to be licensing basis information are addressed by programs under § 53.845 and are specified in an application for a requested activity of the Commission.

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 control the quality of the material, structure, component, or system to predetermined requirements.

Safety criteria means performance-based metrics that establish a level of safety provided in requirements in §§ 53.210 and 53.220.

Safety-related structures, systems, or components means those SSCs that are relied upon to demonstrate compliance with the safety criteria in § 53.210 and warrant special treatment.

Small modular reactor means a power reactor, which may be of modular design as defined in § 52.1 of this chapter, licensed under this part to produce heat energy up to 1,000 megawatts thermal per module.

Site characteristics means the actual physical, environmental, and demographic features of a site. Site characteristics are specified in an early site permit or in a

Preliminary or Final Safety Analysis Report for a limited work authorization, CP, or COL, as applicable.

Site parameters are the postulated physical, environmental, and demographic features of an assumed site. Site parameters are specified in a standard design approval, standard design certification, or ML.

Source material means source material as defined in subsection 11z. of the Atomic Energy Act of 1954, as amended, (the Act) and in the regulations contained in part 40 of this chapter.

Special nuclear material (SNM) means:

(1) Plutonium, uranium-233, uranium enriched in the isotope-233 or in the isotope-235, and any other material which the Commission, pursuant to the provisions of section 51 of the Act, determines to be SNM, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing, but does not include source material.

Special treatment means those requirements, such as QA, design criteria, and programmatic controls, that are taken beyond the procurement, installation, and maintenance of commercial grade products to ensure that SR and NSRSS SSCs will provide defense in depth or perform risk-significant functions. The requirements also ensure that the SSCs will perform under the service conditions and with the reliability assumed in the analysis performed under § 53.450 to demonstrate compliance with the safety criteria in §§ 53.210 for SR SSCs and 53.220 for SR and NSRSS SSCs.

Standard design means a design which is sufficiently detailed and complete to support certification or approval in accordance with subpart H of this part, and which is usable under of this part for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

Standard design approval or design approval means an NRC staff approval, issued under subpart H of this part, of a final standard design for a commercial nuclear plant. The approval may be for either the final design for the entire reactor facility or the final design of major portions thereof.

Standard design certification or design certification means a Commission approval, issued under subpart H of this part, of a final standard design for a nuclear power facility. This design may be referred to as a certified standard design.

Total effective dose equivalent means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Utilization facility means any commercial nuclear reactor other than one designed or used primarily for the formation of plutonium or uranium–233.

Unlikely event sequences means event sequences that are not expected to occur in the life of a commercial nuclear plant and are less likely than anticipated event sequences, but are infrequent rather than rare. Unlikely event sequences take into account the expected response of all SSCs within the plant regardless of safety classification.

Very unlikely event sequences means event sequences that are not expected to occur in the life of a commercial nuclear plant, are less likely than an unlikely event sequence, and are rare. Very unlikely event sequences take into account the expected response of all SSCs within the plant regardless of safety classification.

§ 53.030 [Reserved]

§ 53.040 Written communications.

(a) *General requirements.* All correspondence, reports, applications, and other written communications from the applicant or licensee to the NRC concerning the regulations in this part or individual license conditions must be sent either by mail

addressed: ATTN: Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 8:15 a.m. and 4 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's website at *https://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. If the communication is on paper, the signed original must be sent. If a submission due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions, or the terms and conditions of an early site permit or standard design approval, must be submitted to the persons listed below (addresses for the NRC Regional Offices are listed in appendix D to 10 CFR part 20).

(1) *Applications for amendment of permits and licenses, reports, and other communications.* All written communications (including responses to generic letters, bulletins, information notices, regulatory information summaries, inspection reports, and miscellaneous requests for additional information) that are required of holders of licenses, permits, and design approvals issued pursuant to this part, must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (7) of this section:

to the NRC's Document Control Desk (if on paper, the signed original), with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part.

(2) *Applications for permits and licenses, and amendments to applications.* Applications for licenses, permits, and design approvals and amendments to any of these types of applications 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 facility or the place of manufacture of a reactor licensed under this part, except as otherwise specified in paragraphs (b)(3) through (9) of this section. If the application or amendment is on paper, the submission to the Document Control Desk must be the signed original.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

(4) *Security plan and related submissions.* Written communications, as defined in paragraphs (b)(4)(i) through (v) of this section, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office. If the communication is on paper, the submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Physical security plan;

(ii) Safeguards contingency plan;

(iii) Cybersecurity plan;

(iv) Change to security plan, guard training and qualification plan, safeguards contingency plan, or cybersecurity plan made without prior Commission approval under § 53.1565; and

(v) Application for amendment of physical security plan, guard training and qualification plan, safeguards contingency plan, or cybersecurity plan under § 53.1510.

(5) *Emergency plan and related submissions.* Written communications as defined in paragraphs (b)(5)(i) through (iii) of this section 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 submission to the Document Control Desk must be the signed original. Submissions should include the following as appropriate:

(i) Emergency plan;

(ii) Change to an emergency plan under § 53.1565; and

(iii) Emergency implementing procedures under § 53.855.

(6) *Updated Final Safety Analysis Report.* An updated Final Safety Analysis Report or replacement pages under § 53.1545 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. Paper copy submissions may be made using replacement pages; however, if a licensee chooses to use electronic submission, all subsequent updates or submissions must be performed electronically on a total replacement basis. If the communication is on paper, the submission to the Document Control Desk must be the signed original. If the communications are submitted electronically, see Guidance for Electronic Submissions to the Commission.

(7) *Quality assurance related submissions.*

(i) A change to the Safety Analysis Report QA program description under § 53.1565, or a change to a licensee's NRC-accepted QA 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.

(ii) A change to an NRC-accepted QA 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.

(8) *Certification of permanent cessation of operations.* The licensee's certification of permanent cessation of operations, under subpart G of this part, must state the date on which operations have ceased or will cease, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(9) *Certification of permanent fuel removal.* The licensee's certification of permanent fuel removal, under subpart G of this part, must state the date on which the fuel was removed from the reactor vessel and the disposition of the fuel, and must be submitted to the NRC's Document Control Desk. This submission must be under oath or affirmation.

(c) *Form of communications.* All paper copies submitted to demonstrate compliance with the requirements set forth in paragraph (b) of this section must be typewritten, printed, or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements imposed on paper submissions may be granted for the submission of micrographic, photographic, or similar forms.

(d) *Regulation governing submission.* Licensees, applicants, and holders of standard design approvals submitting correspondence, reports, and other written communications under the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submission, the specific regulation or other basis requiring submission.

§ 53.050 Deliberate misconduct.

(a) Any licensee or applicant for a license; holder of or applicant for a standard design approval; applicant for a standard design certification; employee of a licensee, holder of a standard design approval, or applicant for a license, standard design approval, or standard design certification; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or applicant for a license, holder of or applicant for a standard design approval, or applicant for a standard design certification, who knowingly provides to any licensee, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities in this part, may not—

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, an applicant, or a licensee's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (2) of this section may be subject to enforcement action in accordance with the procedures in subpart B of 10 CFR part 2.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows—

(1) Would cause a licensee or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

§ 53.060 Employee protection.

(a) Discrimination by a Commission licensee, holder of a standard design approval, an applicant for a license, standard design certification, or standard design approval, a contractor or subcontractor of a Commission licensee, holder of a standard design approval, applicant for a license, standard design certification, or standard design approval, against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Act or the Energy Reorganization Act of 1974, as amended.

(1) The protected activities include but are not limited to—

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) of this section or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the NRC to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) of this section; and

(v) Assisting or participating in, or being about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Act.

(b) Any employee who believes that they have been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraph (a), (e), or (f) of this section by a Commission licensee, a holder of a standard design approval, an applicant for a Commission license, standard design certification, or a standard design approval, or a contractor or subcontractor of a Commission licensee, holder of a standard design approval, or any applicant may be grounds for—

(1) Denial, revocation, or suspension of the license or standard design approval;

(2) Withdrawal or revocation of a proposed or final standard design certification;

(3) Imposition of a civil penalty on the licensee, holder of a standard design approval, or applicant (including an applicant for a standard design certification under this part following Commission adoption of final design certification rule) or a contractor or subcontractor of the licensee, holder of a standard design approval, or applicant; or

(4) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each holder or applicant for a license or design approval, must prominently post the revision of NRC Form 3, “Notice to Employees,” referenced in § 19.11(e)(1) of this chapter. This form must be posted at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted no later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(2) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate NRC Regional Office listed in appendix D to 10 CFR part 20, via email to Forms.Resour*ce@nrc.gov*, or by visiting the NRC's online library at *https://www.nrc.gov/reading-rm/doc-collections/forms/.*

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise

discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section, including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

(g) Part 19 of 10 CFR sets forth requirements and regulatory provisions applicable to licensees, holders of a standard design approval, applicants for a license, standard design certification, or standard design approval, and contractors or subcontractors of a Commission licensee, or holder of a standard design approval, and are in addition to the requirements in this section.

§ 53.070 Completeness and accuracy of information.

(a) Information provided to the Commission by a holder of a license, permit, design certification, or standard design approval under this part or an applicant for a license, permit, design certification, or standard design approval under this part, and information required by statute or by the Commission's regulations, orders, license conditions, or terms and conditions of a standard design approval to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

(b) Each applicant or licensee, each holder of a standard design approval under this part, and each applicant for a standard design certification under this part following Commission adoption of a final design certification regulation, must notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant, licensee, or holder violates this paragraph (b) only if the applicant, licensee, or holder fails to notify the Commission of information that the applicant, licensee, or holder has identified as having a significant implication for public health and safety or common defense and security. Notification must be provided to the Administrator of the appropriate Regional Office within 2 working days of identifying the

information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

§ 53.080 Specific exemptions.

(a) The Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of the regulations of this part, which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security.

(b) The Commission will not consider granting an exemption unless special circumstances are present. Special circumstances are present whenever—

(1) Application of the regulation in the particular circumstances conflicts with other rules or requirements of the Commission;

(2) Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule;

(3) Compliance would result in undue hardship or other costs that are significantly in excess of those contemplated when the regulation was adopted, or that are significantly in excess of those incurred by others similarly situated;

(4) The exemption would result in benefit to the public health and safety that compensates for any decrease in safety that may result from the grant of the exemption;

(5) The exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply with the regulation; or

(6) There is present any other material circumstance not considered when the regulation was adopted for which it would be in the public interest to grant an exemption. If such condition is relied on exclusively for demonstrating compliance with paragraph (b)

of this section, the exemption may not be granted until the Executive Director for Operations has consulted with the Commission.

(c) Any person may request an exemption permitting the conduct of construction activities prior to the issuance of a CP. The Commission may grant such an exemption upon considering and balancing the following factors:

(1) Whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any;

(2) Whether redress of any adverse environment impact from conduct of the proposed activities can reasonably be effective should such redress be necessary;

(3) Whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and

(4) The effect of delay in conducting such activities on the public interest, including whether the power needs to be used by the proposed facility, the availability of alternative sources, if any, to meet those needs on a timely basis, and delay costs to the applicant and to consumers.

(d) Issuance of such an exemption must not be deemed to constitute a commitment to issue a CP. During the period of any exemption granted pursuant to paragraph (c) of this section, any activities conducted must be carried out in such a manner as will minimize or reduce their environmental impact.

(e) The Commission's consideration of requests for exemptions from requirements of the regulations of other parts in this chapter that are applicable by virtue of this part must be governed by the exemption requirements of those parts.

§ 53.090 Standards for review.

(a) *Common standards*. In determining that a CP, OL, early site permit, COL, or ML under this part will be issued to an applicant, the Commission will be guided by the following considerations:

(1) Except for an early site permit or ML, the processes to be performed, the operating procedures, the facility and equipment, the use of the facility, and other technical specifications, or the proposals, in regard to any of the foregoing, collectively provide reasonable assurance that the applicant will comply with the regulations in this chapter, including the regulations in 10 CFR part 20, and that the health and safety of the public will not be endangered.

(2) The applicant for a CP, OL, COL, or ML is technically and financially qualified to engage in the proposed activities in accordance with the regulations in this chapter. However, no consideration of financial qualification is necessary for an electric utility applicant for an OL for a utilization facility of the type described in paragraph (d) of this section or for an applicant for an ML.

(3) The issuance of a CP, OL, early site permit, COL, or ML to the applicant will not, in the opinion of the Commission, be inimical to the common defense and security or to the health and safety of the public.

(4) Any applicable requirements of 10 CFR part 51 have been satisfied.

(b) *Additional standards for licenses*. In determining whether a license will be issued to an applicant, the Commission will, in addition to applying the standards set forth in paragraph (a) of this section, consider whether the proposed activities will serve a useful purpose proportionate to the quantities of SNM or source material to be utilized.

(c) *Additional standards and provisions affecting licenses for commercial power*. In addition to applying the standards set forth in paragraphs (a) and (b) of this section, paragraphs (c)(1) through (c)(4) of this section apply in the case of a license for a facility for the generation of commercial power.

(1) The NRC will—

(i) Give notice in writing of each application to the regulatory agency or State as may have jurisdiction over the rates and services incident to the proposed activity;

(ii) Publish notice of the application in trade or news publications as it deems appropriate to give reasonable notice to municipalities, private utilities, public bodies, and cooperatives which might have a potential interest in the utilization or production facility; and

(iii) Publish notice of the application once each week for four consecutive weeks in the *Federal Register*. No license will be issued by the NRC prior to the giving of these notices and until four weeks after the last notice is published in the *Federal Register*.

(2) If there are conflicting applications for a limited opportunity for such license, the Commission will give preferred consideration in the following order: first, to applications submitted by public or cooperative bodies for facilities to be located in high cost power areas in the United States; second, to applications submitted by others for facilities to be located in such areas; third, to applications submitted by public or cooperative bodies for facilities to be located in areas other than high cost power areas; and, fourth, to all other applicants.

(3) The licensee who transmits electric energy in interstate commerce, or sells it at wholesale in interstate commerce, must be subject to the regulatory provisions of the Federal Power Act.

(4) Nothing will preclude any government agency, now or hereafter authorized by law to engage in the production, marketing, or distribution of electric energy, if otherwise qualified, from obtaining a CP, OL, or COL under this part for a utilization facility for the primary purpose of producing electric energy for disposition for ultimate public consumption.

(d) *Licenses for commercial nuclear plants*. A license will be issued, to an applicant who qualifies, for any one or more of the following: to transfer or receive in interstate commerce, or manufacture, produce, transfer, acquire, possess, or use a utilization facility for industrial or commercial purposes.

§ 53.100 Jurisdictional limits.

No permit, license, standard design approval, or standard design certification under this part shall be deemed to have been issued for activities that are not under or within the jurisdiction of the United States.

§ 53.110 Attacks and destructive acts.

Licensees, applicants for licenses, permits, certifications, and design approvals, and applicants for an amendment to any license, permit, certification, or design approval under this part are not required to provide for design features or other measures for the specific purpose of protection against the effects of—

(a) Attacks and destructive acts, including sabotage, directed against the facility by an enemy of the United States, whether a foreign government or other person; or

(b) Use or deployment of weapons incident to U.S. defense activities.

§ 53.115 Rights related to special nuclear material.

(a) No right to the SNM will be conferred by a license issued under this part except as may be defined by the license.

(b) Neither a license issued under this part, nor any right thereunder, nor any right to utilize or produce SNM may be transferred, assigned, or disposed of in any manner, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission, after securing full information, finds that the transfer is in accordance with the provisions of the Act and gives its consent in writing.

§ 53.117 License suspension and rights of recapture.

Any license issued under this part must be subject to suspension and to the rights of recapture of the material or control of the facility reserved to the Commission under section 108 of the Act in a state of war or national emergency declared by Congress.

§ 53.120 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0274.

(b) The approved information collection requirements contained in this part appear in §§ 53.070, 53.080, 53.240, 53.410, 53.420, 53.425, 53.430, 53.440, 53.450, 53.480, 53.500, 53.540, 53.605, 53.610, 53.620, 53.700, 53.710, 53.715, 53.720, 53.730, 53.780, 53.785, 53.805, 53.810, 53.815, 53.830, 53.850, 53.855, 53.865, 53.870, 53.875, 53.880, 53.910, 53.1010, 53.1020, 53.1030, 53.1045, 53.1060, 53.1070, 53.1075, 53.1080, 53.1100, 53.1109, 53.1115, 53.1130, 53.1140, 53.1144, 53.1146, 53.1173, 53. 1182, 53.1188, 53.1200, 53.1206, 53.1209, 53.1210, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1254, 53.1257, 53,1263, 53.1270, 53.1276, 53.1279, 53.1282, 53.1288, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1327, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1384, 53.1410, 53.1413, 53.1416, 53.1419, 53.1437, 53.1449, 53.1452, 53.1458, 53.1470, 53.1505, 53.1510, 53.1515, 53.1525, 53.1530, 53.1535, 53.1540, 53.1545, 53.1550, 53.1560, 53.1565, 53.1570, 53.1575, 53.1580, 53.1620, 53.1630, 53.1645, 53.1690, 53.1720.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. The information collection requirement and the control numbers under which it is approved are as follows:

(1) In §§ 53.765, 53.770, 53.780, and 53.795, NRC Form 396 is approved under control number 3150-0024.

(2) In §§ 53.775 and 53.795, NRC Form 398 is approved under control number 3150-0090.

(3) In § 53.1640, NRC Form 366 is approved under control number 3150-0104.

(4) In § 53.1630, NRC Form 361S is approved under control number 3150-0238.

(5) In § 53.1650, International Atomic Energy Agency Design Information Questionnaire forms are approved under control number 3150–0056.

(6) In § 53.1650, DOC/NRC Form AP–A and associated forms are approved under control numbers 0694–0135.

Subpart B—Technology-Inclusive Safety Requirements

§ 53.210 Safety criteria for design-basis accidents.

Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and analyses of design-basis accidents (DBAs) in accordance with § 53.240 demonstrate the following:

(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 (250 millisieverts) 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 (250 millisieverts) TEDE.[1]

[1] The use of 25 rem 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.

§ 53.220 Safety criteria for licensing-basis events other than design-basis accidents.

Design features and programmatic controls must be provided for each commercial nuclear plant such that identification and analysis of licensing-basis events (LBEs) other than DBAs in accordance with § 53.240 demonstrate the following:

(a) Plant structures, systems, and components (SSCs), personnel, and programs provide the necessary capabilities and maintain the necessary reliability to address LBEs other than DBAs in accordance with §§ 53.240 and 53.450(e), and provide measures for defense in depth in accordance with § 53.250; and

(b) The analysis of risks to public health and safety resulting from LBEs other than DBAs under § 53.450(e) includes comprehensive risk metrics that satisfy associated risk performance objectives that are acceptable to the U.S. Nuclear Regulatory Commission (NRC) and provide an appropriate level of safety.

§ 53.230 Safety functions.

(a) The primary safety function is limiting the release of radioactive materials from the facility and must be maintained during normal operation and for LBEs over the life of the plant.

(b) Additional safety functions needed to support the retention of radioactive materials during LBEs—such as controlling reactivity, heat generation, heat removal, and chemical interactions—must be identified for each commercial nuclear plant.

(c) The primary and additional safety functions are required to satisfy the safety criteria defined in §§ 53.210 and 53.220 and must be fulfilled by the design features, human actions, and programmatic controls specified throughout this part.

§ 53.240 Licensing-basis events.

(a) Licensing-basis events must be identified for each commercial nuclear plant and analyzed under § 53.450 to demonstrate that the safety requirements in this subpart have been satisfied.

(b) The identified LBEs, ranging from anticipated event sequences to very unlikely event sequences, must collectively address appropriate risk-informed combinations of malfunctions of plant SSCs, human errors, facility hazards, and the effects of external hazards.

(c) The analysis of LBEs must—

(1) Include analysis of one or more DBAs under § 53.450(f);

(2) Confirm the adequacy of design features and programmatic controls needed to satisfy the safety criteria defined in §§ 53.210 and 53.220, and

(3) Establish related functional requirements for plant SSCs, personnel, and programs.

§ 53.250 Defense in depth.

(a) Measures must be taken for each commercial nuclear plant to ensure appropriate defense in depth is provided to compensate for uncertainties in the analysis of the safety criteria such that there is reasonable assurance that the safety criteria in this subpart are met over the life of the plant.

(b) The uncertainties that must be addressed under paragraph (a) of this section include those related to the state of knowledge and modeling capabilities, the ability of barriers to limit the release of radioactive materials from the facility during LBEs other than DBAs, the reliability and performance of plant SSCs and personnel, and the effectiveness of programmatic controls.

(c) The safety analysis may not exclusively rely upon a single engineered design feature, human action, or programmatic control, no matter how robust, to address the range of LBEs other than DBAs.

§ 53.260 Normal operations.

Holders of licenses to operate commercial nuclear plants under this part must control public doses and dose rates in unrestricted areas from normal plant operations to meet the requirements in 10 CFR part 20.

§ 53.270 Protection of plant workers.

Holders of licenses to operate commercial nuclear plants under this part must control occupational doses to meet the requirements in 10 CFR part 20.

Subpart C—Design and Analysis Requirements

§ 53.400 Design features for licensing-basis events.

(a) Design features must be provided for each commercial nuclear plant such that, when combined with corresponding human actions and programmatic controls, the plant will satisfy the safety criteria defined in §§ 53.210 and 53.220.

(b) Design features must ensure that the safety functions identified in § 53.230 are fulfilled during licensing-basis events (LBEs).

§ 53.410 Functional design criteria for design-basis accidents.

(a) Functional design criteria must be defined for each design feature classified as safety-related (SR) in terms of its role in demonstrating compliance with the safety criteria defined in § 53.210.

(b) The identification of special treatments associated with the design of SR structures, systems, and components (SSCs) must consider human actions and programmatic controls identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to satisfy the defined functional design criteria and the safety criteria required in § 53.210, and to maintain consistency with analyses required by § 53.450(f).

§ 53.415 Protection against external hazards.

Safety-related SSCs must be protected against or must be designed to withstand the effects of natural phenomena (e.g., earthquakes, tornadoes, hurricanes, floods, tsunami, and seiches) and constructed hazards (e.g., dams, transportation routes, military and industrial facilities) considering an event severity up to the design-basis external hazard levels as determined under § 53.510 without losing the capability to perform the safety functions identified under § 53.230. Specific requirements for earthquake engineering are included in § 53.480.

§ 53.420 Functional design criteria for licensing-basis events other than design-basis accidents.

(a) Functional design criteria must be defined for each design feature classified as SR or non-safety-related but safety-significant (NSRSS) in terms of its role in demonstrating compliance with—

(1) The safety criteria in § 53.220; and

(2) The evaluation criteria in § 53.450(e).

(b) The identification of special treatments associated with the design of SR and NSRSS SSCs must consider human actions and programmatic controls identified and implemented in accordance with this and other subparts to achieve and maintain the reliability and capability of SSCs relied upon to satisfy—

(1) The safety criteria in § 53.220; and

(2) The evaluation criteria in § 53.450(e).

§ 53.425 Design features and functional design criteria for normal operations.

(a) Design features must be provided for each commercial nuclear plant to support the Radiation Protection Program required in § 53.850.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.850.

(c) Functional design criteria, including design objectives for dose to the maximally exposed member of the public, must be defined for design features to show that plant design features and corresponding programmatic controls, including monitoring programs, control liquid, gaseous, and solid wastes, as required under part 20 of this chapter.

§ 53.430 Design features and functional design criteria for protection of plant workers.

(a) Design features must be provided for each commercial nuclear plant such that, when combined with corresponding programmatic controls, the requirements in § 53.270 can be met.

(b) Functional design criteria must be defined for each design feature relied upon to demonstrate compliance with § 53.270.

§ 53.440 Design requirements.

(a)(1) Analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof must demonstrate that each design feature required by § 53.400 meets the defined functional design criteria required by §§ 53.410 and 53.420. This demonstration must consider interdependent effects throughout the commercial nuclear plant and the range of conditions under which the design features required by § 53.400 must function throughout the plant's lifetime.

(2) The design processes for SR and NSRSS SSCs under this part must include administrative procedures for evaluating operating, design, and construction experience and for considering applicable important industry experiences in the design of those SSCs.

(b) The design features classified as SR must, wherever applicable, be designed using generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the U.S. Nuclear Regulatory Commission (NRC).

(c) The materials used for each SR and NSRSS SSC must be qualified for their service conditions over the design life of the SSC as appropriate to satisfy the special treatments established for the SSC under § 53.460.

(d) Possible degradation mechanisms related to aging, fatigue, chemical interactions, operating temperatures, effects of irradiation, and other environmental factors that may affect the performance of SR and NSRSS SSCs must be evaluated and used to inform the design and the development of integrity assessment programs under § 53.870.

(e)(1) Safety-related SSCs and, where appropriate, NSRSS SSCs must be designed and located to minimize, consistent with other safety requirements in this part, the probability and effect of fires and explosions.

(2) Noncombustible and fire-resistant materials must be used wherever practical throughout the facility, particularly in locations with SR and NSRSS SSCs.

(3) Fire detection and fire suppression systems of appropriate capacity and capability must be provided and designed to minimize the adverse effects of fires on SR and NSRSS SSCs.

(4) Fire suppression systems must be designed to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS SSCs to perform their safety functions to satisfy § 53.230.

(f) Safety and security must be considered together in the design process such that, where possible, security issues are effectively resolved through design and engineered security features.

(g) The reactor system and waste stores for each commercial nuclear plant must be capable of achieving and maintaining a subcritical condition during normal operations and following any LBE identified in accordance with § 53.240.

(h) Each commercial nuclear plant must have a capability to provide long-term cooling of the reactor fuel and waste stores during normal operations and following any LBE identified in accordance with § 53.240.

(i) The design, analysis, staffing, and programmatic controls for each commercial nuclear plant must consider the number of reactors, waste stores, and other significant inventories of radioactive materials and the associated operating configurations, common systems, system interfaces, and system interactions.

(j) [Reserved]

(k) Design features, related functional design criteria, programmatic controls, or a combination thereof must be defined such that analyses demonstrate a low risk of permanent injury to the public due to the health effects of the chemical hazards of licensed material.

(l) Measures must be taken during the design of commercial nuclear plants to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste in accordance with § 20.1406 of this chapter.

(m)(1) Each commercial nuclear plant must include criticality monitoring capabilities meeting the requirements of either § 70.24 of this chapter or paragraph (m)(2) of this section.

(2) In lieu of maintaining a monitoring system capable of detecting criticality as described in § 70.24 of this chapter, criticality accident requirements may be satisfied by—

(i) Demonstrating the sub-criticality of special nuclear material, except when it is inside the reactor and the reactor is being operated, by maintaining k-effective below 0.95 at a 95 percent probability, 95 percent confidence level, under conditions that maximize reactivity for the applicable storage and handling configurations, and

(ii) Providing radiation monitors for fuel storage and associated handling areas when fuel is present to detect excessive radiation levels and to support initiating appropriate safety actions.

(3) While a spent fuel transportation package approved under 10 CFR part 71 of this chapter or spent fuel storage cask approved under 10 CFR part 72 is in the special nuclear material handing or storage area, the requirements in 10 CFR parts 71 or 72, as applicable, and the requirements of the certificate of compliance for that package or cask, are the applicable requirements for the fuel within that package or cask.

(n)(1) The design of each commercial nuclear plant must reflect state-of-the-art human factors principles for safe and reliable performance in all locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

(2) The design must provide for the capabilities described in § 53.730(b) to ensure the plant staff are able to monitor plant conditions and respond to events.

(3) The means by which the design and human actions together will achieve the safety requirements of subpart B of this part must be evaluated and used to inform the design and the development of the concept of operations required by § 53.730(c).

(4) A functional requirements analysis and function allocation must be used to ensure that plant design features address how safety functions and functional safety criteria are satisfied, and how the safety functions will be assigned to appropriate combinations of human action, automation, active safety features, passive safety features, or inherent safety characteristics.

§ 53.450 Analysis requirements.

(a) *Requirement to have a probabilistic risk assessment (PRA), or other systematic risk evaluations (SREs), or a combination thereof.* A PRA, other SREs, or a combination thereof for each commercial nuclear plant must be performed and used

together with other generally accepted approaches for systematically evaluating engineered systems to identify potential failures, susceptibility to internal and external hazards, and other contributing factors to event sequences that might challenge the safety functions identified in § 53.230 and to support demonstrating that each commercial nuclear plant meets the safety criteria of § 53.220.

(b) *Specific uses of analyses*. The PRA, other SREs, or a combination thereof, together with other generally accepted approaches for systematically evaluating engineered systems must be used to—

(1) Inform the selection of the LBEs, as described in § 53.240, which must be considered in the design to determine compliance with the safety criteria in subpart B of this part.

(2) Inform the classification of SSCs according to their safety significance in accordance with § 53.460 and to identify the environmental conditions under which the SSCs and operating staff must perform their safety functions.

(3) Evaluate the adequacy of defense-in-depth measures required in accordance with § 53.250.

(4) Identify and assess all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment.

(5) Identify and assess events that challenge plant control and safety systems whose failure could lead to the uncontrolled release of radioactive material to the environment. These include internal events, such as human errors and equipment failures, and external events identified in accordance with subpart D of this part.

(6) Inform the establishment and updating of appropriate measures for plant operations, including availability controls, to ensure that the configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities, availability, and

reliability consistent with satisfying the safety criteria under §§ 53.220 and the analyses of licensing-basis events other than design-basis accidents (DBAs) under § 53.450(e).

(c) *Maintenance and upgrade of analyses*. The PRA, other SREs, or a combination thereof must be maintained (e.g., updated to reflect plant changes such as modifications, procedure changes, or plant performance data) at least every 5 years until the permanent cessation of operations under § 53.1070 and upgraded (e.g., changed in scope or use of new methods) in conformance with generally accepted methods, standards, and practices that have been endorsed or otherwise found acceptable by the NRC.

(d) *Qualification of analytical codes*. The analytical codes used in modeling the physical behavior of plant systems in the analyses of licensing-basis events (including but not limited to thermodynamics, reactor physics, fuel performance, and mechanistic source term codes) must be qualified for the range of conditions for which they are to be used.

(e) *Analyses of licensing-basis events other than design-basis accidents*.

(1) Analyses must be performed for LBEs other than design-basis accidents (DBAs). These LBEs must be identified using insights from a PRA, other SREs, or a combination thereof with other generally accepted approaches for systematically evaluating engineered systems to identify and analyze equipment failures and human errors.

(2) The analysis of LBEs other than DBAs must include definitions of evaluation criteria for each event or specific categories of LBEs to determine the acceptability of the plant response to the challenges posed by internal and external hazards to provide an appropriate level of safety.

(3) The analyses of LBEs other than DBAs must address event sequences from initiation to a defined end state and be used in combination with other engineering

analyses to demonstrate that the functional design criteria required by § 53.420 provide sufficient barriers to the unplanned release of radionuclides to satisfy the evaluation criteria defined for each LBE other than DBAs, to satisfy the safety criteria specified in accordance with § 53.220 and provide defense in depth as required by § 53.250.

(4) The methodology used to identify, categorize, and analyze LBEs must include a means to identify event sequences deemed significant for controlling the risks posed to public health and safety.

(f) *Analysis of design-basis accidents*.

(1) The analysis of LBEs required by § 53.240 must include analysis of DBAs that address possible challenges to the safety functions identified under § 53.230. The events selected as DBAs must be those that, if not terminated, have the potential for exceeding the safety criteria in § 53.210.

(2) The DBAs selected must be analyzed using deterministic methods that address event sequences from initiation to a safe stable end state and assume only the SR SSCs identified under § 53.460 and human actions addressed by the requirements of subpart F of this part are available to perform the safety functions identified in accordance with § 53.230.

(3) The analysis must conservatively demonstrate compliance with the safety criteria in § 53.210.

(g) *Other required analyses*. Analyses must be performed to assess—

(1) *Fire protection.* Fire protection measures to demonstrate, through inclusion of fires in the analysis of LBEs or by separate analyses, that a fire or explosion in any plant area would not—

(i) Prevent equipment from fulfilling the safety functions identified in accordance with § 53.230, or

(ii) Challenge the safety criteria in §§ 53.210 and 53.220.

(2) [Reserved]

(3) *Dose to members of the public.* Measures taken under § 53.425, including estimating—

(i) The quantity of each of the principal radionuclides expected to be released annually to unrestricted areas in liquid effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(ii) The quantities of each of the principal radionuclides of the gases, halides, and particulates expected to be released annually to unrestricted areas in gaseous effluents produced during normal reactor operations and the dose to the maximally exposed member of the public in unrestricted areas.

(iii) The annual external radiation dose in unrestricted areas and the maximally exposed member of the public in unrestricted areas due to direct radiation from contained radiation sources from the commercial nuclear plant during normal reactor operations.

§ 53.460 Safety categorization and special treatments.

(a) Structures, systems, and components must be classified according to their safety significance. The SSC categories must include “Safety-Related,” “Non-Safety-Related but Safety-Significant,” and “Non-Safety-Significant,” as defined in subpart A of this part.

(b) For SR and NSRSS SSCs, the conditions under which they must perform their safety function in § 53.230 must be identified. Special treatments must be established in accordance with this and other subparts to provide confidence that the SSCs will perform under the service conditions and with reliability consistent with the analysis performed under § 53.450 to demonstrate meeting the safety criteria in §§ 53.210 and 53.220.

(1) The special treatments for SR SSCs must include meeting the applicable quality assurance requirements from appendix B 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 when such treatment is needed to address performance requirements, equipment reliability, or uncertainties.

(c) The identification of special treatments for SR and NSRSS SSCs must account for human actions needed to prevent or mitigate LBEs, the need to perform such actions reliably under the postulated environmental conditions, and the role of programs established in accordance with subpart F of this part to provide confidence that those actions will be performed as assumed in the analysis performed in accordance with § 53.450 to demonstrate meeting the applicable criteria in §§ 53.210, 53.220, and 53.450(e).

§ 53.470 [Reserved]

§ 53.480 Earthquake engineering.

(a) *Effects of earthquakes.* Structures, systems, and components classified as SR or NSRSS must be able to withstand the effects of earthquakes, commensurate with the safety significance of the SSC, without loss of capability to perform their role in fulfilling the safety functions required by § 53.230.

(b) *Definitions.* As used in this section—

Design-Basis Ground Motions (DBGMs) are the vibratory ground motions for which certain SSCs must be designed to remain functional.

Operating basis earthquake (OBE) ground motion is the vibratory ground motion for which those features of the commercial nuclear plant necessary for continued

operation without undue risk to the health and safety of the public are designed to remain functional. The OBE ground motion is used in § 53.720.

Response spectrum is a plot of the maximum responses (acceleration, velocity, or displacement) of idealized single-degree-of-freedom oscillators as a function of the natural frequencies of the oscillators for a given damping value. The response spectrum is calculated for a specified vibratory motion input at the oscillators' supports.

Surface deformation is the distortion of geologic strata on or near the ground surface that occurs because of tectonic forces that result from earthquakes.

(c) *Design considerations.*

(1) *Design-Basis Ground Motions.*

(i) The DBGMs must be derived from the Site Ground Motion Response Spectra developed in accordance with § 53.510(c), by taking into consideration the functional design criteria of SSCs in accordance with §§ 53.410 and 53.420. The horizontal component of the DBGM(s) in the free-field at the foundation level of the structures must be an appropriate response spectrum that is determined based on the risk-significance of SSCs and their safety functions. In view of the limited data available on vibratory ground motion of strong earthquakes, it is acceptable that the design response spectra be smoothed spectra.

(ii) The commercial nuclear plant must be designed so that, if the DBGMs occur, the following SSCs remain functional and within applicable stress, strain, and deformation limits:

(A) Structures, systems, and components for which functional design criteria are established in accordance with § 53.410 or § 53.420; and

(B) Structures, systems, and components classified as SR or NSRSS commensurate with safety significance in accordance with § 53.460.

(iii) In addition to seismic loads, applicable concurrent normal operating, functional, and accident-induced loads must be taken into account in the design of the SR SSCs and, commensurate with safety significance, NSRSS SSCs.

(iv) The design of the commercial nuclear plant must take into account the possible effects of seismic-induced ground disruption, such as fissuring, lateral spreads, differential settlement, liquefaction, and landsliding, on the facility foundations.

(v) The SSCs fulfilling the safety functions required by § 53.230 must be demonstrated through design, testing, or qualification methods to be able to fulfill those safety functions during and after the vibratory ground motion associated with the DBGMs.

(vi) The evaluation of SSCs required by this section to show they are able to function during and after earthquake ground motion should consider, if applicable, soil-structure interaction effects and the expected duration of vibratory motion. It is permissible to design for inelastic behavior in some of these SSCs during the DBGMs and under the postulated concurrent loads, provided the necessary safety functions are maintained.

(2) *OBE Ground Motion.* The OBE Ground Motion must be characterized by response spectra. The value of the OBE Ground Motion must be set to one-third or less of the DBGMs response spectra.

(3) [Reserved]

(4) *Required seismic instrumentation.* Suitable instrumentation must be provided so that the seismic response of commercial nuclear plant SR SSCs or NSRSS SSCs can be evaluated promptly after an earthquake.

(d) *Surface deformation.*

(1) The potential for surface deformation must be taken into account in the design of the commercial nuclear plant by providing reasonable assurance that in the

event of deformation, SSCs classified as SR or NSRSS in accordance with § 53.460 will remain functional.

(2) In addition to surface deformation induced loads, the design of SSCs must take into account, commensurate with safety significance, seismic loads and applicable concurrent functional and accident-induced loads.

(3) The design provisions for surface deformation must be based on its postulated occurrence in any direction and azimuth and under any part of the commercial nuclear plant, unless evidence indicates this assumption is not appropriate, and must take into account the estimated rate at which the surface deformation may occur.

(e) *Seismically induced floods and water waves and other design conditions.* Seismically induced floods and water waves from either locally or distantly generated seismic activity and other design conditions determined pursuant to subpart D of this part must be taken into account in the design of the commercial nuclear plant so as to prevent undue risk to the health and safety of the public.

(f) *Analysis.* The analyses required by § 53.450 must address seismic hazards and related SSC responses in determining that the safety criteria defined in § 53.220 will be met.

(g) *Design criteria, human actions, and programmatic controls*. Functional design criteria, human actions, and programmatic controls needed to address seismic events must be identified and implemented in accordance with this and other subparts to achieve and maintain the performance of SSCs relied upon to satisfy the safety criteria in § 53.220 and to maintain consistency with analyses required by § 53.450 when accounting for the site-specific frequencies and magnitudes of earthquakes for a commercial nuclear plant.

Subpart D—Siting Requirements

§ 53.500 General siting and siting assessment.

The purpose of subpart D and the specific requirements therein is to ensure that:

(a) The siting of each commercial nuclear plant is supported by assessments of proposed sites such that the design, including design features and programmatic controls corresponding to the site characteristics, satisfies the safety criteria defined in §§ 53.210 and 53.220. The siting assessment addresses the site characteristics that might contribute to the initiation, progression, or consequences of licensing-basis events (LBEs) analyzed under §§ 53.450 and 53.480 that are identified and mitigated by design features or programmatic controls. The siting assessment takes into consideration the potential adverse impacts that a commercial nuclear plant may have on nearby populations as a result of normal operations or LBEs.

(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.

§ 53.510 External hazards.

(a) *General external hazard requirements.* The design-basis external hazard level for the relevant external hazards for a site must be identified and characterized based on site-specific assessments of natural and constructed hazards with the potential to adversely affect plant functions. The external hazard frequencies and magnitudes determined from the site-specific assessments must take into account uncertainties and variabilities in data, models, and methods relied on to characterize the external hazards.

(b) *Definitions.* As used in this section, the following terms mean:

Geological Siting Factors are geological and seismic factors that may affect the design and operation of the proposed commercial nuclear plant.

Ground Motion Response Spectra (GMRS) are the site-specific GMRS resulting from the geologic investigations and evaluations of the site vicinity and region and used to determine design-basis ground motions for structures, systems, and components under § 53.480.

Probabilistic Seismic Hazard Analysis is an analytical methodology that incorporates uncertainty into estimates of an annual frequency of exceedance for a certain ground motion parameter (e.g., peak ground acceleration, peak ground velocity, response spectral values) at a site.

(c) *Geological investigations*. The GMRS for the site must be determined based on the results of investigations of the geological, seismological, and engineering characteristics of the site and its environs and must be characterized by both horizontal and vertical free-field GMRS at the free ground surface. The size of the region to be investigated and the type of data pertinent to the investigations must be determined based on the nature of the region surrounding the site. Data on vibratory ground motion, earthquake recurrence rates, fault geometry and slip rates, and site subsurface material properties must be obtained by reviewing pertinent literature and carrying out field investigations. Uncertainties are inherent in the parameters and models used to estimate the GMRS for the site. The site assessment must reflect these uncertainties through an appropriate analysis, such as a probabilistic seismic hazard analysis.

(d) *Geologic and seismic siting factors*. The geologic and seismic siting factors considered for design under §§ 53.415 and 53.480 must include, but are not limited to, determination of the potential for surface tectonic and nontectonic deformations, the size and character of seismically induced floods and water waves that could affect a site from either locally or distantly generated seismic activity, soil and rock stability, liquefaction potential, and natural and artificial slope stability.

§ 53.520 Site characteristics.

Site characteristics that might contribute to the initiation, progression, or consequences of LBEs analyzed under § 53.450 must be identified, assessed, and considered in the design and analyses required by subpart C of this part.

§ 53.530 Population-related considerations.

Every site must have an exclusion area, a low-population zone, and a population center distance as defined in § 53.020.

(a) The offsite radiological consequences estimated by the analyses required by § 53.450(f) must be used to confirm that—

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem (250 millisieverts) total effective dose equivalent.

(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 (250 millisieverts) total effective dose equivalent.

(b) The reactor site must either:

(1) 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

(2) Be found acceptable to the U.S. Nuclear Regulatory Commission (NRC) based on assessments of societal risks in comparison to societal benefits for the specific site. 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.

(c) 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-population 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.

§ 53.540 Siting interfaces.

Site characteristics must be addressed by the design features, programmatic controls, and supporting analyses used to demonstrate that the safety criteria in §§ 53.210 and 53.220 are met for each commercial nuclear plant. Site characteristics must be such that adequate emergency plans and security plans can be developed and maintained.

Subpart E—Construction and Manufacturing Requirements

§ 53.600 Construction and manufacturing – scope and purpose.

This subpart applies to those construction and manufacturing activities authorized by a construction permit (CP), combined license (COL), manufacturing license (ML), or limited work authorization (LWA) issued under this part.

§ 53.605 Reporting of defects and noncompliance.

Each CP and ML issued under this part is subject to the terms and conditions in this section, and each COL issued under this part is subject to the terms and conditions in this section until the date that the Commission makes the finding under § 53.1452(g).

(a) *Definitions*. The definitions in § 21.3 of this chapter apply to this section.

(b) *Posting requirements*.

(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this section must post current copies of this section and the regulations in 10 CFR part 21; section 206 of the Energy Reorganization Act of 1974, as amended; and procedures adopted under these regulations. These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to the license are conducted.

(2) If posting of these regulations or the procedures adopted under them is not practical, the licensee may, in addition to posting section 206 of the Energy Reorganization Act of 1974, as amended, post a notice that describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) *Procedures*. The holder of a CP, COL, or ML subject to this section must adopt appropriate procedures to –

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (c)(2) of this section, in all cases within 60 days of discovery, to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected.

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from the discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer, or designated person as discussed in paragraph (d)(5) of this section. The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer of the holder of a CP, COL, or ML subject to this section is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraph (c)(1) or (c)(2) of this section, if the construction or manufacture of a facility or activity, or a basic component supplied for such a facility or activity –

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard;

(ii) Contains a defect; or

(iii) Underwent any significant breakdown in any portion of the quality assurance program (QAP) conducted under the requirements of appendix B to part 50 of this chapter that could have produced a defect in a basic component. These breakdowns in the QAP are reportable whether or not the breakdown actually resulted in a defect in a design approved and released for construction, installation, or manufacture.

(d) *Reporting defects and noncompliance.*

(1) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating that the facility or manufactured reactors fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable regulation, order, or license of the Commission relating to a substantial safety hazard must notify the Commission of the failure to comply through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(2) The holder of a CP, COL, or ML subject to this section that obtains information reasonably indicating the existence of any defect found in the construction or manufacture, or any defect found in the final design of a facility as approved and released for construction or manufacture, must notify the Commission of the defect

through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(3) The holder of a CP, COL, or ML subject to this part, who obtains information reasonably indicating that the QAP has undergone any significant breakdown discussed in paragraph (c)(3)(iii) of this section must notify the Commission of the breakdown in the QAP through a director, responsible officer, or designated person as discussed in paragraph (d)(5) of this section.

(4) When acting as a dedicating entity, the holder of a CP, COL, or ML subject to this section is responsible for identifying and evaluating deviations; reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and maintaining auditable records for the dedication process.

(5) The notification requirements of this paragraph (d) apply to all defects and failures to comply associated with a substantial safety hazard regardless of whether extensive evaluation, redesign, or repair is required to conform to the criteria and bases stated in the Safety Analysis Report, CP, COL, or ML. Evaluation of potential defects and failures to comply and reporting of defects and failures to comply under this section satisfies the CP holder's, COL holder's, and ML holder's evaluation and notification obligations under 10 CFR part 21, and satisfies the responsibility of individual directors or responsible officers or holders of a CP, COL, or ML subject to this section to report defects, and failures to comply associated with substantial safety hazards under section 206 of the Energy Reorganization Act of 1974, as amended. The director or responsible officer may authorize an individual to provide the notification required by this section. However, this does not relieve the director or responsible officer of his or her responsibility under this section.

(e) *Notification – timing and where sent*. The notification required by paragraph (d) of this section must consist of –

(1) Initial notification by telephone, facsimile, or e-mail identified in appendix A to 10 CFR part 73 to the U.S. Nuclear Regulatory Commission (NRC) Operations Center within 2 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or a failure to comply. If the CP, COL, or ML holder elects to use facsimile, verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph (e)(1) does not apply to interim reports described in paragraph (c)(2) of this section.

(2) Written notification submitted to the NRC Document Control Desk by an appropriate method listed in § 53.040, with a copy to the appropriate NRC Regional Administrator at the address specified in appendix D to 10 CFR part 20 and a copy to the appropriate NRC resident inspector, if applicable, within 30 days following receipt of information by the director or responsible corporate officer under paragraph (c)(3) of this section, on the identification of a defect or failure to comply.

(f) *Content of notification*. The written notification required by paragraph (e)(2) of this section must clearly indicate that the written notification is being submitted under this section and include the following information, to the extent known.

(1) Name and address of the individual or individuals informing the Commission.

(2) Identification of the facility, the activity, or the basic component supplied for the facility or the activity within the United States which contains a defect or fails to comply.

(3) Identification of the firm constructing or manufacturing the facility or supplying the basic component which fails to comply or contains a defect.

(4) Nature of the defect or failure to comply and the safety hazard which is created or could be created by the defect or failure to comply.

(5) The date on which the information of a defect or failure to comply was obtained.

(6) In the case of a basic component that contains a defect or failure to comply, the number and location of these components in use at the facility subject to the regulations in this part.

(7) In the case of a completed reactor manufactured under this part, the entities to which the reactor was supplied.

(8) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(9) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to other entities.

(g) *Procurement documents*. Each holder of a CP, COL, or ML subject to this section must ensure that each procurement document for a facility or a basic component specifies the provisions of 10 CFR part 21 or this section that apply, as applicable.

(h) *Coordination with 10 CFR part 21*. The requirements of this section are satisfied when the defect or failure to comply associated with a substantial safety hazard has been previously reported under 10 CFR part 21, under § 73.1205 of this chapter, under this section, or under § 53.1640.

(i) *Records retention*. The holder of a CP, COL, or ML subject to this section must prepare and maintain records necessary to accomplish the purposes of this section, specifically –

(1) Retain procurement documents, which define the requirements that facilities or basic components must satisfy in order to be considered acceptable, for the lifetime of the facility or basic component.

(2) Retain records of evaluations of all deviations and failures to comply under paragraph (c)(1) of this section for the longest of—

(i) Ten years from the date of the evaluation;

(ii) Five years from the date that an early site permit is referenced in an application for a COL; or

(iii) Five years from the date of delivery of a manufactured reactor.

(3) Retain records of all interim reports to the Commission made under paragraph (c)(2) of this section, or notifications to the Commission made under paragraph (d) of this section for the minimum time periods stated in paragraph (i)(2) of this section;

(4) Suppliers of basic components must retain records of—

(i) All notifications sent to affected licensees or purchasers under paragraph (d)(4) of this section for a minimum of 10 years following the date of the notification;

(ii) The facilities or other purchasers to whom the basic components or associated services were supplied for a minimum of 15 years from the delivery of the basic component or associated services.

(5) Maintaining reports in accordance with this section satisfies the recordkeeping obligations under 10 CFR part 21 of the entities, including directors or responsible officers thereof, subject to this section.

§ 53.610 Construction.

(a) *Management and control*. Licensees must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the construction activities:

(1) Programs to ensure that the construction of a commercial nuclear plant supports the eventual compliance with the design and analysis requirements in subpart C of this part.

(2) An organization, headed by qualified personnel, responsible for managing, controlling, and evaluating the adequacy of the construction activities.

(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) Procedures to evaluate the applicability of other national and international construction experience to the planned and ongoing construction activities and to ensure the applicable experience will be provided to those constructing the plant.

(5) A fitness-for-duty program, under 10 CFR part 26.

(6)(i) A QAP meeting the requirements of appendix B of part 50 of this chapter as required by § 53.460(b).

(ii) Appropriate programmatic controls to provide special treatment for non-safety-related but safety-significant structures, systems, and components (SSCs).

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals working with radioactive materials brought onto the site, as applicable.

(8) An information security program in accordance with §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

(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 an LWA under this part.

(1) Licensees must satisfy the following requirements:

(i) As appropriate, considering the types and quantities of radioactive materials being brought onto the site—

(A) The licensee must maintain and follow a special nuclear material (SNM) material control and accounting program, a measurement control program, and other material control procedures that include corresponding record management requirements as required by the provisions of § 70.32 of this chapter. Prior to initial receipt of SNM onsite, the licensee must implement an SNM material control and accounting program in accordance with 10 CFR part 74.

(B) Procedures must be in place to receive, possess, use, and store source, byproduct, and SNM in accordance with applicable portions of 10 CFR parts 30, 40, and 70.

(C) A plant staff training program associated with the receipt of radioactive material must be approved and implemented prior to initial receipt of byproduct, source or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(ii) For construction of a commercial nuclear plant involving multiple reactor units, plans and procedures must be in place to prevent or mitigate potential hazards to the SSCs of operating units resulting from construction activities, including the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation of the operating units are not exceeded as a result of construction activities.

(iii) Procedures must be in place prior to the start of construction activities that describe how construction will be controlled so as not to impact other features important to the design, such as dewatering, slope stability, backfill, compaction, and seepage.

(iv) For LWA holders, a plan must be developed for redress of activities performed under the LWA should one of the following situations arise:

(A) LWA work activities are terminated by the holder of the LWA;

(B) The LWA is revoked by the NRC; or

(C) The Commission denies the associated CP or COL application.

(2)(i) Onsite fresh fuel must be protected and stored in compliance with § 73.67 of this chapter.

(ii) Before initial fuel load into the reactor (or, for a fueled manufactured reactor, before initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), a cybersecurity program that meets the requirements of § 73.54 or § 73.110 of this chapter, a physical security program that meets the requirements of § 73.55 or § 73.100 of this chapter, and an access authorization program that meets the requirements of § 73.56 or § 73.120 of this chapter must be established, as applicable.

(iii) Fire protection measures must be implemented for work and storage areas (including adjacent fire areas that could affect the work or storage area) before initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter). The fire protection measures for areas associated with new fuel (including all fuel handling, fuel storage, and adjacent fire areas that could affect the new fuel) must be implemented before receipt of fuel. Prior to the receipt of fuel, a formal letter of agreement must be in place with the local fire department specifying the nature of arrangements in support of the fire protection program.

(c) *Inspection and acceptance.*

(1) The licensee must have a process for accepting individual or groups of SSCs upon completion of construction and protecting them from damage or tampering as other construction activities continue.

(2) The post-construction acceptance process must address the inspections, tests, analyses, and acceptance criteria specified in the COL under § 53.1440 or the equivalent verifications needed to support the issuance of an operating license under § 53.1387.

§ 53.620 Manufacturing.

(a) *Management and control*. Holders of MLs must ensure that the following plans, programs, and organizational units are developed and implemented to manage and control the manufacturing activities within the scope of the ML:

(1) Programs to ensure that the manufacturing of a manufactured reactor or portions of a manufactured reactor complies with the design and analysis requirements in subpart C of this part. The entity with design authority for the manufactured reactor covered by the ML must be identified in the license.

(2) An organizational and management structure responsible for managing, controlling, and evaluating the adequacy of the reactor design and manufacturing activities.

(3) Procedures describing the qualifications for personnel in key positions in the licensee's management and control organization and the organizational responsibilities, authority, and interfaces with other parts of the licensee's organization.

(4) A program to evaluate the applicability of other national and international design and manufacturing experience to the planned and ongoing manufacturing activities.

(5) A fitness-for-duty program, in accordance with 10 CFR part 26.

(6)(i) A QAP meeting the requirements of appendix B to part 50 of this chapter, to be applied to the design, fabrication, construction, and testing of the SSCs of the manufactured reactor.

(ii) Appropriate programmatic controls to provide special treatment measures for non-safety-related but safety-significant SSCs.

(7) A radiation protection program, in accordance with 10 CFR part 20, that includes measures for monitoring the dose to individuals if the manufacturing activities include working with radioactive materials.

(8) An information security program in accordance with §§ 73.21, 73.22 and 73.23 of this chapter, as applicable.

(b) *Manufacturing activities*. Holders of MLs must satisfy the following requirements:

(1) The manufacturing process must be conducted within facilities for which the ML holder has the authority to establish controls on any activity that might affect manufacturing. The licensee must establish access controls to the portions of each facility involved in the manufacturing processes governed by the ML.

(2) Manufacturing processes must be performed in accordance with the ML and the referenced codes and standards that have been endorsed or otherwise found acceptable by the NRC.

(3) A post-manufacturing inspection and acceptance process must be established and implemented before transporting a manufactured reactor or portions of a manufactured reactor for installation at a commercial nuclear plant. The process must consider the results of inspections, tests, and analyses that have been performed and the acceptance criteria that are necessary and sufficient to conclude that manufacturing activities have been completed in accordance with the ML.

(c) *Control of radioactive materials*. As appropriate considering the types and quantities of radioactive materials being brought into the manufacturing facility—

(1) Procedures must be in place to receive, transfer, possess, and use source, byproduct, and SNM in accordance with the applicable portions of 10 CFR parts 30, 40 and 70.

(2) A fire protection program must be established and implemented before the initial receipt of byproduct, source, or non-fuel SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(3) An emergency plan appropriate for responding to the facility-specific hazards of an accidental release of radioactive material and to limit the health effects of the associated chemical hazards of licensed material must be approved and implemented prior to the receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(4) A plant staff training program associated with the receipt of radioactive material must be approved and implemented before initial receipt of byproduct, source, or SNM (excluding exempt quantities as described in § 30.18 of this chapter).

(5) Security requirements must be implemented for the protection of SNM based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and for the protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable.

(d) *Fuel loading.*

(1)(i) An ML may authorize possession of a manufactured reactor into which the licensee has loaded fresh (unirradiated) fuel pursuant to a license issued under part 70 of this chapter only if the manufactured reactor is configured during its loading, storage, and transport with features to prevent criticality that are specified in the ML.

(ii) The ML applicant may file a separate, subsequent application for the 10 CFR part 70 license or combine the application for the 10 CFR part 70 license with the application for an ML.

(iii) The Commission has determined that any such fueled manufactured reactor in which the features to prevent criticality are in place is not in operation.

(iv) Upon installation of the fueled manufactured reactor in its place of operation and a Commission finding that the acceptance criteria in the COL that authorized reactor construction are met under § 53.1452(g), or that any conditions in the CP that authorized reactor construction are met and the associated operating license (OL) issued, the

features to prevent criticality may be removed. Upon initiating the removal of the features to prevent criticality, the fueled manufactured reactor has commenced operation.

(2) Holders of part 70 licenses authorizing the possession and loading of fresh fuel into manufactured reactors must comply with the requirements of part 70 for the facilities and activities related to the storage, movement, and loading of fresh fuel in the manufactured reactor. Holders of these part 70 licenses must comply with the requirements of Subpart H to part 70, regardless of whether their proposed activities meet the applicability criteria found in 10 CFR 70.60. Procedures, equipment, and personnel required by the 10 CFR part 70 license, must be in place before the receipt of SNM at the manufacturing facility.

(i) Before the receipt of SNM, the licensee must have security programs in place that meet the performance objectives of 10 CFR 73.67, with the following additions and exceptions:

(A) A physical security plan describing the physical security program must be maintained and a cybersecurity program must be established for the possession and loading of fresh fuel into a manufactured reactor authorized by a 10 CFR part 70 license, regardless of fuel type, enrichment, and quantity.

(B) The physical security program must be designed to prevent unintended and uncontrolled criticality events.

(C) The cybersecurity program must provide reasonable assurance that a cyberattack does not adversely impact the functions performed by digital assets necessary for implementing the physical security requirements of this section, or the radiation monitoring and criticality requirements in this section or in 10 CFR part 70.

(D) All holders of a part 70 license that authorizes loading of fresh fuel into a manufactured reactor must perform the screening required in § 73.67(d)(4) of this chapter to confirm the identity, trustworthiness, and reliability of individuals prior to

granting unescorted access to special nuclear material; these determinations must be documented.

(ii) [Reserved]

(3) The loading or unloading of fresh fuel into or from a manufactured reactor and any changes to the configuration of reactivity control and prevention systems for the fueled manufactured reactor must be performed by a certified fuel handler meeting the requirements in subpart F of this part.

(e) *Transportation.*

(1) A holder of an ML may not transport or allow to be removed from the places of manufacture the manufactured reactor or portions thereof as defined in the ML except for either transport to a site for which the Commission has issued a COL or CP that references the subject ML or export in accordance with 10 CFR part 110.

(2) A holder of an ML must include in any contract governing the transport of a manufactured reactor or portions thereof as defined in the ML from the places of manufacture to any other location, a provision requiring that the person transporting the manufactured reactor comply with all shipping requirements in applicable NRC regulations, certificates of compliance, and NRC-issued licenses.

(3) Procedures governing the preparation of the manufactured reactor or portions thereof as defined in the ML for transport and the conduct of the transport must be issued prior to transport. The procedures must implement the protective measures and restrictions described in NRC regulations and NRC-issued licenses to protect the reactor from potential conditions that would adversely affect the safe operation of a commercial nuclear plant.

(4) For a manufactured reactor that is to be loaded with fresh fuel before transport to the place of operation, the ML must specify that transportation will be in accordance with parts 71 and 73 of this chapter.

(f) *Acceptance and installation at the site for which the Commission has issued a COL or CP that references the subject ML*.

(1) Installation at the site for which the Commission has issued a COL or CP that references the subject ML must follow the regulations in § 53.610.

(2) Upon arrival at the site, the manufactured reactor or portions of a manufactured reactor may not be installed in its place of operation unless the COL or CP holder performs inspections sufficient to verify the reactor is in compliance with the ML and has not been damaged in transit. The COL or CP holder must perform these inspections in accordance with documented procedures subject to quality assurance measures commensurate with their importance to safety. In addition, inspections must confirm that the interface requirements between the manufactured reactor or portions of a manufactured reactor and the remaining portions of the commercial nuclear plant are met.

Subpart F—Requirements for Operation

§ 53.700 Operational objectives.

The purpose of subpart F and the specific requirements herein is to ensure that:

(a) Each holder of an operating license (OL) or combined license (COL) under this part develops, implements, and maintains controls for plant structures, systems, and components (SSCs), responsibilities of personnel, and plant programs during the operating life of each commercial nuclear plant such that the requirements defined in subpart B are satisfied. More specifically:

(1) Under § 53.710 through § 53.730, each holder of an OL or COL under this part must maintain the capabilities, availability, and reliability of plant SSCs to ensure that the safety functions identified in § 53.230 will be performed if called upon during licensing-basis events (LBEs).

(2) Under § 53.725 through § 53.830, each holder of an OL or COL under this part must ensure that personnel have adequate knowledge and skills to perform their assigned duties that support the performance of the safety functions identified in § 53.230.

(3) Under § 53.845 through § 53.910, each holder of an OL or COL under this part must implement plant programs sufficient to ensure that the safety functions identified in § 53.230 will be performed if called upon during normal operations and LBEs.

(b) [Reserved]

§ 53.710 Maintaining capabilities and availability of structures, systems, and components.

Measures must be provided for each commercial nuclear plant licensed under this part such that the capabilities, availability, and reliability of plant SSCs, when combined with corresponding programmatic controls and human actions, provide that the safety criteria defined in §§ 53.210 and 53.220 will be met.

(a) Technical specifications must be developed, implemented, and maintained that define conditions or limitations on plant operations that are necessary to ensure that safety-related (SR) SSCs can fulfill the safety functions identified under § 53.230 and support meeting the safety criteria of § 53.210. The technical specifications must describe the following requirements:

(1) Limits on the inventory of radioactive materials within the reactor system and supporting systems with the potential, individually or collectively, to cause a release exceeding the safety criteria in § 53.210 as a result of a design-basis accident analyzed in accordance with § 53.450(f).

(2) Operating limits for the facility that if exceeded could lead to a failure to perform a required safety function necessary to demonstrate compliance with the safety criteria in § 53.210.

(3) For each SSC classified as SR in accordance with § 53.460, technical specifications must define—

(i) *Limiting conditions for operation*. Limiting conditions for operation are the lowest functional capability or performance levels of SR SSCs required to ensure that the design-basis accidents analyzed in accordance with § 53.450(f) satisfy the safety criteria of § 53.210. When a limiting condition for operation is not met, the licensee must shut down the plant or follow any remedial action permitted by the technical specifications until the condition can be met.

(ii) *Surveillance requirements.* Surveillance requirements are requirements relating to test, calibration, or inspection to assure that the necessary quality of systems and components is maintained and that the limiting conditions for operation will be met.

(4) Design elements to be included are those elements of the plant such as materials of construction and geometric arrangements, which, if altered or modified, would have a significant effect on safety and are not covered in categories described in paragraphs (a)(1) through (3) of this section.

(5) Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the plant in a safe manner. Each licensee must submit any reports to the Commission pursuant to approved technical specifications under § 53.040.

(b) Control measures on plant operations, including availability controls, must be developed and implemented to ensure that the configurations and special treatments for SR SSCs and non-safety-related but safety-significant

(NSRSS) SSCs provide the capabilities, availability, and reliability required to demonstrate compliance with the criteria of §§ 53.220 and 53.450(e).[1] The control measures must—

(1)(i) Identify who within the licensee's organization has authority to make configuration changes;

(ii) Establish processes to make configuration changes to NSRSS SSCs; and

(iii) Establish processes to ensure that all organizations of the commercial nuclear plant affected by the configuration changes are formally notified and approve of the change.

(2) Describe how the special treatments for each NSRSS SSC and special treatments for SR SSCs beyond those under paragraph (a) of this section will be established and maintained over the operating life of the commercial nuclear plant.

---

[1] The comprehensive risk metrics and related risk performance objectives established under § 53.220 involve assessing and averaging the risks over a defined period (e.g., plant year) and do not constitute a real-time requirement that must be continuously demonstrated by the licensee.

§ 53.715 Maintenance, repair, and inspection programs.

(a) A program to control maintenance activities and monitor the performance or condition of SR and NSRSS SSCs must be developed, implemented, and maintained.

(b) Whenever a licensee determines through activities related to maintenance, repair, and inspection of SSCs, the activities under § 53.710, or otherwise that the performance or condition of an SR or NSRSS SSC does not demonstrate compliance with established special treatments or performance goals related to capabilities, availability, or reliability, the licensee must take appropriate corrective action.

(c) Performance and condition monitoring activities and associated goals and preventive maintenance activities must be evaluated at least every 24 months. The

evaluations must take into account, where practical, industry-wide operating experience. Adjustments must be made where necessary to ensure that the objective of preventing failures of SSCs through maintenance is appropriately balanced against the objective of minimizing unavailability of SSCs due to monitoring or preventive maintenance.

(d) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee must assess and manage the increase in risk that may result from the proposed maintenance activities.

§ 53.720 Response to seismic events.

If vibratory ground motion exceeding that of the operating basis earthquake Ground Motion or significant plant damage due to vibratory ground motion occurs, the licensee must shut down the commercial nuclear plant. If structures, systems, or components necessary for the safe shutdown of the commercial nuclear plant are not available after the occurrence of this vibratory ground motion, the licensee must consult with the Commission and must propose a plan for the timely, safe shutdown of the commercial nuclear plant. Prior to resuming operations, the licensee must demonstrate to the Commission that those features necessary for continued operation without undue risk to the health and safety of the public or necessary to maintain the licensing basis of the commercial nuclear plant were either not functionally damaged or have been repaired.

§ 53.725 General staffing, training, personnel qualifications, and human factors requirements.

(a) *Two classes of commercial nuclear plants.* Commercial nuclear plants licensed under this part are either of the class of self-reliant-mitigation facilities or of interaction-dependent-mitigation facilities, based upon the similarity of operating and technical characteristics of the plants in the class. A commercial nuclear plant is a self-

reliant-mitigation facility if the U.S. Nuclear Regulatory Commission (NRC) determined as part of its approval of the OL or COL for that plant that its design demonstrates compliance with the criteria of § 53.800(a)(1) through (a)(5). Otherwise, the commercial nuclear plant is an interaction-dependent-mitigation facility.

(b) *Purpose and applicability*. The regulations in §§ 53.725 through 53.830 address areas related to staffing, training, personnel qualifications, and human factors engineering for applicants for or holders of OLs or COLs under this part. These regulations are organized as follows:

(1) Sections 53.725 through 53.745 address general requirements for staffing, training, personnel qualifications, and human factors engineering. The regulations within these sections are applicable to all applicants for or holders of OLs or COLs under this part, except where specifically stated otherwise.

(2) Sections 53.760 through 53.795 address operator and senior operator licensing requirements. The regulations within these sections are applicable to those applicants for or holders of OLs or COLs under this part for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(3) Sections 53.800 through 53.820 address generally licensed reactor operator requirements. The regulations within these sections are in lieu of §§ 53.760 through 53.795 for those applicants for or holders of OLs or COLs under this part for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(4) Section 53.830 provides general personnel training requirements. The regulations within this section are applicable to all applicants for or holders of OLs or COLs under this part.

(c) *Definitions*. When used in §§ 53.725 through 53.830, *applicant* refers to an applicant for an operator or senior operator license; *licensee* refers to the holder of an operator, senior operator, or generally licensed reactor operator license; and *facility licensee* refers to the licensee for the commercial nuclear plant where the applicant would be licensed or the licensee is licensed. As also used in §§ 53.725 through 53.830—

Automation means a device or system that accomplishes (partially or fully) a function or task.

Auxiliary operator means any individual who operates components of a commercial nuclear plant but does not manipulate controls or direct the manipulation of controls of the plant and is not required to be licensed under the provisions of this part.

Controls when used with respect to a nuclear reactor means apparatus and mechanisms, the manipulation of which directly affects the reactivity or power level of the reactor.

Generally licensed reactor operator means any individual licensed under the provisions of § 53.810 to manipulate controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators.

Interaction-dependent-mitigation facility means a commercial nuclear plant design other than one that demonstrates compliance with the operating and technical characteristics defined under § 53.800.

Load following means a commercial nuclear plant automatically changing its output to match expected demand in response to externally originated instructions or signals.

Operator means any individual licensed under the provisions of §§ 53.760 through 53.795 to manipulate controls of an interaction-dependent-mitigation facility.

Performance testing means testing conducted to verify a simulation facility's performance as compared to actual or predicted reference plant performance.

Reference plant means the specific commercial nuclear plant, or plant design for facilities which are not yet constructed, on which a simulation facility's configuration, system control arrangement, and design data are based.

Self-reliant-mitigation facility means a commercial nuclear plant design that demonstrates compliance with the operating and technical characteristics defined under § 53.800.

Senior operator means any individual licensed under the provisions of §§ 53.760 through 53.795 to manipulate controls of an interaction-dependent-mitigation facility and to direct the licensed activities of operators.

Simulation facility means an interface designed to provide a realistic imitation of the operation of a commercial nuclear plant used for the administration of examinations, for training, and/or to demonstrate compliance with experience requirements for applicants or licensees. A simulation facility may rely, in whole or part, upon the physical utilization of the reference plant itself.

Systems approach to training means a training program that includes the following five elements:

(1) Systematic analysis of the jobs to be performed.

(2) Learning objectives derived from the analysis which describe desired performance after training.

(3) Training design and implementation based on the learning objectives.

(4) Evaluation of trainee mastery of the objectives during training.

(5) Evaluation and revision of the training based on the performance of trained personnel in the job setting.

§ 53.726 Communications.

(a) An applicant or licensee or facility licensee must submit any communication or report required by the regulations contained within §§ 53.725 through 53.830 and must submit any application filed under these regulations to the Commission.

(b) Each facility licensee that is required to comply with the requirements of §§ 53.760 through 53.795 (i.e., interaction-dependent-mitigation facilities) must notify the appropriate NRC contact within 30 days of the following in regard to a licensed operator or senior operator:

(1) Permanent reassignment from the position for which the facility licensee has certified the need for a licensed operator or senior operator under § 53.775(a)(1);

(2) Termination of any operator or senior operator; or

(3) Permanent disability or illness as required under § 53.770.

§ 53.728 Completeness and accuracy of information.

Information provided to the Commission by an applicant for an operator or senior operator license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee must be complete and accurate in all material respects.

§ 53.730 Defining, fulfilling, and maintaining the role of personnel in ensuring safe operations.

Each applicant for or holder of an OL or COL for a commercial nuclear plant under this part must comply with the following:

(a) *Human factors engineering design requirements*. The plant design must reflect state-of-the-art human factors engineering principles for safe and reliable performance in all locations that human activities are expected for performing or supporting the continued availability of plant safety or emergency response functions.

(b) *Human system interface design requirements.* The plant design must provide for the following to support operating personnel in monitoring plant conditions and responding to plant events:

(1) Features for displaying to operating personnel a minimum set of parameters that define the safety status of the plant and are capable of displaying both the full range of important plant parameters and data trends on demand, as well as indicating when process limits are being approached or exceeded;

(2) Automatic indication of the bypassed and operable status of safety systems;

(3) Direct indication of SSC status that relates to the ability of the SSC to perform its safety function, such as relief and safety valve position (i.e., open or closed) for barriers important to fulfilling safety functions with such devices, and ultimate heat sink and cooling system status and availability;

(4) Instrumentation to measure, record, and display key plant parameters related to the performance of SSCs and the integrity of barriers important to fulfilling safety functions to support operators in monitoring plant conditions and responding to plant events. Examples include temperatures and pressures within important systems or structures, core or fuel system conditions (including possible damage states), temperatures and levels associated with cooling functions, combustible gas concentrations, radiation levels in systems and within structures, and radioactive effluent releases;

(5) Leakage control and detection in the design of systems that pass through barriers important to fulfilling safety functions for the release of radionuclides. An example is an SSC that penetrates a containment structure that might contain radioactive materials that could contribute to the source term during an accident;

(6) Monitoring of in-plant radiation and airborne radioactivity as appropriate for a broad range of normal operating and accident conditions; and

(7) For self-reliant-mitigation facilities, the plant design must also provide the generally licensed reactor operators with the capability to do the following:

(i) Receive plant operating data, including reactor parameters and information needed for the evaluation of emergency conditions.

(ii) Promptly dispatch operations and maintenance personnel.

(iii) Immediately implement responsibilities under the facility emergency plan, as applicable.

(8) For both interaction-dependent and self-reliant mitigation facilities, the plant design must provide licensed operators with the capability of immediately initiating a reactor shutdown from their location.

(c) *Concept of operations.* A concept of operations that is of sufficient scope and detail to address the following must be provided:

(1) Plant goals;

(2) The roles and responsibilities of operating personnel and automation (or any combination thereof) that are responsible for completing plant functions;

(3) Staffing, qualifications, and training;

(4) The management of normal operations;

(5) The management of off-normal conditions and emergencies;

(6) The management of maintenance and modifications; and

(7) The management of tests, inspections, and surveillances.

(d) *Functional requirements analysis and function allocation*. A functional requirements analysis and a function allocation must be provided that are sufficient to demonstrate compliance with the following:

(1) The functional requirements analysis must address how safety functions and functional safety criteria are satisfied, and

(2) The function allocation must describe how the safety functions will be assigned to human action, automation, active safety features, passive safety features, and/or inherent safety characteristics.

(e) *Operating experience*. A program, during construction and during operation, as applicable, for evaluating and applying operating experience must be developed, implemented, and maintained.

(f) *Staffing plan.* A staffing plan must be developed and comply with the following:

(1) The staffing plan must include a description of how engineering expertise will be available to the on-shift operating personnel during all plant conditions, to assist if they encounter a situation not covered by procedures or training. Engineering expertise includes familiarity with the operation of the plant for which the expertise is provided and one of the following:

(i) A bachelor's degree in engineering, engineering technology, or physical science from an institution accredited by a U.S. Government recognized accrediting body or equivalent; or

(ii) A Professional Engineer's license from a U.S. State or territory.

(2) Applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities must include within their staffing plans a description of how the proposed numbers, positions, and qualifications of operators and senior operators across all modes of plant operations will be sufficient to ensure that plant safety functions will be maintained. This description must be supported by human factors engineering analyses and assessments.

(3) Applicants for or holders of OLs or COLs for self-reliant-mitigation facilities must include within their staffing plans a description of how generally licensed reactor operator staffing that is both sufficient to continually monitor the operations of fueled

reactors and to provide for a continuity of responsibility for facility operations at all times during the operating phase will be maintained.

(4) Applicants for or holders of OLs or COLs under this part must include within their staffing plans a description of how the positions and responsibilities of personnel contained within those plans will adequately satisfy necessary support functions within areas such as plant operations, equipment surveillance and maintenance, radiological protection, chemistry control, fire brigades, engineering, security, and emergency response.

(5) The staffing plan must be approved by the NRC as part of its approval of the OL or COL for the plant. The approved staffing plan is subject to the requirements of § 53.1565.

(g) *Training, examination, and proficiency programs*. Develop, implement, and maintain programs that comply with the following requirements. These programs must be approved by the NRC as part of its approval of the OL or COL for the plant:

(1) For those applicants for or holders of OLs or COLs for interaction-dependent-mitigation facilities:

(i) The operator licensing initial training program required under § 53.780(a);

(ii) The operator licensing initial examination program required under § 53.780(b);

(iii) The operator licensing requalification program required under § 53.780(c); and

(iv) The operator proficiency program required under § 53.780(g).

(2) For those applicants for or holders of OLs or COLs for self-reliant-mitigation facilities, the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(3) The operator licensing requalification programs required under § 53.780(c) or § 53.815(b) must be implemented upon commencing the administration of initial

examinations under the operator licensing examination program required under § 53.780(b) or § 53.815(b), respectively.

§ 53.735 General exemptions.

The regulations in §§ 53.725 through 53.830 do not require a license for an individual who –

(a) Under the direction and in the presence of an operator or senior operator or a generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant as a part of the individual's training in a facility licensee's training program as approved by the Commission to qualify for an operator or senior operator license or a generally licensed reactor operator license there, as appropriate, under these regulations; or

(b) Under the direction and in the presence of a senior operator or generally licensed reactor operator, as appropriate, manipulates the controls of a commercial nuclear plant to load or unload the fuel into, out of, or within the reactor vessel while the reactor is not operating.

§ 53.740 Facility licensee requirements – general.

(a) Facility licensees must demonstrate compliance with the requirements of either §§ 53.760 through 53.795 for interaction-dependent-mitigation facilities or §§ 53.800 through 53.820 for self-reliant-mitigation facilities.

(b) The facility licensee must maintain the staffing complement described under its approved facility staffing plan until such time as the permanent cessation of operations and permanent removal of fuel from the reactor vessel has been certified as described under § 53.1070. The approved staffing plan is subject to the requirements of § 53.1565.

(c) Except as provided under § 53.735, the facility licensee may not permit the manipulation of the controls of a commercial nuclear plant by anyone who is not an operator or senior operator or generally licensed reactor operator, as appropriate.

(d) Facility licensees for interaction-dependent-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 must designate senior operators to be responsible for supervising the licensed activities of operators.

(e) Apparatus and mechanisms other than controls, the operation of which may affect the reactivity or power level of a reactor, must be manipulated only while plant conditions are being monitored by an individual who is an operator or senior operator or a generally licensed reactor operator, as appropriate.

(f)(1) Load following is permitted if at least one of the following is immediately capable of refusing demands when they could challenge the safe operation of the plant or when precluded by the plant equipment conditions:

(i) The actuation of an automatic protection system that utilizes setpoints more conservative than those otherwise credited for the purposes of reactor protection; or

(ii) An automated control system; or

(iii) An operator or senior operator or a generally licensed reactor operator, as appropriate.

(2) The provisions of paragraph (e) of this section do not apply during load following operations.

(g)(1) Facility licensees for interaction-dependent-mitigation facilities must have present during alteration of the core (including fuel loading or transfer) an individual holding a senior operator license, or a senior operator license limited to fuel handling to directly supervise the activity and, during this time, the facility licensee must not assign other duties to this person.

(2) Facility licensees for self-reliant-mitigation facilities must have present during alteration of the core (including fuel loading or transfer) an individual holding a generally licensed reactor operator license to directly supervise the activity and, during this time, the facility licensee must not assign other duties to this person.

(3) The provisions of paragraphs (g)(1) and (2) of this section do not apply to core alterations performed as part of refueling operations while a facility that is capable of online refueling is operating at power.

(h) Facility licensees may take reasonable action that departs from a license condition or a technical specification (contained in a license issued under this part) in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. Such facility licensee action must be approved, as a minimum, by a senior operator or a generally licensed reactor operator, as applicable, or, after certifying the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 by a certified fuel handler, senior operator, or generally licensed reactor operator, as applicable, prior to taking the action.

§ 53.745 Operator license requirements.

A person must be authorized by a license issued by the Commission to perform the function of an operator, senior operator, or generally licensed reactor operator as defined in this part.

§ 53.760 Operator licensing.

(a) *Applicability*. Sections 53.760 through 53.795 address operator and senior operator licensing requirements. The regulations within these sections are applicable to those applicants for or holders of OLs or COLs under this part for interaction-dependent-

mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(b) [Reserved]

§ 53.765 Medical requirements.

(a) An applicant for an operator or senior operator license must have a medical examination by a physician. An operator or senior operator must have a medical examination by a physician every 2 years.

(b) To certify the medical fitness of an applicant for an operator or senior operator license, an authorized representative of the facility licensee must complete and sign NRC Form 396, “Certification of Medical Examination by Facility Licensee,” which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 301-415-7232, or by visiting the NRC’s website at https://www.nrc.gov and selecting forms from the index found on the home page, or by other means provided by the NRC.

(1) NRC Form 396 must certify that a physician has conducted the medical examination of the applicant as required in paragraph (a) of this section.

(2) When the medical certification requests a conditional license based on medical evidence, the medical evidence must be submitted on NRC Form 396 to the Commission to enable the Commission to make a determination in accordance with § 53.775(b).

(c) The facility licensee must document and maintain the results of medical qualifications data, test results, and each operator’s or senior operator’s medical history for the current license period and provide the documentation to the Commission upon request. The facility licensee must retain this documentation while an individual performs the functions of an operator or senior operator.

§ 53.770 Incapacitation because of disability or illness.

If, during the term of the operator or senior operator license, the licensee develops a permanent physical or mental condition that causes the licensee to fail to demonstrate compliance with the requirements of § 53.775(b)(1)(i), the facility licensee must notify the Commission within 30 days of learning of the diagnosis. For conditions for which a conditional license (as described in § 53.775(b)) is requested, the facility licensee must provide medical certification on NRC Form 396 to the Commission (as described in § 53.765(b)).

§ 53.775 Applications for operators and senior operators.

(a) *How to apply*.

(1) The applicant for an operator or senior operator license must—

(i) Complete NRC Form 398, “Personal Qualification Statement-- Licensee,” which can be obtained by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling 301-415-5877, or by visiting the NRC’s website at https://www.nrc.gov and selecting forms from the index found on the home page, or by other means provided by the NRC;

(ii) File an original of NRC Form 398, or an equivalent electronic submittal, together with the information required in paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, with the appropriate Regional Administrator.

(iii) Provide evidence that the applicant, as a trainee, has successfully demonstrated competence in manipulating the controls of either the facility for which a license is sought or a simulation facility that demonstrates compliance with the requirements of § 53.780(e). For operators applying for a senior operator license, certification that the operator has successfully operated the controls of the facility as an operator will be accepted; and

(iv) Provide certification by the facility licensee of medical condition and general health on NRC Form 396, to comply with § 53.765.

(2) The Commission may at any time after the application has been filed, and before the license has expired, require further information under oath or affirmation to enable it to determine whether to grant or deny the application or whether to revoke, modify, or suspend the license.

(3) An applicant whose application has been denied because of a medical condition or their general health may submit a further medical report at any time as a supplement to the application.

(4) Each application and statement must contain complete and accurate disclosure as to all matters required to be disclosed. The applicant must sign statements required by paragraphs (a)(1)(i) and (a)(1)(ii) of this section.

(b) *Disposition of an initial application.*

(1) *License approval*. The Commission will approve an initial application if it finds that the following criteria are met:

(i) *Health*. The applicant's medical condition and general health will not adversely affect the performance of assigned operator or senior operator job duties or cause operational errors endangering public health and safety. The Commission will base its finding upon the certification by the facility licensee as detailed in § 53.765(b).

(ii) *Examination.* The applicant has passed the requisite examination in accordance with § 53.780(b). The examination determines whether the applicant for an operator's or senior operator's license has learned to operate a facility competently and safely, and additionally, in the case of a senior operator, whether the applicant has learned to supervise the licensed activities of operators competently and safely.

(2) *Conditional license*. If an applicant's general medical condition does not demonstrate compliance with the minimum standards under § 53.775(b)(1)(i), the Commission may approve the application and include conditions in the license to accommodate the medical condition. The Commission will consider the

recommendations and supporting evidence of the facility licensee and of the examining physician (provided on NRC Form 396) in arriving at its decision.

(c) *Re-applications.*

(1) An applicant whose application for a license has been denied because of failure to pass the examination may file a new application. The application must be submitted on NRC Form 398 and include a statement signed by an authorized representative of the facility licensee by whom the applicant will be employed that states in detail the extent of the applicant's additional training and remediation since the denial and certifies that the applicant is ready for re-examination.

(2) An applicant who has passed a portion of the examination and failed another may request in a new application on NRC Form 398 to be excused from re-examination on the portions of the examination that the applicant has passed. The Commission may in its discretion grant the request if it determines that sufficient justification is presented.

§ 53.780 Training, examination, and proficiency program.

(a) *Operator licensing initial training program*.

(1) A program that is based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the training of applicants for operator and senior operator licenses. The program must ensure that applicants at the facility will possess the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be approved by the Commission prior to its use for training applicants, as described under § 53.730(g). The approved operator licensing initial training program is subject to the requirements of § 53.1565.

(2) The facility licensee must maintain operator licensing initial training program records documenting the initial operator licensing training administered and completed by each applicant. The facility licensee must retain these records during the period in

which any trainees subsequently remain licensed as operators or senior operators at the facility.

(b) *Operator licensing initial examination program*.

(1) The facility licensee must establish and implement an examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform operator and senior operator duties, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining applicants, as described under § 53.730(g). The approved operator licensing initial examination program is subject to the requirements of § 53.1565.

(2) The facility licensee must submit prepared examinations to the Commission for review and approval in advance of their administration.

(3) The Commission will either administer an approved examination or allow the facility licensee to administer the examination. The facility licensee must ensure that sufficient advance notification is provided to the Commission to either administer the examination or allow for a representative of the Commission to be afforded the opportunity to be present when the facility licensee administers the examination.

(4) Graded examination documentation for each applicant must be provided to the Commission for review in making operator licensing decisions.

(5) The facility licensee must maintain operator licensing initial examination program records documenting the participation of each operator and senior operator applicant in the initial examination. The records must contain copies of examinations administered, the answers given by the applicant, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an applicant exhibited deficiencies. The facility licensee must retain these records

during the period in which the associated operators or senior operators remain licensed at the facility.

(c) *Operator licensing requalification program.*

(1) A program based upon a systems approach to training, as defined by § 53.725(b), must be utilized for the continuing training of operators and senior operators.

(i) The program must ensure that operators and senior operators at the facility maintain the knowledge, skills, and abilities necessary to protect the public health and maintain those plant safety functions specific to the facility design. The program must be conducted for a continuous period not to exceed 24 months in duration.

(ii) The program must be approved by the Commission prior to its use for continuing training, as described under § 53.730(g). The approved operator licensing requalification program is subject to the requirements of § 53.1565.

(2) The following requirements apply to operator licensing requalification programs:

(i) The facility licensee must propose a requalification examination program for testing, for each requalification period, a sample of the topics included under the systems approach to training, to include both the examination methods and criteria to be used to assess passing performance. The program must provide for valid and reliable examinations and be approved by the Commission prior to its use for examining operators and senior operators, as described under § 53.730(g). The approved requalification examination program is subject to the requirements of § 53.1565.

(ii) The following requirements apply to the requalification examination program:

(A) The facility licensee must make prepared requalification examinations available to the Commission for review.

(B) The facility licensee must ensure that a representative of the Commission is afforded the opportunity to be present during requalification examination administration.

(C) The facility licensee must ensure that each operator and senior operator is administered a complete requalification examination on a periodicity not to exceed 24 months. Additionally, the facility licensee must ensure that any licensed operator or senior licensed operator who either demonstrates unsatisfactory performance on, or fails to complete, this biennial requalification examination is removed from the performance of licensed operator and senior licensed operator duties until any necessary remedial training has been completed and a retake examination has been passed.

(D) The facility licensee must promptly provide a summary of examination results to the NRC for each operator and senior operator following the completion of the requalification examination.

(3) The facility licensee must maintain operator licensing requalification program records documenting the participation of each operator and senior operator in the requalification program. The records must contain copies of examinations administered, the answers given by the operator or senior operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which an operator or senior operator exhibited deficiencies. The facility licensee must retain these records until the operator’s or senior operator’s license is renewed.

(d) *Examination integrity*. Applicants, operators and senior operators, and facility licensees must not engage in any activity that compromises the integrity of any application or examination required by §§ 53.760 through 53.795. The integrity of an examination is considered compromised if any activity, regardless of intent, affected, or, but for detection, could have affected the consistent administration of the examination. This includes activities related to the preparation and certification of applications and all

activities related to the preparation, administration, and grading of examinations required by §§ 53.760 through 53.795.

(e) *Simulation facilities.*

(1) This section addresses the use of a simulation facility for the administration of examinations, for training, or to demonstrate compliance with experience requirements for applicants for operator and senior operator licenses.

(2) Simulation facilities used for training purposes, for demonstrating compliance with experience requirements, or for the conduct of examinations under § 53.780(b) and (c) must demonstrate compliance with the following criteria as they relate to the facility licensee's reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform operator and senior operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the most recent fuel load in the reference commercial nuclear plant or, prior to initial fuel load (or, for a fueled manufactured reactor, prior to initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), replicate the intended initial fuel load for the reference commercial nuclear plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulation facility fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(3) Facility licensees that maintain a simulation facility that has been approved by the Commission for training purposes, demonstrating compliance with experience

requirements, or the conduct of examinations under § 53.780(b) and (c) for the facility licensee's reference plant must:

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(2) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification as to why the presence of such discrepancies will not adversely affect simulator performance with respect to the criteria of paragraph (e)(2) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of the initial license examination or requalification examination available for NRC review, prior to or concurrent with preparations for each initial license examination or requalification examination; and

(v) Maintain the provisions for license application and examination integrity consistent with § 53.780(d).

(4) A simulation facility must demonstrate compliance with the requirements of paragraphs (e)(2) and (e)(3) of this section for the Commission to accept the simulation facility for conducting initial examinations as described in § 53.780(b), requalification training as described in § 53.780(c), or performing control manipulations that affect reactivity to establish eligibility for an operator or senior operator license as described in § 53.775(a).

(f) *Waiver of examination requirement.* On application, the Commission may waive any or all of the requirements for an initial licensing examination if it finds that the applicant has demonstrated the required knowledge, skills, and abilities to safely operate

the plant, and is capable of continuing to do so. The Commission may make such a finding based on demonstration of the following:

(1) Recent operating experience at a comparable facility;

(2) Proof of the applicant's past competent and safe performance; and

(3) Proof of the applicant's current qualifications.

(g) *Proficiency.* The facility licensee must develop, implement, and maintain a proficiency program to ensure that operators and senior operators will actively perform the functions of an operator or senior operator, respectively, as needed to maintain proficiency with on-shift duties and familiarity with plant status. This program must include those steps that will be taken to re-establish proficiency when it cannot be maintained. This program must be approved by the Commission as part of its approval of the OL or COL for the plant. The approved proficiency program is subject to the requirements of § 53.1565.

(h) *Records.* Each record required by this section must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

§ 53.785 Conditions of operator and senior operator licenses.

Each operator and senior operator license contains and is subject to the following conditions whether stated in the license or not:

(a) Neither the license nor any right under the license may be assigned or otherwise transferred.

(b) The license is limited to the facility or facilities for which it is issued.

(c) The license is limited to those controls of the facility or facilities specified in the license.

(d) The license is subject to, and the licensee must observe, all applicable rules, regulations, and orders of the Commission.

(e) The licensee must maintain or re-establish proficiency in accordance with the facility licensee's Commission-approved proficiency program required under § 53.780(g).

(f) The licensee must be subject to the facility's Commission-approved operator licensing requalification and requalification examination programs required under § 53.780(c).

(g) The licensee must have a biennial medical examination as described by § 53.765.

(h) The licensee must notify the Commission within 30 days about a conviction for a felony.

(i) The licensee must not consume or ingest alcoholic beverages within the protected area of commercial nuclear plants. The licensee must not use, possess, or sell any illegal drugs. The licensee must not perform activities authorized by a license issued under this part while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform his or her licensed duties. For the purpose of this paragraph (i), with respect to alcoholic beverages and drugs, the term "under the influence" means the licensee exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR part 26, or as established by the facility licensee. The term "under the influence" also means the licensee could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the facility licensee for its fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform licensed duties.

(j) Each licensee must participate in the drug and alcohol testing programs as required under 10 CFR part 26.

(k) The licensee must comply with any other conditions that the Commission may impose to protect health or to minimize danger to life or property.

§ 53.790 Issuance, modification, and revocation of operator and senior operator licenses.

(a) *Issuance of operator and senior operator licenses.* If the Commission determines that an applicant for an operator license or a senior operator license demonstrates compliance with the requirements of the Atomic Energy Act of 1954, as amended, (the Act) and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary.

(b) *Modification and revocation of operator and senior operator licenses.*

(1) The terms and conditions of all operator and senior operator licenses are subject to amendment, revision, or modification by reason of rules, regulations, or orders issued in accordance with the Act or any amendments thereto.

(2) Any license may be revoked, suspended, or modified, in whole or in part—

(i) For any material false statement in the application or in any statement of fact required under section 182 of the Act;

(ii) Because of conditions revealed by the application or statement of fact or any report, record, inspection, or other means that would warrant the Commission to refuse to grant a license on an original application;

(iii) For willful violation of, or failure to observe, any of the terms and conditions of the Act or the license, or of any rule, regulation, or order of the Commission;

(iv) For any conduct determined by the Commission to be a hazard to safe operation of the facility; or

(v) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.785(i) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.

§ 53.795 Expiration and renewal of operator and senior operator licenses.

(a) *Expiration*.

(1) Each operator license and senior operator license expires 6 years after the date of issuance, upon termination of employment with the facility licensee, or upon determination by the facility licensee that the licensed individual no longer needs to maintain a license.

(2) If a licensee files an application for renewal or an upgrade of an existing license on NRC Form 398 at least 30 days before the expiration of the existing license, it does not expire until disposition of the application for renewal or for an upgraded license has been finally determined by the Commission. Filing by mail will be deemed to be complete at the time the application is postmarked

(b) *Renewal*.

(1) The applicant for renewal of an operator license or senior operator license must—

(i) Complete and sign NRC Form 398 and include the number of the license for which renewal is sought.

(ii) File an original of NRC Form 398 as specified in § 53.775.

(iii) Provide written evidence of the applicant’s experience under the existing license and the approximate number of hours that the licensee has operated the facility.

(iv) Provide a statement by an authorized representative of the facility licensee that during the effective term of the current license the applicant has satisfactorily completed the requalification program for the facility for which operator or senior operator license renewal is sought.

(v) Provide evidence that the applicant has discharged the license responsibilities competently and safely. The Commission may accept as evidence of the applicant's having met this requirement a certificate of an authorized representative of the facility licensee or holder of an authorization by which the licensee has been employed.

(vi) Provide certification by the facility licensee of medical condition and general health on NRC Form 396, to comply with § 53.765.

(2) The license will be renewed if the Commission finds that—

(i) The medical condition and the general health of the licensee continue to be such as not to cause operational errors that endanger public health and safety. The Commission will base this finding upon the certification by the facility licensee as described in § 53.765(b).

(ii) The licensee –

(A) Is capable of continuing to competently and safely assume licensed duties;

(B) Has successfully completed a requalification program that has been approved by the Commission as required by § 53.780(c); and

(C) Has passed the requalification examinations as required by § 53.780(c).

(iii) There is a continued need for an operator to operate or for a senior operator to supervise operators at the facility designated in the application.

(iv) The past performance of the licensee has been satisfactory to the Commission. In making its finding, the Commission will include in its evaluation information such as notices of violations or letters of reprimand in the licensee's docket.

§ 53.800 Facility licensees for self-reliant-mitigation facilities.

(a) A commercial nuclear plant is a self-reliant-mitigation facility if the NRC determined as part of its approval of the OL or COL for that plant that its design demonstrates compliance with the criteria in paragraphs (a)(1) though (a)(5) of this section. A self-reliant-mitigation facility is of a class, based upon the similarity of operating and technical characteristics of the plants in the class, such that its licensee must comply with the requirements of §§ 53.800 through 53.820 in lieu of those in §§ 53.760 through 53.795.

(1) The safety performance criteria of §§ 53.210 and 53.220 must be met without reliance upon human action for credited event mitigation.

(2) The results of the probabilistic risk assessment (PRA), other systematic risk evaluations, or a combination thereof required by § 53.450(a) must demonstrate that the evaluation criteria for the events analyzed in accordance with § 53.450 will be met without reliance on human actions to achieve acceptable event mitigation.

(3) The functional requirements analysis and function allocation performed under § 53.730(d) must demonstrate that functions required for safety are not reliant upon credited human action.

(4) The plant response to events analyzed under § 53.450 must rely exclusively on safety features and characteristics that will neither be rendered unavailable by credible human errors of commission or omission nor credibly require manual human operation in response to equipment failures. Compliance with this paragraph (a)(4) may be achieved through the use of SSCs that function through inherent characteristics or that have engineered protections against human failures.

(5) Assessments of credited human actions within the analysis of design-basis accidents (DBAs) and across the range of LBEs other than DBAs do not identify important human actions needed to ensure appropriate defense in depth is provided, as required by § 53.250.

(b) [Reserved]

§ 53.805 Facility licensee requirements related to generally licensed reactor operators.

(a) Licensees for self-reliant-mitigation facilities that have not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070 must demonstrate compliance with the following requirements:

(1) Ensure that, in addition to being qualified to perform those items identified by the facility-specific systems approach to training conducted under § 53.815, generally licensed reactor operators are qualified to safely and competently—

(i) Perform administrative tasks, including compliance with technical specifications, and perform operability determinations;

(ii) Implement maintenance and configuration controls;

(iii) Comply with radioactive release limitations;

(iv) Understand plant operating data, including reactor parameters, and evaluate emergency conditions;

(v) Initiate a reactor shutdown from necessary locations;

(vi) Dispatch and direct operations and maintenance personnel;

(vii) Implement any applicable responsibilities under the facility emergency plan; and

(viii) Make required notifications to local, State, participating Tribal, and Federal authorities.

(2) Develop, implement, and maintain facility technical specifications that provide the necessary administrative controls to ensure the implementation of the requirements in this section.

(3) Develop, implement, and maintain the generally licensed reactor operator training, examination, and proficiency programs required under § 53.815.

(4) Ensure that generally licensed reactor operators are subject to the facility's generally licensed reactor operator training, examination, and proficiency programs required under § 53.815. Ensure that generally licensed reactor operators are subject to and comply with the applicable programmatic requirements for personnel required under 10 CFR parts 26 and 73. An individual that is not in compliance with any of these programs is not qualified to be in a position that may involve the manipulation of the controls of the commercial nuclear plant.

(5) Report annually to the NRC the identity of all generally licensed reactor operators at the commercial nuclear plant, including all additions and deletions since the previous report.

(6) Ensure that the facility design continues to meet the criteria of § 53.800.

(b) [Reserved]

§ 53.810 Generally licensed reactor operators.

(a) A general license to manipulate the controls of a self-reliant-mitigation facility and to direct the licensed activities of generally licensed reactor operators is hereby issued to any individual employed in a position that may involve the manipulation of the controls of that self-reliant-mitigation facility and who observes the restrictions of this section.

(b) A generally licensed reactor operator must comply with the operating procedures and other conditions specified in the license authorizing operation of the facility.

(c) The general license is limited to the facility or facilities at which the operator is employed.

(d) The Commission will suspend the general license on an individual operator basis for violations of any provision of the Act or any rule or regulation issued thereunder whenever the Commission deems such suspension desirable, including—

(1) For willful violation of, or failure to observe, any of the terms and conditions of the Act or the general license, or of any rule, regulation, or order of the Commission;

(2) For any conduct determined by the Commission to be a hazard to safe operation of the facility; or

(3) For the sale, use, or possession of illegal drugs, or refusal to participate in the facility drug and alcohol testing program, or a confirmed positive test for drugs, drug metabolites, or alcohol in violation of the conditions and cutoff levels established by § 53.810(f) or the consumption of alcoholic beverages within the protected area of commercial nuclear plants, or a determination of unfitness for scheduled work as a result of the consumption of alcoholic beverages.

(e) The Commission may require information from a generally licensed reactor operator to determine whether a general license should be revoked or suspended with respect to that operator.

(f) The generally licensed reactor operator must not consume or ingest alcoholic beverages within the protected area of commercial nuclear plants. The generally licensed reactor operator must not use, possess, or sell any illegal drugs. The generally licensed reactor operator must not perform activities requiring a general license while under the influence of alcohol or any prescription, over-the-counter, or illegal substance that could adversely affect his or her ability to safely and competently perform these activities. For the purpose of this paragraph (f), with respect to alcoholic beverages and drugs, the term "under the influence" means the generally licensed reactor operator exceeded, as evidenced by a confirmed test result, the lower of the cutoff levels for drugs or alcohol contained in 10 CFR part 26, or as established by the facility licensee.

The term “under the influence” also means the generally licensed reactor operator could be mentally or physically impaired as a result of substance use including prescription and over-the-counter drugs, as determined under the provisions, policies, and procedures established by the facility licensee for its fitness-for-duty program, in such a manner as to adversely affect his or her ability to safely and competently perform generally licensed reactor operator duties.

(g) The generally licensed reactor operator must notify the Commission within 30 days about a conviction for a felony.

§ 53.815 Generally licensed reactor operator training, examination, and proficiency programs.

(a) *Applicability*. The requirements of this section apply to each licensee of a self-reliant-mitigation facility that has not yet certified the permanent cessation of operations and permanent removal of fuel from the reactor vessel as described under § 53.1070.

(b) *Requirements*.

(1) The facility licensee must develop, implement, and maintain training and examination programs that demonstrate compliance with the requirements of paragraphs (b)(2) through (b)(3) of this section.

(2) The training program must provide for both the initial and continuing training of generally licensed reactor operators and be derived from a systems approach to training as defined in this part.

(3)(i) The training program must incorporate the instructional requirements necessary to provide qualified generally licensed reactor operators to operate and maintain the facility in a safe manner in all modes of operation. The training program must comply with the facility license, including all technical specifications and applicable regulations. The facility licensee must periodically evaluate and revise the training program as appropriate to reflect industry experience and relevant changes, including

changes to the facility, procedures, regulations, and quality assurance (QA) requirements. Facility licensee management must periodically review the training program for effectiveness.

(ii) The training program must ensure that generally licensed reactor operators have and maintain the necessary knowledge, skills, and abilities.

(iii) The training program must include the generally licensed reactor operator manipulating the controls of either the facility or a simulation facility that demonstrates compliance with the requirements of § 53.815(e).

(iv) The training program must include an initial examination program for testing a representative sample of the knowledge, skills, and abilities needed to safely perform generally licensed reactor operator duties, to include both the examination methods and criteria to be used to assess passing performance. The facility licensee must provide the opportunity for a representative of the Commission to be present during initial examination administration.

(v) The training program must include a requalification examination program for testing a sample of the topics included under the systems approach to training, to include the examination methods and criteria to be used to assess passing performance. The requalification examination program must specify an appropriate periodicity for administering a complete requalification examination to each generally licensed reactor operator, and the facility licensee must provide the opportunity for a representative of the Commission to be present during requalification examination administration.

(A) The facility licensee must ensure that any generally licensed reactor operator who either demonstrates unsatisfactory performance on, or fails to complete, the requalification examination is removed from the performance of generally licensed reactor operator duties until such time that any necessary remedial training has been completed and a retake examination has been passed.

(B) [Reserved]

(vi) The training program must be approved by the Commission prior to its use, as described under § 53.730(g). The examination program must provide for valid and reliable examinations and must be approved by the Commission prior to their use, as described under § 53.730(g). The approved programs are subject to the requirements of § 53.1565.

(c) *Records.* The following is required regarding the documentation of the generally licensed reactor operator training and examination programs:

(1) Sufficient records must be maintained by the facility licensee to maintain the integrity of the programs and kept available for NRC inspection to verify the adequacy of the programs.

(2) The facility licensee must maintain records documenting the participation of each generally licensed reactor operator in the training and examination programs. The records must contain copies of examinations administered, the answers given by the generally licensed reactor operator, documentation of the grading of examinations, and documentation of any additional training administered in areas in which a generally licensed reactor operator exhibited deficiencies. The facility licensee must retain these records while the associated generally licensed reactor operators remain employed at the facility.

(3) Each record required by this part must be legible throughout the retention period. The record may be the original, a reproduced copy, or an electronic copy provided that the copy is authenticated by authorized personnel.

(d) *Examination integrity.* Generally licensed reactor operators and facility licensees must not engage in any activity that compromises the integrity of any examination conducted under the generally licensed reactor operator training and examination programs. The integrity of an examination is considered compromised if any

activity, regardless of intent, affected, or, but for detection, could have affected the consistent administration of the examination. This includes all activities related to the preparation, administration, and grading of examinations.

(e) *Simulation facilities.*

(1) Simulation facilities used for training purposes, for maintaining proficiency, or for the conduct of examinations must demonstrate compliance with the following criteria as they relate to the facility licensee's reference plant:

(i) The simulation facility must be of sufficient scope and fidelity for individuals to acquire and demonstrate the necessary knowledge, skills, and abilities to safely perform generally licensed reactor operator duties.

(ii) The simulation facility must utilize models relating to nuclear, thermal-hydraulic, and other applicable design-specific characteristics that either replicate the most recent fuel load in the reference commercial nuclear plant or, prior to initial fuel load (or, for a fueled manufactured reactor, prior to initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), replicate the intended initial fuel load for the reference commercial nuclear plant, with the exception of those portions of the simulation facility that utilize the reference plant itself.

(iii) Simulator fidelity must be demonstrated so that significant control manipulations are completed without procedural exceptions, simulator performance exceptions, or deviation from the approved training scenario sequence.

(2) Facility licensees that maintain a simulation facility for training purposes, for maintaining proficiency, or for the conduct of examinations must—

(i) Conduct performance testing throughout the life of the simulation facility in a manner sufficient to ensure that paragraph (e)(1) of this section is met;

(ii) Retain the results of performance testing for 4 years after the completion of each performance test or until superseded by updated test results;

(iii) Promptly correct modeling and hardware discrepancies and discrepancies identified from scenario validation and from performance testing or provide justification for why the presence of such discrepancies will not adversely affect the criteria of paragraph (e)(1) of this section;

(iv) Make the results of any uncorrected performance test failures that may exist at the time of an inspection available for NRC review; and

(v) Maintain the provisions for examination integrity consistent with § 53.815(d).

(f) *Waiver of examination requirement*. The facility licensee may waive any or all of the requirements for an examination in accordance with the facility licensee's Commission-approved generally licensed reactor operator training and examination programs.

(g) *Proficiency.* The facility licensee must develop, implement, and maintain a proficiency program to allow generally licensed reactor operators to maintain proficiency regarding position functions and familiarity with plant status. This program must include those steps that will be taken in order to re-establish proficiency when it cannot be maintained.

§ 53.820 Cessation of individual applicability.

The general license ceases to be applicable on an individual basis once a generally licensed reactor operator is no longer being employed in a position that may involve the manipulation of the controls of the self-reliant mitigation facility.

§ 53.830 Training and qualification of commercial nuclear personnel.

(a) This section addresses personnel training requirements. The regulations within this section are applicable to all applicants for or holders of OLs or COLs under this part.

(b) Prior to initial fuel load (or, for a fueled manufactured reactor, prior to initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), each

holder of an operating or COL under this part must, with sufficient time to provide trained and qualified personnel to operate the facility, establish, implement, and maintain a training program that demonstrates compliance with the requirements of paragraphs (c) and (d) of this section.

(c) The training program must be derived from a systems approach to training as defined in this part and must provide, at a minimum, for the training and qualification of the following categories of commercial nuclear personnel:

(1) Supervisors (e.g., shift supervisors);

(2) Technicians (e.g., maintenance, chemistry, and radiological); and

(3) Other appropriate operating personnel (e.g., auxiliary operators, certified fuel handlers, and individuals who provide engineering expertise to on-shift operating personnel).

(d) The training program must incorporate the instructional requirements necessary to provide qualified personnel to operate components of a commercial nuclear plant and maintain the facility in a safe manner in all modes of operation. The training program must be developed to be in compliance with the facility license, including all technical specifications and applicable regulations.

(1) The training program must be periodically evaluated and revised as appropriate to reflect industry experience and relevant changes, including changes to the facility, procedures, regulations, and QA requirements. The training program must be periodically reviewed by facility licensee management for effectiveness.

(2) Sufficient records must be maintained by the facility licensee to maintain program integrity and kept available for NRC inspection to verify the adequacy of the training program.

§ 53.845 Programs.

(a) The required plant programs under this part must include but are not necessarily limited to the programs described in the following sections of this subpart. Licensees may combine, separate, and otherwise organize programs and related documents as appropriate for the technologies and organizations associated with the commercial nuclear plant.

(b) In addition to the programs described in the following sections, programs must be provided for each commercial nuclear plant, if necessary, to ensure that the performance of design features and human actions are consistent with the analyses performed under §§ 53.450 and 53.730 and that the plant will demonstrate compliance with the safety criteria defined in §§ 53.210 and 53.220.

§ 53.850 Radiation protection.

(a) Each holder of an OL or COL under this part must develop, implement, and maintain a Radiation Protection Program for operations that is commensurate with the scope and extent of licensed activities under this part and includes measures for limiting and monitoring radioactive plant effluents and limiting and monitoring the dose to individuals working with radioactive materials in accordance with 10 CFR part 20.

(b) Each holder of an OL or COL under this part must develop, implement, and maintain a program for the control of radioactive effluents and for environmental monitoring. The program must be contained in an Offsite Dose Calculations Manual, must be implemented by procedures, and must include remedial actions to be taken whenever the program limits are exceeded. The Offsite Dose Calculations Manual must—

(1) Contain the methodology and parameters used in the calculation of offsite doses resulting from radioactive gaseous and liquid effluents, in the calculation of gaseous and liquid effluent monitoring alarm and trip setpoints, and in the conduct of the radiological environmental monitoring program; and

(2) Contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the Annual Radiological Environmental Operating and Radioactive Effluent Release Reports required by § 53.1645.

(c) Each holder of an OL or COL under this part must develop, implement, and maintain a Process Control Program that identifies the administrative and operational controls for solid radioactive waste processing, process parameters, and surveillance requirements sufficient to ensure compliance with the requirements of 10 CFR part 20, 10 CFR part 61, and 10 CFR part 71.

§ 53.855 Emergency preparedness.

(a) Each holder of an OL or COL under this part must have an emergency response plan that must contain information needed to demonstrate compliance with either the requirements in § 50.160 of this chapter or the requirements in appendix E to part 50 and the planning standards of § 50.47(b) of this chapter.

(b) No initial OL, initial COL, or early site permit that includes complete and integrated emergency plans will be issued under this part unless a finding is made by the NRC, in accordance with § 50.47 of this chapter, that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

§ 53.860 Security programs.

(a) *Physical protection program.* Each holder of an OL or COL under this part must develop, implement, and maintain a physical protection program under the following requirements:

(1) The licensee must implement security requirements for the protection of special nuclear material based on the type, enrichment, and quantity in accordance with 10 CFR part 73, as applicable, and implement security requirements for the

protection of Category 1 and Category 2 quantities of radioactive material in accordance with 10 CFR part 37, as applicable; and

(2) The licensee must demonstrate compliance with the provisions set forth in either § 73.55 or § 73.100 of this chapter.

(b) *Fitness-for-duty*. Each holder of an OL or COL under this part must develop, implement, and maintain a fitness-for-duty program under 10 CFR part 26.

(c) *Access authorization*. Each holder of an OL or COL under this part must develop, implement, and maintain an access authorization program under § 73.56 or § 73.120 of this chapter, as applicable.

(d) *Cybersecurity*. Each holder of an OL or COL under this part must develop, implement, and maintain a cybersecurity program under § 73.54 or § 73.110 of this chapter.

(e) *Information security*. Each holder of an OL or COL under this part must develop, implement, and maintain an information protection system under §§ 73.21, 73.22, and 73.23 of this chapter, as applicable.

§ 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. A written quality assurance program manual must be developed and used to guide the conduct of the program.

§ 53.870 Integrity assessment programs.

Each holder of an OL or COL under this part must develop, implement, and maintain an integrity assessment program to monitor, evaluate, and manage—

(a) The effects of plant aging on SR and NSRSS SSCs. The program may refer to surveillances, tests, and inspections conducted for specific SSCs in accordance with

other requirements in this part or conducted in accordance with applicable consensus codes and standards endorsed or otherwise found acceptable by the NRC;

(b) Cyclic or transient load limits to ensure that SR and NSRSS SSCs are maintained within the applicable design limits; and

(c) Degradation mechanisms related to chemical interactions, operating temperatures, effects of irradiation, and other environmental factors to ensure that the capabilities, availability, and reliability of SR and NSRSS SSCs demonstrate compliance with the functional design criteria of §§ 53.410 and 53.420.

§ 53.875 Fire protection.

(a)(1) Each holder of an OL or COL under this part must have a fire protection plan that describes the overall fire protection program for the facility; identifies the various positions within the licensee's organization that are responsible for the program; states the authorities that are delegated to each of these positions to implement those responsibilities; and outlines the plans for fire protection, fire detection and suppression capability; and limitation of fire damage.

(2) The fire protection plan must also describe specific features necessary to implement the program described in paragraph (a)(1) of this section such as the following: administrative controls and personnel requirements for fire prevention and manual fire suppression activities; automatic and manually operated fire detection and suppression systems; and the means to limit fire damage to SSCs so that the capability to demonstrate compliance with the requirements of § 53.210 is ensured.

(b)(1) Each holder of an OL or COL under this part must develop a performance-based or deterministic fire protection program that demonstrates compliance with the safety criteria outlined in §§ 53.210 and 53.220, related safety functions outlined in § 53.230, and defense in depth as outlined in § 53.250 with specific fire protection measures related to fire prevention, fire detection, and fire suppression.

(2) The fire protection program must comply with the following:

(i) Safety-related and, where appropriate, NSRSS SSCs must be designed, located, and maintained to minimize, consistent with other safety requirements, the probability and effect of fires and explosions.

(ii) Noncombustible and fire-resistant materials must be used wherever practical throughout the facility, particularly in locations with SR and NSRSS SSCs.

(iii) Fire detection and fire suppression systems of appropriate capacity and capability must be provided and designed and maintained to minimize the adverse effects of fires on SR and NSRSS SSCs.

(iv) Fire suppression systems must be designed and maintained to ensure that their rupture or inadvertent operation does not significantly impair the ability of SR and NSRSS SSCs to perform their safety functions to satisfy § 53.230.

§ 53.880 Inservice inspection and inservice testing.

(a) Each holder of an OL or COL under this part must develop, implement, and maintain a program for inservice inspection (ISI) and inservice testing (IST) prior to receiving an OL or COL. The ISI/IST programs must, wherever applicable, be in accordance with generally accepted consensus codes and standards that have been endorsed or otherwise found acceptable by the NRC. The ISI/IST program must include all inspections and tests required by the codes and standards used in the design and be supplemented by risk insights that identify the most important SSCs to plant safety. The types of testing and inspections and their frequency should be informed by risk insights to maintain the reliability and performance of SSCs consistent with the associated design and analyses activities involving those SSCs. Risk insights must also be used to determine when to conduct the inspections and tests (e.g., full power, shutdown, refueling) to minimize risk to the plant workers and the public. The ISI/IST program must

be documented in a written manual and managed by qualified personnel reporting to the director, responsible officer, or designated person.

(b) Prior to plant operation, baseline inspections and testing must be performed using the same techniques as will be used for future inspections and testing. The results of these inspections and testing must be used as benchmarks for evaluating the results of future inspections and testing. Sufficient room and support must be provided to accommodate the personnel, ISI/IST equipment, and shielding necessary to perform the inspections and testing. Acceptance criteria for determining whether corrective action is needed must be developed (or taken from the codes and standards used in the design) for evaluating the results of the inspections and testing. The results of the inspections and testing must be provided to the director, responsible officer, or designated person who is responsible for determining what, if any, corrective action is needed and when it should be taken. The ISI/IST results and corrective actions must be documented and the documentation retained for the life of the plant.

§ 53.910 Procedures and guidelines.

(a) Each holder of an OL or COL under this part must have a program for developing, implementing, and maintaining an integrated set of procedures, guidelines, and related supporting activities to support normal operations and respond to possible unplanned events.

(b) The program required by paragraph (a) of this section must include but is not limited to development, implementation, maintenance, and supporting activities of procedures and guidelines for the following:

(1) Plant operations;

(2) Maintenance activities under § 53.715;

(3) Program requirements under this subpart;

(4) Emergency operating procedures, if developed to address the role of human actions in responding to LBEs;

(5) Accident management guidelines, if developed to address the role of human actions in responding to LBEs;

(6) Procedures for each area in which licensed special nuclear material is handled, used, or stored to protect personnel upon the sounding of a criticality alarm required by § 53.440(m); and

(7) Procedures that describe how the licensee will address the following areas if the licensee is notified of a potential aircraft threat:

(i) Verification of the authenticity of threat notifications;

(ii) Maintenance of continuous communication with threat notification sources;

(iii) Contacting all onsite personnel and applicable offsite response organizations;

(iv) Onsite actions necessary to enhance the capability of the facility to mitigate the consequences of an aircraft impact;

(v) Measures to reduce visual discrimination of the site relative to its surroundings or individual buildings within the protected area;

(vi) Dispersal of equipment and personnel, as well as rapid entry into site protected areas for essential onsite personnel and offsite responders who are necessary to mitigate the event; and

(vii) Recall of site personnel.

Subpart G—Decommissioning Requirements

§ 53.1000 Scope and purpose.

This subpart defines the requirements related to decommissioning for applicants for, or holders of, an operating license (OL) or combined license (COL). The requirements related to maintaining financial assurance for decommissioning are in §§ 53.1010 through 53.1060. The requirements for transitioning from operations to

decommissioning and for the release of property and termination of the license are in §§ 53.1070 through 53.1080.

§ 53.1010 Financial assurance for decommissioning.

(a) This section establishes requirements for indicating to the U.S. Nuclear Regulatory Commission (NRC) how an applicant for or holder of an OL or COL under this part will provide reasonable assurance that funds will be available for the decommissioning process. Reasonable assurance consists of a series of steps as provided in paragraph (b) of this section and §§ 53.1020, 53.1030 and 53.1040. Funding for the decommissioning of commercial nuclear plants may also be subject to the regulation of Federal or State government agencies (e.g., Federal Energy Regulatory Commission (FERC) and State Public Utility Commissions) that have jurisdiction over rate regulation. The requirements of this subpart, in particular § 53.1020, are in addition to, and not a substitution for, other requirements, and are not intended to be used by themselves or by other agencies to establish rates.

(b) Each applicant for an OL or COL under this part must prepare a plan and an associated decommissioning report that ensures and documents that adequate funding will be available to decommission the facility. Each holder of an OL or COL must implement and maintain the plan.

(1)(i) Before the Commission issues an OL under this part, the applicant must update the decommissioning report to certify that it has provided financial assurance for decommissioning in the amount proposed in the application and approved by the NRC under § 53.1020.

(ii) No later than 30 days after the Commission issues the notice of intended operation under § 53.1452 for a COL under this part, the licensee must update the decommissioning report to certify that it has provided financial assurance for

decommissioning in the amount proposed in the application and approved by the NRC under § 53.1020.

(2) The amount of financial assurance for decommissioning to be provided must be based on a site-specific cost estimate for decommissioning the facility under § 53.1020.

(3) The amount of financial assurance for decommissioning to be provided must be adjusted annually using a rate at least equal to that stated in § 53.1030.

(4) The amount of financial assurance for decommissioning to be provided must be covered by one or more of the methods described in § 53.1040 as acceptable to the NRC. A copy of the financial instrument obtained to satisfy the requirements of § 53.1040 must be submitted to the NRC as part of the application for an OL under this part; however, an applicant for or holder of a COL need not obtain such financial instrument or submit a copy to the Commission except as provided in § 53.1060(b).

§ 53.1020 Cost estimates for decommissioning.

Cost estimates for decommissioning must be site-specific. Site-specific decommissioning cost estimates (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.

§ 53.1030 Annual adjustments to cost estimates for decommissioning.

Each holder of an OL or COL under this part must annually adjust the cost estimate for decommissioning to account for escalation in labor, energy, and waste burial costs. Licensees may elect to use either a site-specific adjustment factor, approved as part of the plan and associated decommissioning report required by § 53.1010, in paragraph (a) of this section or the generic adjustment factor in paragraph (b) of this section.

(a) A site-specific adjustment factor must address the estimated contributions and escalation of costs for the following aspects of decommissioning:

(1) Labor, materials, and services;

(2) Energy and waste transportation; and

(3) Radioactive waste burial or other disposition.

(b) A generic adjustment factor must be at least equal to 0.65 L + 0.13 E + 0.22 B, 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."

§ 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 licensee assets and outside the administrative control of the 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. A licensee that has prepaid funds based on a site-specific 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. A licensee may use a credit of greater than 2 percent if the licensee's rate-setting authority has specifically authorized a higher rate. 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 licensee assets and outside the administrative control of the 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. A licensee that has collected funds based on a site-specific 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. A licensee may use a credit of greater than 2 percent if the

licensee's rate-setting authority has specifically authorized a higher rate. Actual earnings on existing funds may be used to calculate future fund needs. A 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 a 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 a 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 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 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 a licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the 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 licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. 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.

§ 53.1045 Limitations on the use of decommissioning trust funds.

(a)(1) Decommissioning trust funds may be used by licensees if—

(i) The withdrawals are for expenses for decommissioning activities consistent with the definition of decommission or decommissioning in § 53.020;

(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and

(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

(2) Initially, 3 percent of the amount determined in accordance with § 53.1020 may be used for decommissioning planning. For licensees that have submitted the certifications required under § 53.1070 and commencing 90 days after the NRC has received the post-shutdown decommissioning activities report (PSDAR) required by § 53.1060, an additional 20 percent may be used. An updated site-specific DCE must be submitted to the NRC prior to the licensee using any funding in excess of these amounts.

(b) Licensees that are not "electric utilities" as defined in § 53.020 that use prepayment or an external sinking fund to provide financial assurance must provide in the terms of the arrangements governing the trust, escrow account, or Government fund, used to segregate and manage the funds that—

(1) The trustee, manager, investment advisor, or other person directing investment of the funds—

(i) Is prohibited from investing the funds in securities or other obligations of the licensee or any other owner or operator of any commercial nuclear plant or their affiliates, subsidiaries, successors or assigns, or in a mutual fund in which at least 50 percent of the fund is invested in the securities of a licensee or parent company whose subsidiary is an owner or operator of a foreign or domestic commercial nuclear plant. However, the funds may be invested in securities tied to market indices or other non-nuclear sector collective, commingled, or mutual funds, provided that no more than 10 percent of trust assets may be indirectly invested in securities of any entity owning or operating one or more commercial nuclear plants.

(ii) Is obligated at all times to adhere to a standard of care set forth in the trust, which either shall be the standard of care, whether in investing or otherwise, required by State or Federal law or one or more State or Federal regulatory agencies with jurisdiction over the trust funds, or, in the absence of any such standard of care, whether

in investing or otherwise, that a prudent investor would use in the same circumstances. The term "prudent investor," shall have the same meaning as set forth in FERC's “Regulations Governing Nuclear Plant Decommissioning Trust Funds” at 18 CFR 35.32(a)(3), or any successor regulation.

(2) The licensee, its affiliates, and its subsidiaries are prohibited from being engaged as investment manager for the funds or from giving day-to-day management direction of the funds’ investments or direction on individual investments by the funds, except in the case of passive fund management of trust funds where management is limited to investments tracking market indices.

(3) The trust, escrow account, Government fund, or other account used to segregate and manage the funds may not be amended in any material respect without written notification to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the proposed effective date of the amendment. The licensee must provide the text of the proposed amendment and a statement of the reason for the proposed amendment. The trust, escrow account, Government fund, or other account may not be amended if the person responsible for managing the trust, escrow account, Government fund, or other account receives written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period.

(4) Except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a disbursement or

payment has been given to the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30 working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.1040 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(c) Licensees that are "electric utilities" under § 53.020 that use prepayment or an external sinking fund to provide financial assurance must include a provision in the terms of the trust, escrow account, Government fund, or other account used to segregate and manage funds that except for withdrawals being made under paragraph (a) of this section or for payments of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, no disbursement or payment may be made from the trust, escrow account, Government fund, or other account used to segregate and manage the funds until written notice of the intention to make a

disbursement or payment has been given the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, at least 30 working days before the date of the intended disbursement or payment. The disbursement or payment from the trust, escrow account, Government fund or other account may be made following the 30 working day notice period if the person responsible for managing the trust, escrow account, Government fund, or other account does not receive written notice of objection from the Director, Office of Nuclear Reactor Regulation, or Director, Office of Nuclear Material Safety and Safeguards, as applicable, within the notice period. Disbursements or payments from the trust, escrow account, Government fund, or other account used to segregate and manage the funds, other than for payment of ordinary administrative costs (including taxes) and other incidental expenses of the fund (including legal, accounting, actuarial, and trustee expenses) in connection with the operation of the fund, are restricted to decommissioning expenses or transfer to another financial assurance method acceptable under § 53.1040 until final decommissioning has been completed. After decommissioning has begun and withdrawals from the decommissioning fund are made under paragraph (a) of this section, no further notification need be made to the NRC.

(d) A licensee that is not an "electric utility" under § 53.020 and using a surety method, insurance, or other guarantee method to provide financial assurance must provide that the trust established for decommissioning costs to which the surety or insurance is payable contains in its terms the requirements in § 53.1045(b)(1) through (b)(4).

§ 53.1050 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure a 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 licensee's State Public Utility Commission, take additional actions as appropriate on a case-by-case basis, including modification of a licensee's schedule for the accumulation of decommissioning funds.

§ 53.1060 Reporting and recordkeeping requirements.

(a) Each holder of an OL under this part or holder of a COL under this part after the date that the Commission has made the finding under § 53.1452(g) must report, at least once every 2 years, by March 31, on the status of its certification of decommissioning funding for each commercial nuclear reactor or part of a commercial nuclear reactor that it owns. The information in this report must include, at a minimum, the amount of decommissioning funds estimated to be required under §§ 53.1020 and 53.1030; the amount of decommissioning funds accumulated to the end of the calendar year preceding the date of the report; a schedule of the annual amounts remaining to be collected; the assumptions used regarding rates of escalation in decommissioning costs, rates of earnings on decommissioning funds, and rates of other factors used in funding projections; any contracts upon which the licensee is relying under § 53.1040(e); any modifications occurring to a licensee's method of providing financial assurance since the last submitted report; and any material changes to trust agreements. If any of the preceding items is not applicable, the licensee should so state in its report. Any licensee for a plant that is within 5 years of the projected end of its operation, or where conditions have changed such that it will close within 5 years (before the end of its licensed life), or that has already closed (before the end of its licensed life), or that is involved in a merger or an acquisition must submit this report annually.

(b) Each holder of a COL under this part must, 2 years before and 1 year before the scheduled date for initial loading of fuel (or, for a fueled manufactured reactor, 2 years before and 1 year before the scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1)) submit a report to the NRC

containing a certification updating the DCEs and a copy of the financial instrument to be used to satisfy § 53.1040. No later than 30 days after the Commission publishes notice in the *Federal Register* under § 53.1452(a), the licensee must submit an updated decommissioning report required under § 53.1010(b)(1)(ii), including a copy of the financial instrument obtained to satisfy § 53.1040.

(c) Each licensee must keep records of information important to the safe and effective decommissioning of the facility in an identified location until the license is terminated by the Commission. If records of relevant information are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when significant contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored and of locations of possible inaccessible contamination such as buried pipes that may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee must substitute appropriate records of available information concerning these areas and locations.

(3) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(4) Records of—

(i) The licensed site area, as originally licensed and any revisions, which must include a site map and any acquisition or use of property outside the originally licensed site area for the purpose of receiving, possessing, or using licensed materials;

(ii) The licensed activities carried out on the acquired or used property; and

(iii) The release and final disposition of any property recorded in paragraph (c)(4)(i) of this section, the historical site assessment performed for the release, radiation surveys performed to support release of the property, submittals to the NRC made under § 53.1070, and the methods employed to ensure that the property met the radiological criteria of subpart E of 10 CFR part 20 at the time the property was released.

(d) Each holder of an OL or COL under this part must at or about 5 years prior to the projected end of operations submit a preliminary DCE which includes an up-to-date assessment of the major factors that could affect the cost to decommission.

(e) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a PSDAR to the NRC, and a copy to the affected State(s). The PSDAR must contain a description of the planned decommissioning activities along with a schedule for their accomplishment, a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements, and a site-specific DCE, including the projected cost of managing irradiated fuel.

(f) For decommissioning activities that delay completion of decommissioning by including a period of storage or surveillance, the licensee must provide a means of adjusting cost estimates and associated funding levels over the storage or surveillance period.

(g) After submitting its site-specific DCE required by paragraph (e) of this section, and until the licensee has completed its final radiation survey and demonstrated that residual radioactivity has been reduced to a level that permits termination of its license, the licensee must annually submit to the NRC, by March 31, a financial assurance status report. The report must include the following information, current through the end of the previous calendar year:

(1) The amount spent on decommissioning, both cumulative and over the previous calendar year, the remaining balance of any decommissioning funds, and the amount provided by other financial assurance methods being relied upon;

(2) An estimate of the costs to complete decommissioning, reflecting any difference between actual and estimated costs for work performed during the year, and the decommissioning criteria upon which the estimate is based;

(3) Any modifications occurring to a licensee's current method of providing financial assurance since the last submitted report; and

(4) Any material changes to trust agreements or financial assurance contracts.

(5) If the sum of the balance of any remaining decommissioning funds, plus earnings on such funds calculated at not greater than a 2 percent real rate of return, together with the amount provided by other financial assurance methods being relied upon, does not cover the estimated cost to complete the decommissioning, the financial assurance status report must include additional financial assurance to cover the estimated cost of completion.

(h) After submitting its site-specific DCE required by paragraph (e) of this section, the licensee must annually submit to the NRC, by March 31, a report on the status of its funding for managing irradiated fuel. The report must include the following information, current through the end of the previous calendar year:

(1) The amount of funds accumulated to cover the cost of managing the irradiated fuel;

(2) The projected cost of managing irradiated fuel until title to the fuel and possession of the fuel is transferred to the Secretary of Energy; and

(3) If the funds accumulated do not cover the projected cost, a plan to obtain additional funds to cover the cost.

§ 53.1070 Termination of license.

For each holder of an OL or COL under this part—

(a)(1) When the licensee has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.040(b)(8);

(2) When appropriate to support decommissioning activities and the eventual permanent removal of fuel from the reactor vessel, the licensee must develop defueled technical specifications by reviewing the operational technical specifications and determining which specifications no longer apply during decommissioning and which ones should remain applicable. The licensee must make the appropriate submittals to the NRC in accordance with § 53.1510 to request changes to the technical specifications; and

(3)(i) Once fuel has been permanently removed from the reactor vessel, the licensee must submit a written certification to the NRC that meets the requirements of § 53.040(b)(9); and

(ii) The licensee must establish and maintain staffing consisting of certified fuel handlers, as defined under § 53.020, and other non-licensed personnel with appropriate qualifications, and in sufficient numbers, to ensure support for facility operations and radiological control activities, as required by the facility defueled technical specifications. These personnel must be subject to the training requirements of § 53.830.

(b) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel, or when a final legally effective order to permanently cease operations has come into effect, the license issued under this part no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor vessel.

(c) Decommissioning will be completed within 60 years of permanent cessation of operations. Completion of decommissioning beyond 60 years will be approved by the Commission only when necessary to protect public health and safety. Factors that will be considered by the Commission in evaluating an alternative that provides for completion of decommissioning beyond 60 years of permanent cessation of operations include unavailability of waste disposal capacity and other site-specific factors affecting the licensee's capability to carry out decommissioning, including presence of other nuclear facilities at the site.

(d)(1) Prior to or within 2 years following permanent cessation of operations, the licensee must submit a PSDAR and site-specific DCE in accordance with § 53.1060(e).

(2) The NRC must notice receipt of the PSDAR and make the PSDAR publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee’s facility. The NRC must publish a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(e) Licensees must not perform any major decommissioning activities, as defined in § 53.020, until 90 days after the NRC has received the licensee's PSDAR submittal and until certifications of permanent cessation of operations and permanent removal of

fuel from the reactor vessel, as required under paragraph (a) of this section, have been submitted.

(f) Licensees must not perform any decommissioning activities, as defined in § 53.020, that—

(1) Foreclose release of the site for possible unrestricted use;

(2) Result in significant environmental impacts not previously reviewed; or

(3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

(g) In taking actions permitted under § 53.1540 following submittal of the PSDAR, the licensee must notify the NRC in writing, and send a copy to the affected State(s), before performing any decommissioning activity inconsistent with, or making any significant schedule change from, those actions and schedules described in the PSDAR, including changes that increase the decommissioning cost by more than 20 percent from the previously provided DCE.

(h) Licensees may use decommissioning trust funds consistent with the limitations of § 53.1045(a). Licensees must report on the status of decommissioning trust funds consistent with the requirements of § 53.1060.

(i) Licensees must submit an application for termination of license in accordance with § 53.1070. The application for termination of license must be accompanied or preceded by a license termination plan to be submitted for NRC approval.

(1) The license termination plan must be a supplement to the Final Safety Analysis Report or equivalent and must be submitted at least 2 years before termination of the license date.

(2) The license termination plan must include—

(i) A site characterization;

(ii) Identification of remaining dismantlement activities;

(iii) Plans for site remediation;

(iv) Detailed plans for the final radiation survey;

(v) A description of the end use of the site, if restricted;

(vi) An updated site-specific estimate of remaining decommissioning costs;

(vii) A supplement to the environmental report, pursuant to § 51.53 of this chapter, describing any new information or significant environmental change associated with the licensee's proposed termination activities; and

(viii) Identification of parts, if any, of the facility or site that were released for use before approval of the license termination plan.

(3) Following receipt of the license termination plan, the NRC must make the license termination plan publicly available and publish notice of its availability for public comment in the *Federal Register*. The NRC must also schedule a public meeting readily accessible to individuals in the vicinity of the licensee’s facility upon receipt of the license termination plan. The NRC must publish a notice in the *Federal Register* and in a forum, such as local newspapers, that is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

(j) If the license termination plan demonstrates that the remainder of decommissioning activities will be performed in accordance with the regulations in this chapter, will not be inimical to the common defense and security or to the health and safety of the public, and will not have a significant effect on the quality of the environment and after notice to interested persons, the Commission will approve the plan, by license amendment, subject to such conditions and limitations as it deems appropriate and necessary and authorize implementation of the license termination plan.

(k) The Commission will terminate the license if it determines that—

(1) The remaining dismantlement has been performed in accordance with the approved license termination plan, and

(2) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E of 10 CFR part 20.

§ 53.1075 Program requirements during decommissioning.

(a) Licensees that have submitted the certifications required under § 53.1070 must maintain a decommissioning fire protection program to address the potential for fires that could cause the release or spread of radioactive materials.

(1) The objectives of the decommissioning fire protection program are to

(i) Reasonably prevent these fires from occurring;

(ii) Rapidly detect, control, and extinguish those fires that do occur and that could result in a radiological hazard; and

(iii) Ensure that the risk of fire-induced radiological hazards to the public, environment, and plant personnel is minimized.

(2) The licensee must assess the decommissioning fire protection program on a regular basis. The licensee must revise the decommissioning fire protection program documentation as appropriate throughout the various stages of facility decommissioning.

(3) The licensee may make changes to the decommissioning fire protection program without NRC approval if these changes do not reduce the effectiveness of fire protection for structures, systems, and components that could result in a radiological hazard, taking into account the decommissioning plant conditions and activities.

(b) [Reserved]

§ 53.1080 Release of part of a commercial nuclear plant or site for unrestricted use.

(a) Prior written NRC approval is required to release part of a commercial nuclear plant or site for unrestricted use at any time before receiving approval of a license termination plan. Section 53.1060 specifies recordkeeping requirements associated with partial release. Holders of an OL or COL under this part seeking NRC review and approval must—

(1) Evaluate the effect of releasing the property to ensure that—

(i) The dose to individual members of the public does not exceed the limits and standards of subpart D of 10 CFR part 20;

(ii) There is no reduction in the effectiveness of emergency planning or physical security;

(iii) Effluent releases remain within license conditions;

(iv) The environmental monitoring program and offsite dose calculation manual are revised to account for the changes;

(v) The siting criteria of subpart D of this part continue to be met; and

(vi) All other applicable statutory and regulatory requirements continue to be met.

(2) Perform a historical site assessment of the part of the commercial nuclear plant or site to be released; and

(3) Perform surveys adequate to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402 of this chapter for impacted areas.

(b) For release of non-impacted areas, the licensee may submit a written request for NRC review and approval of the release if a license amendment is not otherwise required. The request submittal must include—

(1) The results of the evaluations performed in accordance with paragraphs (a)(1) and (a)(2) of this section;

(2) A description of the part of the commercial nuclear plant or site to be released;

(3) The schedule for release of the property;

(4) The results of the evaluations performed in accordance with § 53.1540; and

(5) A discussion that provides the reasons for concluding that the environmental impacts associated with the licensee's proposed release of the property will be bounded by appropriate previously issued environmental impact statements.

(c) After receiving a request from the licensee for NRC approval of the release of a non-impacted area, the NRC must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified; and

(3) If determining that the licensee's submittal is adequate, inform the licensee in writing that the release is approved.

(d) For release of impacted areas, the licensee must submit an application for amendment of its license for the release of the property. The application must include—

(1) The information specified in paragraphs (b)(1) through (b)(3) of this section;

(2) The methods used for and results obtained from the radiation surveys required to demonstrate compliance with the radiological criteria for unrestricted use specified in § 20.1402; and

(3) A supplement to the environmental report, under § 51.53 of this chapter.

(e) After receiving a license amendment application from the licensee for the release of an impacted area, the NRC must—

(1) Determine whether the licensee has adequately evaluated the effect of releasing the property as required by paragraph (a)(1) of this section;

(2) Determine whether the licensee's classification of any release areas as non-impacted is adequately justified;

(3) Determine whether the licensee's radiation survey for an impacted area is adequate; and

(4) If determining that the licensee's submittal is adequate, approve the licensee's amendment application.

(f) The NRC must publish notice receipt of the release approval request or license amendment application in the *Federal Register* and make the approval request or license amendment application available for public comment. Before acting on an approval request or license amendment application submitted in accordance with this section, the NRC must conduct a public meeting readily accessible to individuals in the vicinity of the licensee's facility for the purpose of obtaining public comments on the proposed release of part of the commercial nuclear plant or site. The NRC must publish a document in the *Federal Register* and in a forum, such as local newspapers, which is readily accessible to individuals in the vicinity of the site, announcing the date, time, and location of the meeting, along with a brief description of the purpose of the meeting.

Subpart H—Licenses, Certifications, and Approvals

§ 53.1100 Filing of application for licenses, certifications, or approvals; oath or affirmation.

(a) *Serving of applications*.

(1) Each filing of an application for a standard design approval, standard design certification, or license under this part, and any amendments to the applications, must be submitted to the U.S. Nuclear Regulatory Commission (NRC) under § 53.040, as applicable.

(i) Any person, except one excluded by § 53.1118, may file an application for a manufacturing license (ML), combined license (COL), construction permit (CP), or operating license (OL) under this part with the Director, Office of Nuclear Reactor Regulation.

(ii) Any person who may apply for a CP or for a COL under this part, may file an application for an early site permit (ESP) with the Director, Office of Nuclear Reactor Regulation. An application for an early site permit may be filed notwithstanding the fact that an application for a CP or a COL has not been filed in connection with the site for which a permit is sought.

(iii) Any person may submit a proposed standard design for a commercial nuclear plant to the NRC for its review. The submittal may consist of either the final design for the entire facility or the final design for major portions thereof.

(iv) An application for design certification may be filed notwithstanding the fact that an application for a CP, COL, or ML for such a facility has not been filed. The application must comply with §§ 2.811 through 2.819 of this chapter.

(2) Each applicant for a construction permit (CP), early site permit, combined license (COL), or manufacturing license (ML) under this part must, upon notification by the presiding officer designated to conduct the public hearing required by the Atomic Energy Act of 1954, as amended, (the Act) update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the presiding officer. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the NRC as specified in § 53.040, as applicable.

(3) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding and must certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements under this part.

(4) At the time of filing an application, the Commission will make available at the NRC website, https://www.nrc.gov, a copy of the application, subsequent amendments, and other records pertinent to the matter that is the subject of the application for public

inspection and copying.

(5) The serving of copies required by this section must not occur until the application has been docketed under § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 53.040, as applicable, to enable the Director, Office of Nuclear Reactor Regulation to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation*. Each application for a standard design approval, standard design certification, or license, including, whenever appropriate, a CP or early site permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

(c) [Reserved]

(d) [Reserved]

(e) *Filing fees*. Each application for a standard design approval, standard design certification, or commercial nuclear plant license under this part, including, whenever appropriate, a CP, COL, operating license (OL), ML, or early site permit, other than a license exempted from 10 CFR part 170, must be accompanied by the fee prescribed in 10 CFR part 170. No fee will be required to accompany an application for renewal, amendment, or termination of a CP, OL, COL, or ML, except as provided in § 170.21 of this chapter.

(f) *Environmental report*. An application for a CP, OL, early site permit, design certification, COL, or ML for a commercial nuclear plant must be accompanied by an environmental report required under 10 CFR part 51.

§ 53.1101 Requirement for license.

Except as provided in § 53.1120, no person within the United States may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, possess, or

use any utilization facility except as authorized by a license issued by the Commission.

§ 53.1103 Combining applications and licenses.

(a) An applicant may combine several applications in one application for different kinds of licenses under the regulations in this chapter.

(b) The Commission may combine in a single license the activities of an applicant which would otherwise be licensed separately.

§ 53.1106 Elimination of repetition.

An applicant may incorporate by reference in its application information contained in previous applications, statements, or reports filed with the Commission, provided, however, that such references are clear and specific.

§ 53.1109 Contents of applications; general information.

Each application must include, unless otherwise indicated in this subpart—

(a) Name of applicant;

(b) Address of applicant;

(c) Description of business or occupation of applicant;

(d)(1) If applicant is an individual, the citizenship of applicant;

(2) If applicant is a partnership, the name, citizenship and address of each partner and the principal location where the partnership does business;

(3) If applicant is a corporation or an unincorporated association, the following information:

(i) The State where it is incorporated or organized and the principal location where it does business;

(ii) The names, addresses and citizenship of its directors and of its principal officers; and

(iii) Whether it is owned, controlled, or dominated by an alien, a foreign corporation, or foreign government, and if so, give details; or

(4) If the applicant is acting as agent or representative of another person in filing the application, identify the principal and furnish information required under this paragraph (d) with respect to such principal;

(e) The class and type of license applied for, the use to which the facility will be put, the period of time for which the license is sought, and a list of other licenses, except operator's licenses, issued or applied for in connection with the proposed facility;

(f) [Reserved]

(g)(1) Except as provided in paragraph (g)(2) of this section, 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 submit the radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway emergency planning zone (EPZ),[1] and the plans of State governments wholly or partially within the ingestion pathway EPZ.[2] 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 10 miles (16 km) in radius and the ingestion pathway EPZ must consist of an area about 50 miles (80 km) in radius. 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. The size of the EPZs also may be determined on a case-by-case basis for gas-cooled reactors and for reactors with an authorized power level less than 250 megawatt thermal. The plans for the ingestion pathway must focus on such

actions as are appropriate to protect the food ingestion pathway.

(2) Applicants for commercial nuclear plants consisting of either small modular reactors or non-light-water reactors complying with § 50.160 of this chapter who apply for a CP, an OL, a COL, or an early site permit under this part must submit as part of the application the 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) Public dose, as defined in § 20.1003 of this chapter, is projected to exceed 10 millisieverts (1 rem) 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) If the application is for an OL or COL or if the application is for an early site permit and contains plans for coping with emergencies under § 53.1146(b)(2)(ii), and if the plume exposure pathway EPZ extends beyond the site boundary:

(A) The applicant must submit radiological emergency response plans of State, local, and participating Tribal governmental entities in the United States that are wholly or partially within the plume exposure pathway EPZ.

(B) The exact configuration of the plume exposure pathway EPZ surrounding the facility 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.

(iii) If the application is for an early site permit that, under § 53.1146(b)(2)(i), proposes major features of the emergency plans and describes the EPZ, and if the EPZ extends beyond the site boundary, then the exact configuration of the plume exposure pathway EPZ surrounding the facility 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.

(h) [Reserved]

(i) A list of the names and addresses of such regulatory agencies as may have jurisdiction over the rates and services incident to the proposed activity, and a list of trade and news publications which circulate in the area where the proposed activity will be conducted and which are considered appropriate to give reasonable notice of the application to those municipalities, private utilities, public bodies, and cooperatives, which might have a potential interest in the facility; and

(j) If the application contains Restricted Data or classified National Security information, confirmation that all Restricted Data and classified National Security information are separated from the unclassified information.

[1] EPZs are discussed in NUREG–0396, U.S. Environmental Protection Agency 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] If the State, local, and participating Tribal emergency response plans have been previously provided to the NRC for inclusion in the facility docket, the applicant need only provide the appropriate reference to meet this requirement.

§ 53.1112 Environmental conditions.

(a) Each CP, early site permit, and COL under this part may include conditions to address environmental issues during construction. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report submitted pursuant to § 51.50 of this chapter, as analyzed and evaluated in the NRC record of decision and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data, and any conditions and monitoring requirement for the protection of the nonaquatic environment.

(b) Each license authorizing operation of a commercial nuclear plant under this part, and each license for a commercial nuclear plant for which the certification of permanent cessation of operations required under § 53.1070 has been submitted may include conditions to address environmental issues during operation and decommissioning. These conditions are to be set out in an attachment to the license, which is incorporated in and made a part of the license. These conditions will be derived from information contained in the environmental report or the supplement to the environmental report submitted under §§ 51.50 and 51.53 of this chapter as analyzed and evaluated in the NRC record of decision, and will identify the obligations of the licensee in the environmental area, including, as appropriate, requirements for reporting and keeping records of environmental data and any conditions and monitoring requirement for the protection of the nonaquatic environment.

§ 53.1115 Agreement limiting access to classified information.

As part of its application and in any event before the receipt of Restricted Data or classified National Security Information or the issuance of a license or standard design approval under this part, or before the Commission has adopted a final standard design certification rule under this part, the applicant must agree in writing that it will not permit any individual to have access to or any facility to possess Restricted Data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95. The agreement of the applicant becomes part of the license or standard design approval.

§ 53.1118 Ineligibility of certain applicants.

Any person who is a citizen, national, or agent of a foreign country, or any corporation, or other entity which the Commission knows or has reason to believe is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government, will be ineligible to apply for and obtain a license unless—

(a) The Commission determines that issuance of the applicable license to the entity is not inimical to the common defense and security or the health and safety of the public; and

(b) The entity is an alien, corporation, or other entity that is owned, controlled, or dominated by the government of, a corporation that is incorporated in, or an alien who is a citizen or national of Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, or the United Kingdom.

§ 53.1120 Exceptions and exemptions from licensing requirements.

Nothing in this part must be deemed to require a license for—

(a) The manufacture, production, or acquisition by the Department of Defense of any utilization facility authorized pursuant to section 91 of the Act or the use of such facility by the Department of Defense or by a person under contract with and for the account of the Department of Defense;

(b) Except to the extent that the Department of Energy facilities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974, as amended, are involved—

(1)(i) The processing, fabrication or refining of special nuclear material (SNM) or the separation of SNM, or the separation of SNM from other substances by a prime contractor of the Department of Energy under a prime contract for—

(A) The performance of work for the Department of Energy at a United States Government-owned or controlled site;

(B) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(C) The use or operation of a utilization facility in a United States owned vehicle or vessel; or

(ii) The processing, fabrication or refining of SNM of the separation of SNM, or the separation of SNM from other substances by a prime contractor or subcontractor of the Commission or the Department of Energy under a prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or

(2)(i) The construction or operation of a utilization facility for the Department of Energy at a United States Government-owned or controlled site, including the transportation of the utilization facility to or from such site and the performance of contract services during temporary interruptions of such transportation; or the construction or operation of a utilization facility for the Department of Energy in the performance of research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof; or the use or operation of a utilization facility for the Department of Energy in a United States Government-owned vehicle or vessel; provided that such activities are conducted by a prime contractor of the Department of Energy under a prime contract with the Department of Energy; or

(ii) The construction or operation of a utilization facility by a prime contractor or subcontractor of the Commission or the Department of Energy under his or her prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety; or

(c) The transportation or possession of any utilization facility by a common or

contract carrier or warehouse employee in the regular course of carriage for another or storage incident thereto.

§ 53.1121 Public inspection of applications.

Applications and documents submitted to the Commission in connection with applications may be made available for public inspection under the provisions of part 2 of this chapter.

§ 53.1124 Relationship between sections.

(a) *Limited work authorization.* An application for a limited work authorization (LWA) under this part may be submitted as part of an application for an early site permit, CP, or COL under this part as required in § 53.1130(a)(2).

(b) *Early site permit*. (1) A holder of an early site permit may request an LWA.

(2) An application for a CP or COL under this part may, but need not, reference an early site permit.

(c) *Standard design approval.* An application for a standard design approval under this part may, but need not, reference an OL or custom COL under this part that is essentially the same as the information supporting the standard design for which approval is being requested.

(d) *Standard design certification.* An application for a standard design certification under this part may, but need not, reference an OL or custom COL under this part that is essentially the same as the standard design for which certification is being requested.

(e) *Manufacturing license.*

(1) A manufactured reactor or portions thereof as defined in an ML issued under this part may be either transported to and installed at a site for which a COL or CP under this part has been issued or exported in accordance with part 110.

(2) An ML applicant under this part may reference a standard design certification or a standard design approval under this part in its application.

(f) *Construction permit.* An application for a CP may, but need not, reference a standard design certification, standard design approval, or ML issued under this part, respectively, and may also reference an early site permit issued under this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for a CP that references a standard design certification issued under this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(g) *Operating license.*

(1) An application for an OL under this part may, but need not, reference an early site permit, standard design certification, or standard design approval issued under this part. In the absence of a demonstration that an entity other than the one originally sponsoring a standard design certification is qualified to supply a design, the Commission will entertain an application for an OL that references a standard design certification issued under this part only if the entity that sponsored the certification supplies the design for the applicant's use.

(2) The holder of a CP must, at the time of submission of the Final Safety Analysis Report (FSAR), file an application for an OL.

(h) *Combined licenses.* An application for a COL under this part may, but need not, reference an early site permit, standard design certification, standard design approval, or ML issued under this part. In the absence of a demonstration that an entity other than the one originally sponsoring and obtaining a standard design certification is qualified to supply a design, the Commission will entertain an application for a COL that references a standard design certification issued under this part only if the entity that sponsored the certification supplies the design for the applicant's use.

§ 53.1130 Limited work authorizations.

(a) *Request for limited work authorization*.

(1) Any person to whom the Commission may otherwise issue either a license or permit related to a commercial nuclear plant may request an LWA allowing that person to perform the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, and installation of the foundation, including placement of concrete, any of which are for a structure, system, or component (SSC) of the facility for which either a CP or COL is otherwise required under § 53.610.

(2) An application for an LWA may be submitted as part of a complete application for a CP or COL in accordance with § 2.101(a)(1) through (a)(5) of this chapter, or as a partial application in accordance with § 2.101(a)(9) of this chapter. An application for an LWA by the holder of an early site permit must be submitted as a complete application in accordance with § 2.101(a)(1) through (a)(4) of this chapter.

(3) The application must include—

(i) A Safety Analysis Report required by § 53.1146, § 53.1309 or § 53.1416, as applicable, a description of the activities requested to be performed, and the design and construction information otherwise required by the Commission's rules and regulations to be submitted for a CP or COL under this part but limited to those portions of the facility that are within the scope of the LWA. The Safety Analysis Report must demonstrate that activities conducted under the LWA will be conducted in compliance with the technically relevant Commission requirements in 10 CFR chapter I applicable to the design of those portions of the facility within the scope of the LWA;

(ii) An environmental report in accordance with § 51.49 of this chapter; and

(iii) A plan for redress of activities performed under the LWA, should limited work activities be terminated by the holder, or the LWA be revoked by the NRC or upon effectiveness of the Commission's final decision denying the associated CP or COL application, as applicable.

(b) *Issuance of limited work authorization*. (1) The Director, Office of Nuclear Reactor Regulation may issue an LWA only after—

(i) The NRC staff issues the final environmental impact statement for the LWA under part 51 of this chapter;

(ii) The presiding officer makes the finding in § 51.105(c) or § 51.107(d) of this chapter, as applicable;

(iii) The Director determines that the applicable standards and requirements of the Act, and the Commission's regulations applicable to the activities to be conducted under the LWA, have been met, the applicant is technically qualified to engage in the activities authorized, and that issuance of the LWA will provide reasonable assurance of adequate protection to public health and safety and will not be inimical to the common defense and security; and

(iv) The presiding officer finds that there are no unresolved safety issues relating to the activities to be conducted under the LWA that would constitute good cause for withholding the authorization.

(2) Each LWA will specify the activities that the holder is authorized to perform.

(c) *Effect of limited work authorization*. 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 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).

(d) *Implementation of redress plan*. If construction is terminated by the holder, the underlying application is withdrawn by the applicant or denied by the NRC, or the

LWA is revoked by the NRC, then the holder must begin implementation of the redress plan in a reasonable time. The holder must also complete the redress of the site no later than 18 months after termination of construction, revocation of the LWA, or upon effectiveness of the Commission's final decision denying the associated CP application or the associated COL application, as applicable.

§ 53.1140 Early site permits.

Sections 53.1140 through 53.1188 set out the requirements and procedures applicable to Commission issuance of an early site permit under this part for approval of a site for a commercial nuclear plant separate from the filing of an application for a CP or COL for the facility.

§ 53.1144 Contents of applications for early site permits; general information.

The application must contain all of the information required by § 53.1109(a) through (d) and (j).

§ 53.1146 Contents of applications for early site permits; technical information.

(a) The application must contain—

(1) A Site Safety Analysis Report that must include the following:

(i) The specific number, type, and thermal power level of the facilities, or range of possible facilities, for which the site may be used;

(ii) The anticipated maximum levels of radiological and thermal effluents each facility will produce;

(iii) The type of cooling systems, including intakes and outflows, where appropriate, that may be associated with each facility;

(iv) The boundaries of the site;

(v) The proposed general location of each facility on the site;

(vi) The external hazards and site characteristics required by this part;

(vii) The location and description of any nearby industrial, military, or

transportation facilities and routes;

(viii) The existing and projected future population profile of the area surrounding the site;

(ix) A description and assessment of the site on which a facility is to be located. The assessment must address the requirements of subpart D of this part;

(x) Information demonstrating that site characteristics are such that adequate security plans and measures can be developed; and

(xi) A description of the quality assurance program (QAP) required by appendix B to part 50 of this chapter applied to site-related activities for the future design, fabrication, construction, and testing of the SSCs of a facility or facilities that may be constructed on the site.

(2) A complete environmental report as required by § 51.50(b) of this chapter.

(b)(1) The Site Safety Analysis Report must identify physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. If physical characteristics are identified that could pose a significant impediment to the development of emergency plans, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment.

(2) The Site Safety Analysis Report may also—

(i) Propose major features of the emergency plans, under either § 50.160 or the requirements in appendix E to part 50 and § 50.47(b) of this chapter, as applicable, such as the exact size and configuration of the EPZs, for review and approval by the NRC, in consultation with the Federal Emergency Management Agency (FEMA), as applicable, in the absence of complete and integrated emergency plans; or

(ii) Propose complete and integrated emergency plans for review and approval by the NRC, in consultation with FEMA, as applicable, in accordance with either

§ 50.160 or the requirements in appendix E to part 50 and § 50.47(b) of this chapter. To the extent approval of emergency plans is sought, the application must contain the information required by § 53.1109(g).

(3) Emergency plans submitted under paragraph (b)(2)(ii) of this section must include the proposed inspections, tests, and analyses that the holder of a COL referencing the early site permit must 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, the facility has been constructed and will be operated in conformity with the emergency plans, the provisions of the Act, and the Commission's rules and regulations. Major features of an emergency plan submitted under paragraph (b)(2)(i) of this section may include proposed inspections, tests, analyses, and acceptance criteria (ITAAC).

(4) Under paragraphs (b)(1) and (b)(2)(i) of this section, the Site Safety Analysis Report must include, where appropriate, a description of contacts and arrangements made with Federal, State, participating Tribal, and local governmental agencies with emergency planning responsibilities. The Site Safety Analysis Report must contain any certifications that have been obtained. If these certifications, where appropriate, cannot be obtained, the Site Safety Analysis Report must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site. Under the option set forth in paragraph (b)(2)(ii) of this section, the applicant must make good faith efforts, where appropriate, to obtain from the same governmental agencies certifications that—

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(iii) That these agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(c) An applicant may request that an LWA under § 53.1130 be issued in conjunction with the early site permit. The application must include the information otherwise required by § 53.1130.

(d) Each applicant for an early site permit under this part must protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

§ 53.1149 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the applicable standards set out in this part. In addition, the Commission must prepare an environmental impact statement during review of the application, under the applicable provisions of 10 CFR part 51. The Commission must determine, after consultation with FEMA, as applicable, whether the information required of the applicant by § 53.1146(b)(1) shows that there is no significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 53.1146(b)(2)(i) are acceptable under either § 50.160 or appendix E to part 50 and § 50.47(b) of this chapter, and whether any emergency plans submitted by the applicant under § 53.1146(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

(b) *Administrative review of applications; hearings*. An early site permit application is subject to all procedural requirements in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of hearing in § 2.104(a) and (d) of this chapter, provided that the designated sections may not be construed to require that the

environmental report, or draft or final environmental impact statement includes an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources. The presiding officer in an early site permit hearing must not admit contentions proffered by any party concerning an assessment of the benefits of construction and operation of the reactor or reactors, or an analysis of alternative energy sources if those issues were not addressed by the applicant in the early site permit application. All hearings conducted on applications for early site permits filed under this part are governed by the procedures contained in subparts C, G, L, and N of 10 CFR part 2, as applicable.

§ 53.1155 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application for an early site permit to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS must report on those portions of the application which concern safety.

§ 53.1158 Issuance of early site permit.

(a) After conducting a hearing under § 53.1149(b) and receiving the report to be submitted by the ACRS under § 53.1155, the Commission may issue an early site permit, in the form the Commission deems appropriate, if the Commission finds that—

(1) An application for an early site permit demonstrates compliance with the applicable standards and requirements of the Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the site is in conformity with the provisions of the Act and the Commission's regulations;

(4) The applicant is technically qualified to engage in any activities authorized;

(5) The proposed ITAAC, including any on emergency planning, are necessary and sufficient, within the scope of the early site permit, to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license,

the provisions of the Act, and the Commission's regulations;

(6) Issuance of the permit will not be inimical to the common defense and security or to the health and safety of the public;

(7) Any significant adverse environmental impact resulting from activities requested under § 53.1146(c) can be redressed; and

(8) The findings required by 10 CFR part 51 have been made.

(b) The early site permit must specify the site characteristics, design parameters, and terms and conditions of the early site permit the Commission deems appropriate. Before issuance of either a CP or COL referencing an early site permit, the Commission must find that any relevant terms and conditions of the early site permit have been met. Any terms or conditions of the early site permit that could not be met by the time of issuance of the CP or COL, must be set forth as terms or conditions of the CP or COL.

(c) The early site permit must specify those § 53.1130(b) activities requested under § 53.1146(c) that the permit holder is authorized to perform.

§ 53.1161 Extent of activities permitted.

If the activities authorized by § 53.1158(c) are performed and the site is not referenced in an application for a CP or a COL issued under this part while the permit remains valid, 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.

§ 53.1164 Duration of permit.

(a) Except as provided in paragraph (b) of this section, an early site permit issued under this subpart may be valid for not less than 10, nor more than 20 years from the

date of issuance.

(b) An early site permit continues to be valid beyond the date of expiration in any proceeding on a CP application or a COL application that references the early site permit and is docketed before the date of expiration of the early site permit, or, if a timely application for renewal of the permit has been docketed, before the Commission has determined whether to renew the permit.

(c) An applicant for a CP or COL may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

(d) Upon issuance of a CP or COL, a referenced early site permit is subsumed, to the extent referenced, into the CP or COL.

§ 53.1167 Limited work authorization after issuance of early site permit.

A holder of an early site permit may request an LWA under § 53.1130.

§ 53.1170 Transfer of early site permit.

An application to transfer an early site permit will be processed under § 53.1570.

§ 53.1173 Application for renewal.

(a) Not less than 12, nor more than 36 months before the expiration date stated in the early site permit, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. 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 under § 2.309 of this chapter.

(c) An early site permit, either original or renewed, for which a timely application for renewal has been filed, remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in

certain proceedings in accordance with the provisions of § 53.1164(b).

§ 53.1176 Criteria for renewal.

(a) The Commission must grant the renewal if it determines that—

(1) 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

(2) Any new requirements the Commission may wish to impose—

(i) Are necessary for adequate protection to public health and safety or common defense and security;

(ii) Are necessary for compliance with the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; or

(iii) Would provide a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal under the provisions of § 53.1176(a) does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way that it is used to correct the deficiencies cited in the denial of the renewal.

§ 53.1179 Duration of renewal.

Each renewal of an early site permit may be for not less than 10, nor more than 20 years, plus any remaining years on the early site permit then in effect before renewal.

§ 53.1182 Use of site for other purposes.

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. If the permit holder informs the Director that the holder no longer intends to use the site for a commercial nuclear plant, the Director may terminate the permit.

§ 53.1188 Finality of early site permit determinations.

(a) *Commission finality*.

(1) While an early site permit is in effect under § 53.1164 or § 53.1179, the Commission may not change or impose new site characteristics, design parameters, or terms and conditions, including emergency planning requirements, on the early site permit unless the Commission—

(i) Determines that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders applicable and in effect at the time the permit was issued;

(ii) Determines the modification is necessary to assure adequate protection of the public health and safety or the common defense and security;

(iii) Determines that a modification is necessary based on an update under paragraph (b) of this section; or

(iv) Issues a variance requested under paragraph (d) of this section.

(2) In making the findings required for issuance of a CP, COL, or OL, or the findings required by § 53.1452(g), or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, if the application for the CP, COL, or OL references an early site permit, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(i) If the Commission grants a CP application that references an early site permit and an application for an OL references the CP, the Commission must treat as resolved those matters resolved in the proceeding for the issuance or renewal of the early site permit, except as provided for in paragraphs (b), (c), and (d) of this section.

(ii) If the early site permit approved an emergency plan (or major features thereof) that is in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes to the early site permit emergency plan (or major features thereof) that are identical to changes made to the licensee's emergency plans under § 53.1565 occurring after issuance of the early site permit.

(iii) If the early site permit approved an emergency plan (or major features thereof) that is not in use by a licensee of a commercial nuclear plant, the Commission must treat as resolved changes that are equivalent to those that could be made under § 53.1565 without prior NRC approval had the emergency plan been in use by a licensee.

(b) *Updating of early site permit-emergency preparedness*. An applicant for a CP, OL, or COL who has filed an application referencing an early site permit issued under this subpart must update the emergency preparedness information that was provided under § 53.1146(b) and discuss whether the updated information materially changes the bases for compliance with applicable NRC requirements.

(c) *Hearings and petitions*.

(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; or

(v) Any significant environmental issue that was not resolved in the early site permit proceeding, or 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.

(2) Any person may file a petition requesting that the site characteristics, design parameters, or terms and conditions of the early site permit be modified, or that the permit be suspended or revoked. The petition will be considered under § 2.206 of this chapter. Before construction commences, the Commission must consider the petition and determine whether any immediate action is required. If the petition is granted, an appropriate order will be issued. Construction under the CP or COL will not be affected by the granting of the petition unless the order is made immediately effective. Any change required by the Commission in response to the petition must demonstrate compliance with the requirements of paragraph (a)(1) of this section.

(d) *Variances*. An applicant for a CP, OL, or COL referencing an early site permit may include in its application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the early site permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria applicable to the application for the original or renewed early site permit. Once a CP or COL referencing

an early site permit is issued, variances from the early site permit will not be granted for that CP or COL.

(e) *Early site permit amendment*. The holder of an early site permit may not make changes to the early site permit or the Site Safety Analysis Report without prior Commission approval. The request for a change to the early site permit must be in the form of an application for a license amendment and must demonstrate compliance with the requirements of §§ 53.1510 and 53.1520.

§ 53.1200 Standard design approvals.

Sections 53.1200 through 53.1221 set out procedures for the filing, NRC staff review, and referral to the ACRS of standard designs, or major portions thereof, for a commercial nuclear plant under this part.

§ 53.1206 Contents of applications for standard design approvals; general information.

The application must contain all of the information required by § 53.1109(a) through (c) and (j).

§ 53.1209 Contents of applications for standard design approvals; technical information.

(a) *Major portion of a standard design.* If the applicant seeks review of a major portion of a standard design, the application need only contain the information required by this section to the extent the requirements are applicable to the major portion of the standard design for which NRC staff approval is sought. If an applicant seeks approval of a major portion of the design, the scope of the application for which approval is sought must include all functional design criteria necessary to demonstrate compliance with the safety criteria in §§ 53.210, 53.220 and 53.450(e), as applicable, for the major portion of the standard design for which NRC staff approval is sought. Such applicants must identify conditions related to interfaces with systems outside the scope of the major

portion of the standard design for which NRC staff approval is sought, and functional or physical boundary conditions between the major portion of the standard design for which NRC staff approval is sought and the remainder of the standard design. These conditions must be demonstrated when the standard design approval is incorporated into a subsequent CP, design certification, ML, or COL application.

(b) *Final Safety Analysis Report.* The application must contain an FSAR that describes the facility and the limits on its operation, presents a safety analysis of the SSCs and of the facility, or major portions thereof, for which the applicant seeks design approval, and must include the following information:

(1) *Site parameters*. The 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.

(2) *Design information.* Except as specified in this paragraph (b), an application for a standard design approval for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification under § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the standard design approval.

§ 53.1210 Contents of applications for standard design approvals; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Availability controls (if not included in the FSAR)*. A description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for safety-related (SR) SSCs and non-safety-related but safety-significant (NSRSS) SSCs provide the capabilities and reliabilities required to demonstrate compliance with the safety criteria of § 53.220.

(2) *Safeguards information*. A description of the program to protect Safeguards

Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(b) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

§ 53.1212 Standards for review of applications.

Applications filed under this part will be reviewed under the standards set out in 10 CFR parts 20, 53, and 73.

§ 53.1215 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1218 Staff approval of design.

(a) Upon completion of its review of a submittal under §§ 53.1200 through 53.1221 and receipt of a report by the ACRS under § 53.1215, the NRC staff must publish a determination in the *Federal Register* as to whether or not the design is acceptable, subject to appropriate terms and conditions, and make an analysis of the design in the form of a report available at the NRC website, https://www.nrc.gov.

(b) A standard design approval issued under this section is valid for 15 years from the date of issuance and may not be renewed. A design approval continues to be valid beyond the date of expiration in any proceeding on an application for a CP, OL, COL, or ML under this part that references the design approval and is docketed before the date of expiration of the design approval.

§ 53.1221 Finality of standard design approvals; information requests.

(a) An approved design must be used by and relied upon by the NRC staff and the ACRS in their reviews of any standard design certification or individual facility license application under this part that incorporates by reference a standard design approved under this part unless there exists significant new information that substantially affects the earlier determination or other good cause.

(b) The determination and report by the NRC staff do not constitute a commitment to issue a permit or license, or in any way affect the authority of the Commission, Atomic Safety and Licensing Board Panel, or presiding officers in any proceeding under part 2 of this chapter.

(c) Except for information requests seeking to verify compliance with the current licensing basis of the standard design approval, information requests to the holder of a standard design approval must be evaluated before issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each evaluation performed by the NRC staff must be in accordance with § 53.1580 and must be approved by the Executive Director for Operations or authorized designee before issuance of the request.

(d) The Commission will require, before granting a CP, COL, OL, or ML that references a standard design approval, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination, including the determination that the application is consistent with the design approval information. This information may be acquired by appropriate arrangements with the design approval applicant.

§ 53.1230 Standard design certifications.

Sections 53.1230 through 53.1263 set forth the requirements and procedures applicable to the Commission's issuance of rules granting standard design certifications for commercial nuclear plants under this part separate from the filing of an application for a CP or COL for such a facility.

§ 53.1236 Contents of applications for standard design certifications; general information.

The application must contain all of the information required by § 53.1109(a) through (c) and (j).

§ 53.1239 Contents of applications for standard design certifications; technical information.

The application must contain a level of design information sufficient to enable the Commission to judge the applicant's proposed means of assuring that construction conforms to the design and to reach a final conclusion on all safety questions associated with the design before the certification is granted. The information submitted for a design certification must include performance requirements and design information sufficiently detailed to permit the preparation of acceptance and inspection requirements by the NRC. The Commission will require, before design certification, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination.

(a) *Final Safety Analysis Report.* The application must contain an FSAR that describes the facility and the limits on its operation, and presents a safety analysis of the SSCs, and must include the following information:

(1) *Site parameters*. The 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.

(2*) Plant description and safety functions.*

(i) *General plant description*. A general description of the commercial nuclear plant including reactor type, the intended use of the reactor, nuclear design (e.g., neutron spectrum, reactor control, multi-unit reactor control), overall layout of the plant including significant plant features and SSCs, maximum power level and the nature and inventory of radioactive materials.

(ii) *Safety functions*. A description of the primary and additional safety functions required under § 53.230 and a summary of how each safety function is satisfied.

(3) *Design features and functional design criteria – licensing-basis events*.

(i) A description of the design features required by § 53.400 and the functional design criteria required by §§ 53.410 and 53.420 that, when combined with corresponding human actions and programmatic controls, demonstrate that the plant will demonstrate compliance with the safety criteria defined in § 53.210 and established in accordance with § 53.220 during licensing-basis events (LBEs).

(ii) A description of how design features demonstrate compliance with the requirements of § 53.440(a) through (i) and (k) through (m).

(4) *Design features supporting normal operations*. A description of the design features required by § 53.425 to support the holder of an OL or COL complying with § 53.260 during normal operations.

(5) [Reserved]

(6) *Earthquake engineering*. The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(7) *Programmatic controls and interfaces*.

(i) A description of the corresponding programmatic controls and interfaces necessary to achieve and maintain the reliability and capability of SSCs relied upon to

demonstrate compliance with the functional design criteria required by §§ 53.410 and 53.420 and the safety criteria in §§ 53.210 and 53.220 and necessary to maintain consistency with analyses required by § 53.450.

(ii) For an application for a multi-unit commercial nuclear plant, the programmatic controls and interfaces must also be described for different modular configurations, as required by § 53.440(i), including any restrictions that will be necessary during the construction and startup of any given unit to ensure the safe operation of the overall commercial nuclear plant to be licensed under this part.

(8) *Programmatic controls for normal operations*. A description of how programmatic controls, including monitoring programs, would provide assurance that design features and procedures will enable the holder of an OL or COL to comply with § 53.260.

(9) *Design features supporting the protection of plant workers*. A description of the design features required by § 53.430 to support the holder of an OL or COL complying with § 53.270.

(10) *Programmatic controls for protection of plant workers*. A description of how programmatic controls, including monitoring programs, would provide assurance that design features and procedures will enable the holder of an OL or COL to comply with § 53.270.

(11) *Codes and standards*. A description of generally accepted consensus codes and standards used to design the design features, as required by § 53.440(b).

(12) *Materials*. A description of the materials used for SR and NSRSS SSCs and a description of the qualification of these materials for their service conditions over the plant lifetime, as required by § 53.440(c).

(13) *Integrity assessment program*. A description of a design integrity assessment program that addresses the elements described in § 53.440(d).

(14) [Reserved]

(15) *Criticality*. Information demonstrating how the applicant will comply with requirements for criticality accidents in § 53.440(m).

(16) *Multi-unit plants.* For an application for standard design certification of a multi-unit commercial nuclear plant, the possible operating configurations of the reactor units, including common systems, interface requirements, and system interactions, as required by § 53.440(i).

(17) *SSC classification.*

(i) The classification of SSCs according to their safety significance under § 53.460(a).

(ii) For SR and NSRSS SSCs, the conditions under which they must perform the safety functions required by § 53.230, including environmental conditions.

(18) *Probabilistic risk assessment or other systematic risk evaluations (SREs)*. A description of the probabilistic risk assessment (PRA), other SREs, or a combination thereof required by § 53.450(a) and associated results.

(19) *Analyses*. A description of the analyses performed under § 53.450(b) through (g) that includes the following information:

(i) A description of the analysis of LBEs and its results, as described in § 53.240. This analysis description must—

(A) Address the elements in § 53.450(e) and (f); and

(B) Under § 53.460(c) —

(*1*) Describe any human actions that are necessary to prevent or mitigate LBEs;

(*2*) Describe how those human actions are capable of being reliably performed under the postulated environmental conditions present; and

(*3*) Describe how those human actions would be addressed by programs established under subpart F of this part.

(ii)(A) A description of how SSCs relied on to meet the safety criteria defined in § 53.210 are protected against or designed to withstand the effects of external hazards under § 53.510.

(B) The information necessary to demonstrate that the commercial nuclear plant complies with the earthquake engineering criteria in § 53.480.

(iii) A description of the defense-in-depth measures required by § 53.250.

(iv) A description of all plant operating states where there is the potential for the uncontrolled release of radioactive material to the environment, as required by § 53.450(b)(4).

(v) A description of the events that challenge plant control and safety systems whose failure could lead to an undesirable end state and/or radioactive material release, as required by § 53.450(b)(5).

(vi) A description of the analytical codes used in modeling plant behavior in analyses of LBEs and how these codes are qualified for the range of conditions for which they were used, as required by § 53.450(d).

(vii) A description of the results of other analyses required by § 53.450(g).

(20) *Special treatments*. A description of special treatments established as required by § 53.460.

(21) [Reserved]

(22) *Quality assurance.* A description of the QAP applied to the design of the SSCs of the commercial nuclear plant, as required by § 53.460(b). The description of the QAP for a commercial nuclear plant must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter were satisfied.

(23) *Design features and controls to address the minimization of contamination.* The information required by § 20.1406 of this chapter.

(24) *Interface requirements*.

(i) A description analysis, and evaluation of the interfaces between the standard design and the balance of the commercial nuclear plant that may impact the ability of the plant to demonstrate compliance with the functional design criteria or the safety criteria of subparts B and C of this part.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the certified design under this subpart. The method to be used for verification of interface requirements must be included as part of the proposed ITAAC required by § 53.1241(a)(3).

(iii) A representative conceptual design for those portions of the plant for which the application does not seek certification to aid the NRC in its review of the FSAR and to permit assessment of the adequacy of the interface requirements under paragraph (a)(24)(i) of this section.

(25) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(26) *Technical specifications*. Proposed technical specifications prepared under § 53.710(a) for those areas addressed by the design certification.

(27) *Role of personnel.* Information to address the following for the role of personnel in ensuring safe operations:

(i) A description of how the human factors engineering design requirements of § 53.440(n)(1) are addressed;

(ii) A description of how the human system interface design requirements of § 53.440(n)(2) are addressed;

(iii) A concept of operations that is of sufficient scope and detail to address the

requirements of § 53.440(n)(3);

(iv) A functional requirements analysis and function allocation that is of sufficient scope and detail to address the requirements of § 53.440(n)(4).

(b) [Reserved]

§ 53.1241 Contents of applications for standard design certifications; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Environmental report*. An environmental report as required by § 51.55 of this chapter.

(2) *Availability controls (if not included in the FSAR)*. A description of the controls on plant operations, including availability controls, to provide reasonable confidence that the configurations and special treatments for SR and NSRSS SSCs provide the capabilities and reliabilities required to demonstrate compliance with the safety criteria of § 53.220.

(3) *Inspections, tests, analyses, and acceptance criteria.* The proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Act, and the Commission's rules and regulations.

(4) *Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(b) If there are SSCs of the plant which required research and development to confirm the adequacy of their design, provide a report in the application which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

§ 53.1242 Review of applications.

(a*) Standards for review of applications.* Applications filed under this part will be reviewed for compliance with the standards set out in 10 CFR parts 20, 51, 53, and 73.

(b) *Administrative review of applications; hearings.*

(1) A standard design certification is a rule that will be issued under the provisions of subpart H of 10 CFR part 2, as supplemented by the provisions of this section. The Commission must initiate the rulemaking after an application has been filed under § 53.1100(a)(1)(iii) and must specify the procedures to be used for the rulemaking. The notice of proposed rulemaking published in the *Federal Register* must provide an opportunity for the submission of comments on the proposed design certification rule. If, at the time a proposed design certification rule is published in the *Federal Register* under this paragraph (b)(1), the Commission decides that a legislative hearing should be held, the information required by § 2.1502(c) of this chapter must be included in the *Federal Register* document for the proposed design certification.

(2) Following the submission of comments on the proposed design certification rule, the Commission may, at its discretion, hold a legislative hearing under the procedures in subpart O of part 2 of this chapter. The Commission must publish a document in the *Federal Register* of its decision to hold a legislative hearing. The document must contain the information specified in § 2.1502(c) of this chapter and specify whether the Commission or a presiding officer will conduct the legislative hearing.

(3) Notwithstanding anything in § 2.390 of this chapter to the contrary, proprietary

information will be protected in the same manner and to the same extent as proprietary information submitted in connection with applications for licenses, provided that the design certification will be published in chapter I of this title.

(c) *Reference to an issued operating license or combined license*. In those cases where a design certification application is preceded by the issuance of an OL or custom COL for a commercial nuclear plant that is essentially the same as the standard design for which certification is being requested, the NRC review will follow the processes for referencing a standard design approval in § 53.1221, to the extent practicable.

§ 53.1245 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1248 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 53.1242 on an application for a standard design certification and receiving the report to be submitted by the ACRS under § 53.1245, 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—

(1) The application demonstrates compliance with the applicable standards and requirements of the Act and the Commission's regulations;

(2) Notifications, if any, to other agencies or bodies have been duly made;

(3) There is reasonable assurance that the standard design conforms with the provisions of the Act and the Commission's regulations;

(4) The applicant is technically qualified;

(5) The proposed ITAAC are necessary and sufficient, within the scope of the standard design, to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been

constructed and will be operated in accordance with the design certification, the provisions of the Act, and the Commission's regulations;

(6) Issuance of the standard design certification will not be inimical to the common defense and security or to the health and safety of the public;

(7) The findings required by part 51 of this chapter have been made; and

(8) The applicant has implemented the QAP described or referenced in the Safety Analysis Report.

(b) The design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the design certification rule.

(c) After the Commission has adopted a final design certification rule, the applicant must not permit any individual to have access to or any facility to possess restricted data or classified National Security Information until the individual and/or facility has been approved for access under the provisions of 10 CFR parts 25 and/or 95, as applicable.

§ 53.1251 Duration of certification.

(a) Except as provided in paragraph (b) of this section, a standard design certification issued under this subpart is valid for 40 years from the effective date of the rule.

(b) A standard design certification continues to be valid beyond the date of expiration in any proceeding on an application for a COL or an OL under this part that references the standard design certification and is docketed either before the date of expiration of the certification, or, if a timely application for renewal of the certification has been filed, before the Commission has determined whether to renew the certification. A design certification also continues to be valid beyond the date of expiration in any

hearing held under § 53.1452 before operation begins under a COL that references the design certification.

(c) An applicant for a CP, OL, COL, or ML under this part may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 53.1254 Application for renewal.

(a) Not less than 12 nor more than 36 months before the expiration of the initial 40-year period, or any later renewal period, any person may apply for renewal of the certification. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application. The Commission will require, before renewal of certification, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. Notice and comment procedures must be used for a rulemaking proceeding on the application for renewal. The Commission, in its discretion, may require the use of additional procedures in individual renewal proceedings.

(b) A design certification, either original or renewed, for which a timely application for renewal has been filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in certain proceedings under § 53.1251.

§ 53.1257 Criteria for renewal.

(a) The Commission must issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Act and the Commission’s regulations applicable and in effect at the time the

certification was issued.

(b) The Commission may impose other requirements if it determines that—

(1) They are necessary for adequate protection to public health and safety or common defense and security;

(2) They are necessary for compliance with the Commission’s regulations and orders applicable and in effect at the time the design certification was issued; or

(3) There is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementing those requirements are justified in view of this increased protection.

(c) In addition, the applicant for renewal may request an amendment to the design certification. The Commission must grant the amendment request if it determines that the amendment will comply with the Act and the Commission's regulations in effect at the time of renewal. If the amendment request entails such an extensive change to the design certification that an essentially new standard design is being proposed, an application for a design certification must be filed in accordance with this subpart.

(d) Denial of renewal does not bar the applicant, or another applicant, from filing a new application for certification of the design, which proposes design changes that correct the deficiencies cited in the denial of the renewal.

§ 53.1260 Duration of renewal.

Each renewal of certification for a standard design will be for not less than 10, nor more than 40 years.

§ 53.1263 Finality of standard design certifications.

(a)(1) While a standard design certification rule is in effect under § 53.1251 or § 53.1260, the Commission may not modify, rescind, or impose new requirements on the certification information, whether on its own motion, or in response to a petition from any

person, unless the Commission determines in a rulemaking that the change—

(i) Is necessary either to bring the certification information or the referencing plants into compliance with the Commission's regulations applicable and in effect at the time the certification was issued;

(ii) Is necessary to provide adequate protection of the public health and safety or the common defense and security;

(iii) Reduces unnecessary regulatory burden and maintains protection to public health and safety and the common defense and security;

(iv) Provides the detailed design information to be verified under those ITAAC that are directed at certification information (i.e., design acceptance criteria);

(v) Is necessary to correct material errors in the certification information;

(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; or

(vii) Contributes to increased standardization of the certification information.

(2)(i) In a rulemaking under § 53.1263(a)(1), except for § 53.1263(a)(1)(ii), 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.

(ii) The rulemaking procedures for changes under § 53.1263(a)(1) must provide for notice and opportunity for public comment.

(3) Any modification the NRC imposes on a design certification rule under paragraph (a)(1) of this section will be applied to all plants referencing the certified design, except those to which the modification has been rendered technically irrelevant by action taken under paragraphs (a)(4) or (b) of this section.

(4) The Commission may not impose new requirements by plant-specific order

on any part of the design of a specific plant referencing the design certification rule if that part was approved in the design certification while a design certification rule is in effect under § 53.1248, unless—

(i) A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security; and

(ii) Special circumstances as defined in § 53.080 are present. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances which § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

(5) Except as provided in § 2.335 of this chapter, in making the findings required for issuance of a COL, CP, OL, or ML, or for any hearing under § 53.1452, the Commission must treat as resolved those matters resolved in connection with the issuance or renewal of a design certification rule.

(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. In addition to the factors listed in § 53.080, the Commission must consider whether the special circumstances that § 53.080 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. 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.

(c) The Commission will require, before granting a CP, COL, OL, or ML that references a design certification rule, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and

installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination, including the determination that the application is consistent with the certification information. This information may be acquired by appropriate arrangements with the design certification applicant.

§ 53.1270 Manufacturing licenses.

Sections 53.1270 through 53.1295 set out the requirements and procedures applicable to Commission issuance of a license under this part authorizing manufacture of manufactured reactors to be installed at sites not identified in the ML application.

§ 53.1276 Contents of applications for manufacturing licenses; general information.

Each application for an ML must include the information contained in § 53.1109(a) through (e), and (j).

§ 53.1279 Contents of applications for manufacturing licenses; technical information.

(a) *Final Safety Analysis Report-siting and design.* The application must include an FSAR containing the information set forth below, with a level of design information sufficient to enable the Commission to judge the applicant's proposed means of ensuring that the manufacturing conforms to the design and to reach a final conclusion on all safety questions associated with the design, permit the preparation of construction and installation specifications by an applicant who seeks to use the manufactured reactor, and permit the preparation of acceptance and inspection requirements by the NRC. The application must include the following information:

(1) *Site parameters.* The 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.

(2) *Design information.* The design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (27) for those portions of a commercial nuclear plant included in the manufactured reactor.

(3) *Quality assurance program.* A description of the QAP applied to the design, and to be applied to the fabrication and testing of the SSCs of the manufactured reactor under § 53.620(a)(6), including a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied;

(4) *Conceptual designs*. Representative conceptual designs for one or more commercial nuclear plants using the manufactured reactor;

(5) *Operating configurations*. If multiple manufactured reactors may be installed at a commercial nuclear plant, a description of the possible operating configurations, including common systems, interface requirements, and system interactions. The final safety analysis must also account for differences among the possible configurations, including any restrictions that will be necessary during the construction and startup of a given manufactured reactor to ensure the safe operation of any commercial nuclear reactor already operating;

(6) *Interface requirements.*

(i) The interface requirements between the manufactured reactor and the remaining portions of the commercial nuclear plant or connections to other facilities outside of the commercial nuclear plant.

(ii) Confirmation that interface requirements are verifiable through inspections, testing, or analysis. These requirements must be sufficiently detailed to allow for completion of the final safety analysis by license applicants that reference the manufactured reactor manufactured under this subpart. Applicants for a COL under this part will need to verify the interface requirements at the installation site. The method to be used for verification of interface requirements must be included as part of the

proposed ITAAC required by § 53.1282(a).

(iii) Information to support development of radiation monitoring programs required under subpart F of this part by an applicant for a COL, including potential pathways for radionuclides produced within the manufactured reactor to enter interfacing systems.

(b) *Final Safety Analysis Report - manufacturing information*. The FSAR must include the following information related to the manufacturing processes, organization, controls, and inspections:

(1) A description, including references to generally accepted consensus codes and standards, of the processes that will be used to procure, fabricate, and assemble components that make up the manufactured reactor. The description should clearly define which activities are proposed to be within the scope of the ML and those, such as the making of a component to be procured from a separate company for installation in the manufactured reactor, that are not considered to be within the scope of the ML;

(2) A description of the organizational and management structure singularly responsible for direction of design and manufacture of the manufactured reactor. The information should include a description of the management plans, technical qualifications, and controls in place to demonstrate compliance with the requirements of § 53.620;

(3) A description of the inspections and tests to be performed as part of the manufacturing process, including the inspection of procured components, inspection and testing of fabrication processes such as the molding, welding, or coating of components, and inspections and testing of the assembled manufactured reactor or portions of the manufactured reactor;

(4) A description of the fitness-for-duty program required by part 26 of this chapter and its implementation.

(c) *Final Safety Analysis Report - deployment of the completed manufactured*

reactor. The application must include a description of the following information related to the deployment of a manufactured reactor:

(1) Procedures governing the preparation of the manufactured reactor or portions of the manufactured reactor for shipping to the site where it is to be operated; the conduct of shipping; and verifying the condition of the shipped items upon receipt at the site;

(2) Details of the interaction of the design, manufacture, and installation of a manufactured reactor within the applicant's organization and the manner by which the applicant will ensure close integration between the designer, contractors, and any facility in which the manufactured reactor is to be installed;

(3) Measures to be used for the control of interfaces, including the consideration of key site parameters, between the holder of the ML and the holder of the COL or CP for the commercial nuclear plant at which the manufactured reactor is to be installed.

(d*) Final Safety Analysis Report - special considerations for factory fueling*. In addition to the above paragraphs (a) through (c) of this section, an application for an ML for a manufactured reactor that will be fueled at the factory under a 10 CFR Part 70 license must include the following information related to loading fuel and the required features to prevent criticality and to otherwise provide assurance that the fueled manufactured reactor can be successfully transported, installed, and operated at a site for which the Commission has issued a COL or a CP and OL that authorizes construction and operation of a commercial nuclear plant using the manufactured reactor:

(1) A description of the procedures used during the fueling of the manufactured reactor that ensure that the configuration of fuel within the fueled manufactured reactor is consistent with the design and analyses supporting operation of the manufactured reactor under the COL or OL at the place of operation. The description may reference

the applicable 10 CFR part 70 application and other sections of the Safety Analysis Report supporting the ML license application.

(i) The application must describe the measures taken for in-factory inspections and non-nuclear testing performed to ensure that the configuration of fuel within the fueled manufactured reactor is consistent with the design and analyses supporting operation of the manufactured reactor under the COL or OL at the place of operation.

(ii) The application must describe the design features included in the manufactured reactor to prevent criticality, the associated functional design criteria applied to those design features, and the physical and programmatic controls implemented during manufacturing, storage, and transport that are credited to assure the features function as designed when subject to potential hazards and human errors. The descriptions must include how those measures will be controlled during installation under the ML and removal under the COL or OL at the place of operation.

(2) A description of the procedures governing the transfer of responsibilities for the fueled manufactured reactor from the holder of the ML to the holder of the COL or CP and OL for the installation site.

(3) If available at the time of filing the ML application or, if not available at the time of filing the ML application, submitted as an amendment to the ML or ML application at the time of filing the Part 70 application, a description of the programs needed to demonstrate compliance with the requirements of § 53.620(d) and 10 CFR parts 70, 71, and 73 for the receipt, storage, and loading of SNM into a manufactured reactor and the transport of the fueled manufactured reactor to a site for which the Commission has issued a COL or CP and OL that authorizes construction and operation of a commercial nuclear plant using the manufactured reactor, including the following.

(i) A physical security program in accordance with § 53.620(d)(2)(i).

(ii) A cybersecurity program in accordance with § 53.620(d)(2)(i).

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

(a) *Inspections, tests, analyses, and acceptance criteria*.

(1) The application must contain proposed inspections, tests, and analyses that the COL or CP holder must 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 ML, 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 that 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* notice required by § 53.1285 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 ML application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the manufactured reactor as used in a commercial nuclear plant.

(c) *Safeguards information*. The application must contain a description of the

program to protect safeguards information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(d) *Performance demonstration.* A description of how the performance of each design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

§ 53.1285 Review of applications.

(a) *Standards for review of applications.* Applications for MLs under this part will be reviewed according to the applicable standards set out in this subpart as well as applicable standards in 10 CFR parts 20, 25, 26, 51, 53, 70, 71, 73, and 75.

(b) *Administrative review of applications, hearings.* A proceeding on an ML is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing in § 2.101(a)(1) through (4) of this chapter, and the requirements for issuance of a notice of proposed action in § 2.105 of this chapter, *provided, howeve*r, that the designated sections may not be construed to require that the environmental report or draft or final environmental impact statement include an assessment of the benefits of constructing and/or operating the manufactured reactor or an evaluation of alternative energy sources. All hearings on MLs are governed by the hearing procedures contained in 10 CFR part 2, subparts C, E, G, L, and N.

§ 53.1286 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application which concern safety.

§ 53.1287 Issuance of manufacturing licenses.

(a) After completing any hearing under § 53.1285(b), and receiving the report submitted by the ACRS, the Commission may issue an ML if the Commission finds

that—

(1) Applicable standards and requirements of the Act and the Commission's regulations have been met;

(2) There is reasonable assurance that the manufactured reactor will be manufactured, and can be transported, incorporated into a commercial nuclear plant, and operated in conformity with the ML, the provision of the Act, and the Commission’s regulations;

(3) The proposed manufactured reactor can be incorporated into a commercial nuclear plant and operated at sites having characteristics that fall within the site parameters postulated for the design of the manufactured reactors without undue risk to the health and safety of the public;

(4) The applicant is technically qualified to design and manufacture the proposed manufactured reactor;

(5) The proposed ITAAC are necessary and sufficient, within the scope of the ML, to provide reasonable assurance that the manufactured reactor has been manufactured and will be operated in conformity with the license, the provisions of the Act, and the Commission's regulations;

(6) The issuance of a license to the applicant will not be inimical to the common defense and security or to the health and safety of the public; and

(7) The findings required by 10 CFR part 51 have been made.

(b) Each ML issued under this subpart must specify—

(1) Terms and conditions as the Commission deems necessary and appropriate;

(2) Technical specifications for operation of the manufactured reactor, as the Commission deems necessary and appropriate;

(3) Significant site parameters and significant design characteristics for the manufactured reactor;

(4) The interface requirements to be met by the site-specific elements of the facility, such as the energy conversions systems and ultimate heat sink, not within the scope of the manufactured reactor; and

(5) The entity with design authority for the manufactured reactor covered by the license.

§ 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, or the requirements for the manufacture of the manufactured reactor, 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.

(2) Any modification to the design of a manufactured reactor that is imposed by the Commission under paragraph (a)(1) of this section will be applied to all manufactured reactors manufactured under the license, including those that have already been transported and sited, except those manufactured reactors to which the modification has been rendered technically irrelevant or otherwise unnecessary by action taken under § 53.1530, § 53.1550, or paragraph (b) of this section.

(3) In making the findings required under this part for issuance of a COL, CP, or OL, in any hearing under § 53.1452, or in any enforcement hearing other than one initiated by the Commission under paragraph (a)(1) of this section, for which a manufactured reactor manufactured under this subpart is referenced or used, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the ML, including the adequacy of design of the

manufactured reactor, the costs and benefits of severe accident mitigation design alternatives, and the bases for not incorporating severe accident mitigation design alternatives into the design of the manufactured reactor to be manufactured.

(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 Commission may grant a request only if it determines that the departure will comply with the requirements of § 53.080 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.

§ 53.1291 Duration of manufacturing licenses.

An ML issued under this part is valid for not less than 5, nor more than 40 years from the date of issuance. Upon expiration of the ML, the manufacture of any uncompleted manufactured reactors must cease unless a timely application for renewal has been docketed with the NRC.

§ 53.1293 Transfer of manufacturing licenses.

An ML may be transferred under § 53.1570.

§ 53.1295 Renewal of manufacturing licenses.

(a)(1) Not less than 12 months, nor more than 5 years before the expiration of the ML, or any later renewal period, the holder of the ML issued under this part may apply for a renewal of the license. An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.

(2) The filing of an application for a renewed license must be in accordance with subpart A of 10 CFR part 2 and § 53.1100.

(3) An ML issued under this part, either original or renewed, for which a timely

application for renewal has been filed, remains in effect until the Commission has made a final determination on the renewal application.

(4) Any person whose interest may be affected by renewal of the license may request a hearing on the application for renewal. 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 § 2.104 of this chapter.

(b) The Commission may grant the renewal if the Commission determines—

(1) The ML complies with the Act and the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; and

(2) Any new requirements the Commission may wish to impose are—

(i) Necessary for adequate protection to public health and safety or common defense and security;

(ii) Necessary for compliance with the Commission's regulations and orders applicable and in effect at the time the ML was originally issued; or

(iii) A substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the new requirements, and the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(c) A renewed ML may be issued for a term of not less than 5, nor more than 40 years, plus any remaining years on the ML then in effect before renewal. The renewed license must be subject to the requirements of § 53.1288.

§ 53.1300 Construction permits.

Sections 53.1300 through 53.1348 set out the requirements and procedures applicable to Commission issuance of a CP for commercial nuclear plants. A CP for the construction of a commercial nuclear plant under this part will be issued before the issuance of an OL if the application is otherwise acceptable and will be converted upon

completion of the facility and Commission action, into an OL as provided under §§ 53.1360 through 53.1405.

§ 53.1306 Contents of applications for construction permits; general information.

An application for a CP must include the information required by § 53.1109 and the following information:

(a) Information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, under the regulations in this chapter, the activities for which the permit is sought. As applicable, the applicant should provide information that demonstrates that the applicant appears to be financially qualified to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility, a financial capacity plan, and any source(s) of funds available at the time of application to cover these costs. If available funding at the time of application is 50 percent or less, the applicant should include proposed license conditions to facilitate verification that funding is available prior to the start of construction.

(b) If the applicant proposes to construct or alter a facility, the application must state the earliest and latest dates for completion of the construction or alteration.

§ 53.1309 Contents of applications for construction permits; technical information.

The application must contain a Preliminary Safety Analysis Report (PSAR) that describes the facility and the limits on its operation and presents a preliminary safety analysis of the SSCs of the facility as a whole. The PSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a conclusion on safety matters that must be resolved by the Commission before issuance of a CP:

(a)(1) *Site information.* An application for a CP for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x).

(2) *Design information*. Except as specified in this paragraph (a)(2), an application for a CP for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (a)(21), (a)(23), and § 53.1239(a)(26) through (27).

(i) *Quality assurance program.* A description of the QAP 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 to part 50 of this chapter will be satisfied.

(ii) *Preliminary design information.* The information provided in the application may include some aspects of the design that are not fully developed, and the information is therefore preliminary. The completed design, including any changes during construction, must be described in the FSAR required in § 53.1369 that supports an application for an OL.

(iii) *Planned research or testing*. Descriptions of how design features and related functional design criteria will fulfill the safety criteria in subpart B and how that has been or will be demonstrated through either analysis, appropriate test programs, experience, or a combination thereof. Where any design feature has not been fully developed or demonstrated to fulfill the functional design criteria at the time of an application for a CP, the applicant must provide a plan for future analysis, research and development, test programs, gathering of experience, or a combination thereof to provide reasonable confidence that the required demonstration will be available for an application for an OL

(iv) *Programmatic controls*. Descriptions of the programmatic controls may include those to be provided in the FSAR or other licensing-basis documents because they are necessary to achieve and maintain the reliability and capability of SSCs relied upon to demonstrate compliance with the established safety criteria and functional design criteria required in subpart B, and to maintain consistency with analyses required

by § 53.450.

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities under the regulations in this chapter.

(4) *Emergency preparedness*. A description of the applicant's preliminary plans for coping with emergencies based on:

(i) Except as provided in paragraph (a)(4)(ii) of this section, the requirements in appendix E to part 50.

(ii) For a commercial nuclear plant consisting of either small modular reactors or non-light-water reactors, the requirements in either § 50.160 or appendix E to part 50.

(5) *Physical security*. A report that provides a preliminary description of how the site characteristics support the development of adequate security plans and measures consistent with the requirements in § 53.540.

(6) *Fitness-for-duty program*. A description of the fitness-for-duty (FFD) program required by 10 CFR part 26 and its implementation.

(b) A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

§ 53.1312 Contents of applications for construction permits; other application content.

(a) In addition to the PSAR, the application must include the following:

(1) An environmental report either under § 51.50(a) of this chapter if an LWA under § 53.1130 is not requested in conjunction with the CP application, or under §§ 51.49 and 51.50(a) of this chapter if an LWA is requested in conjunction with the CP application; or

(2) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the CP, the information otherwise required by § 53.1130, in

accordance with either § 2.101(a)(1) through (a)(5), or § 2.101(a)(9) of this chapter.

(b) If the CP application references an early site permit, standard design approval, standard design certification, or ML issued under this part, then the following requirements apply:

(1) The PSAR need not contain information or analyses submitted to the Commission in connection with the referenced NRC approval, license, , or certification, provided, however, that the PSAR incorporates the material by reference and confirms that the site and design of the facility falls within parameter values postulated in the referenced NRC approval, license, or certification.

(2) The PSAR must provide a means to demonstrate that all terms and conditions that have been included in the referenced NRC approval, license, or certification will be satisfied by the date of issuance of the OL, as appropriate. If the PSAR does not demonstrate that each site characteristic falls within the corresponding postulated site parameter and each design characteristic of the facility falls within the corresponding postulated design parameter, the application must justify a departure, variance, or exemption from the referenced NRC approval, license, or certification in regard to that particular site or design characteristic in compliance with the requirements of this part.

(3) If a referenced early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the PSAR 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.

§ 53.1315 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. A proceeding on a CP application 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 CP applications are governed by the procedures contained in 10 CFR part 2.

§ 53.1318 Finality of referenced NRC approvals, permits, and certifications.

If the application for a CP under this part references an early site permit, standard design approval, standard design certification, or ML, the scope and nature of matters resolved for the application are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, 53.1263, and 53.1288.

§ 53.1324 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1315, in accordance with the finality provisions in § 53.1318.

§ 53.1327 Authorization to conduct limited work authorization activities.

(a) If the application does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130, the applicant may not perform those activities without obtaining the separate authorization required by § 53.1130. Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by paragraph (a) of this section, the application for the CP is withdrawn or denied, then the applicant must implement an approved site redress plan.

§ 53.1330 Exemptions, departures, and variances.

(a) Applicants for a CP under this part, or any amendment to a CP, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a CP who has filed an application referencing an NRC approval, license, or certification issued under this part may include in the application a request for exemptions, departures, or variances related to the subject referenced NRC approval, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1333 Issuance of construction permits.

(a) After conducting a hearing in accordance with § 53.1315 and receiving the report submitted by the ACRS, the Commission may issue a CP only if the Commission finds that—

(1) The applicant has described the proposed design of the facility and has identified the major features or components incorporated therein for the protection of the health and safety of the public;

(2) Such further technical or design information as may be required to complete the safety analysis, and which can reasonably be left for later consideration, will be supplied in the FSAR;

(3) Safety features or components, if any, that require research and development have been described by the applicant and the applicant has identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(4) On the basis of the foregoing, there is reasonable assurance of the following—

(i) Such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility; and

(ii) Taking into consideration the site criteria contained in subpart D to this part, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public.

(b) A CP must contain the terms and conditions for the permit, as the Commission deems necessary and appropriate. The Commission may, in its discretion, incorporate in any CP provisions requiring the applicant to furnish periodic reports of the progress and results of research and development programs designed to resolve safety questions.

§ 53.1336 Finality of construction permits.

Notwithstanding any provision in § 53.1590, a CP constitutes an authorization to proceed with construction but does not constitute Commission approval of the safety of any design feature or specification unless the applicant specifically requests such approval and such approval is incorporated in the permit. The applicant, at its option, may request such approvals in the CP or by amendment to the CP. If approved by the NRC and included in the permit, the NRC will consider modifications to the approved design features or specifications in accordance with § 53.1590.

§ 53.1342 Duration of construction permits.

(a) A CP will state the earliest and latest dates for completion of construction or alteration of the facility, not to exceed 40 years from date of issuance.

(b) If the proposed construction or alteration of the facility is not completed by the latest completion date, the CP shall expire, and all rights are forfeited. However, upon good cause shown, the Commission will extend the completion date for a reasonable

period of time. The Commission will recognize, among other things, developmental problems attributed to the experimental nature of the facility or fire, flood explosion, strike, sabotage, domestic violence, enemy action an act of the elements, and other acts beyond the control of the permit holder, as a basis for extending the completion date.

§ 53.1345 Transfer of construction permits.

A CP may be transferred under § 53.1570.

§ 53.1348 Termination of construction permits.

When a permit holder has determined to permanently cease construction, the holder must, within 30 days, submit a written certification to the NRC.

§ 53.1360 Operating licenses.

Sections 53.1360 through 53.1405 set out the requirements and procedures applicable to Commission issuance of an OL for a nuclear power facility.

§ 53.1366 Contents of applications for operating licenses; general information.

An application for an OL must include the information required by § 53.1109 and, except for an electric utility applicant, information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the license is sought. As applicable, the applicant must submit information that demonstrates the applicant appears to be financially qualified to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility and a financial capacity plan and must indicate any source(s) of funds available at the time of application to cover these costs. If available funding at the time of application is 50 percent or less, the applicant should include proposed license conditions to facilitate verification that funding is available prior to the start of operations.

§ 53.1369 Contents of applications for operating licenses; technical information.

Final Safety Analysis Report. The application must contain an FSAR that describes the facility and the limits on its operation and presents a safety analysis of the SSCs of the facility as a whole. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of an OL:

(a) *Site information*. An application for an OL for a commercial nuclear reactor must include the site information equivalent to that required for an early site permit in § 53.1146(a)(1)(iv) through (x), including all current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the CP, relating to site evaluation factors identified in this part.

(b) *Design information*. Except as specified in this paragraph (b), an FSAR for an OL for a commercial nuclear plant must include the final design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (7), (a)(9), (a)(11) and (12), (a)(14) through (21), (a)(23), and (a)(25).

(1) The completed design, including any changes during construction, must be described.

(2) Where any design feature had not been fully developed or demonstrated at the time of application for the CP, the applicant must provide the analysis, research and development, test programs, gathering of experience, or a combination thereof to provide the required demonstration to fulfill the functional design criteria.

(c) [Reserved]

(d) *Integrity assessment program*. A description of an Integrity Assessment Program that addresses the elements described in § 53.870.

(e) *Safeguards information.* A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(f) *Emergency response facility or facilities*. Description of location and capabilities to be established for command and control, support, and coordination of onsite and offsite, as applicable, functions during reactor accident conditions.

(g) *Role of personnel.*

(1) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(i) Human factors engineering design requirements of § 53.730(a);

(ii) Human system interface design requirements of § 53.730(b);

(iii) Concept of operations of § 53.730(c);

(iv) Functional requirements analysis and function allocation of § 53.730(d);

(2) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(3) A staffing plan and supporting analyses as required by § 53.730(f).

(h) *Training, examination, and proficiency programs.*

(1) A description of the training, examination, and proficiency programs required by § 53.730(g);

(2) A description of the training programs required by § 53.830.

(i) *Emergency plan*. Emergency plans complying with the requirements of § 53.855.

(1) Include all emergency plan certifications, as applicable, that have been obtained from the State, local, and participating Tribal governmental agencies with emergency planning responsibilities that are wholly or partially within the EPZ plume exposure pathway. These certifications must state that—

(i) The proposed emergency plans are practicable;

(ii) These agencies are committed to participating in any further development of

the plans, including any required field demonstrations; and

(iii) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(2) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(3) If complete and integrated emergency plans were approved as part of an early site permit, or submitted, reviewed, and approved as part of the CP application, new certifications that demonstrate compliance with the requirements of paragraph (i)(1) of this section are not required.

(j) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(k) *Maintenance program*. A description of a maintenance program under § 53.715.

(l) *Quality assurance*. A description of the QAP that demonstrates compliance with the requirements under § 53.865.

(m) *Radiation protection program*. A radiation protection program description under § 53.850.

(n) *Security program*. A physical security plan that describes how the applicant will comply with § 53.860 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(o) *Safeguards contingency plan*. A safeguards contingency plan in accordance

with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the SNM and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan. (Implementing procedures required for this plan need not be submitted for approval.)[1]

(p) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(q) *Cybersecurity plan*. A cybersecurity plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(r) *Security, safeguards, and cybersecurity plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cybersecurity plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cybersecurity plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(s) *Fire protection program*. A description of the fire protection program under § 53.875.

(t) *Inservice inspection/inservice testing program*. A description of the inservice inspection and inservice testing programs under § 53.880.

(u) [Reserved]

(v) [Reserved]

(w) *General employee training*. A description of the training program required to

demonstrate compliance with § 53.830 and its implementation.

(x) *Fitness-for-duty program*. A description of the FFD program required by 10 CFR part 26 and its implementation.

(y) *Other programs*. A description and evaluation of the results of the applicant's programs, including research and development, if any, to demonstrate that any safety questions identified at the CP stage have been resolved.

(z) *Safety design feature performance*. A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

(aa) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).

[1] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency plan.

§ 53.1372 Contents of applications for operating licenses; other application content.

In addition to the FSAR, the application must also include the following:

(a) *Environmental report*. An environmental report in accordance with § 51.53(b) of this chapter.

(b) *Availability controls (if not included in the FSAR*). A description of the controls on plant operations, including availability controls, to provide reasonable confidence of safe operation and that the configurations and special treatments for SR and NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220 if not addressed by Technical Specifications under § 53.1369(aa).

§ 53.1375 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 26, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. 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.

§ 53.1381 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1375.

§ 53.1384 Exemptions, departures, and variances.

(a) Applicants for an OL under this part, or any amendment to an OL, may include in the application a request for an exemption from one or more of the Commission's regulations. The Commission may grant an exemption request if it determines that the exemption complies with § 53.080.

(b) An applicant for an OL who has filed an application referencing an NRC approval, permit, license, or certification issued under this part may include in the application a request for departures, variances, or exemptions related to the subject referenced NRC approval, permit, license, or certification. In determining whether to grant the departure, variance, or exemption, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed approval, license, or certification.

§ 53.1387 Issuance of operating licenses.

Upon completion of the construction or alteration of a facility, in compliance with the terms and conditions of the construction permit and subject to any necessary testing

of the facility for health or safety purposes, the Commission will, in the absence of good cause shown to the contrary, issue an OL or an appropriate amendment of the license, as the case may be.

(a)(1) After receiving the report submitted by the ACRS, the Commission may issue an OL if the Commission finds that—

(i) Construction of the facility has been substantially completed in conformity with the CP and the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) The facility will operate in conformity with the application as amended, the provisions of the Act, and the rules and regulations of the Commission;

(iv) There is reasonable assurance that—

(A) The activities authorized by the OL can be conducted without endangering the health and safety of the public; and

(B) Such activities will be conducted in compliance with the regulations in this chapter.

(v) The applicant is technically and financially qualified to engage in the activities authorized, however, no finding of financial qualification is necessary for an electric utility applicant for an OL;

(vi) Issuance of the license will not be inimical to the common defense and security or to the health and safety of the public;

(vii) The applicable provisions of 10 CFR part 140 have been satisfied; and

(viii) The findings required by 10 CFR part 51 have been made.

(2) [Reserved]

(b) [Reserved]

(c) The OL will include appropriate provisions with respect to any uncompleted

items of construction and such limitations or conditions as are required to assure that operation during the period of the completion of such items will not endanger public health and safety.

(d) The Commission will issue an OL in such form and containing such conditions and limitations, including technical specifications, as it deems necessary and appropriate.

§ 53.1390 Backfitting of operating licenses.

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.

§ 53.1396 Duration of operating licenses.

The Commission will issue an OL under this part for the term requested by the applicant, not to exceed 40 years from the date of issuance, or for the estimated useful life of the facility if the Commission determines that the estimated useful life is less than the term requested.

§ 53.1399 Transfer of an operating license.

An OL may be transferred under § 53.1570.

§ 53.1402 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1405 Continuation of an operating license.

Each OL for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control, and

maintenance of the spent fuel in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the OL for the facility.

§ 53.1410 Combined licenses.

Sections 53.1410 through 53.1461 set out the requirements and procedures applicable to Commission issuance of COLs for commercial nuclear plants under this part.

§ 53.1413 Contents of applications for combined licenses; general information.

An application for a COL must include the information required by § 53.1109 and, except for an electric utility applicant in regard to financial assurance required after a Commission finding under § 53.1452, the application must include information sufficient to demonstrate to the Commission the financial qualification of the applicant to carry out, in accordance with the regulations in this chapter, the activities for which the permit or license is sought. As applicable, the following should be provided:

(a) The information that demonstrates that the applicant appears to be financially qualified to cover estimated construction costs and related fuel cycle costs, including estimates of the total construction costs and related fuel cycle costs of the facility, a financial capacity plan, and any source(s) of funds available at the time of application to cover these costs. If available funding at the time of application is 50 percent or less, the applicant should include proposed license conditions to facilitate verification that funding is available prior to the start of construction.

(b) The applicant must submit information that demonstrates the applicant appears to be financially qualified to cover estimated operation costs for the period of the license. The applicant must submit estimates for total annual operating costs for each of the first 5 years of operation of the facility, a financial capacity plan and indicate any

source(s) of funds available at the time of application to cover these costs. If available funding at the time of application is 50 percent or less, the applicant should include proposed license conditions to facilitate verification that funding is available prior to the start of operations.

§ 53.1416 Contents of applications for combined licenses; technical information.

(a) The application must contain an FSAR that describes the facility and the limits on its operation and presents a safety analysis of the SSCs of the facility as a whole. The Commission will require, before issuance of a COL, that information normally contained in engineering documents, such as analyses, drawings, procurement specifications, or construction and installation specifications, be completed and available for audit if the more detailed information is necessary for the Commission to verify the information in the application and make its safety determination. The FSAR must include the following information, at a level of detail sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a COL:

(1) *Site information*. An application for a COL for a commercial nuclear reactor must include the site information required for an early site permit in § 53.1146(a)(1)(iv) through (x).

(2) *Design information*. An application for a COL for a commercial nuclear plant must include the design information equivalent to that required for a standard design certification as defined in § 53.1239(a)(2) through (7), (a)(9), (a)(11), (a)(12), (a)(14) through (21), and (a)(23).

(3) *Technical qualifications*. A description of the technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(4) *Integrity assessment program*. A description of an Integrity Assessment

Program that addresses the elements described in § 53.870.

(5) *Safeguards information*. A description of the program to protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

(6) *Emergency response facility or facilities*. Description of the locations and capabilities to be established for command and control, support, and coordination of onsite and offsite, as applicable, functions during reactor accident conditions.

(7) *Role of personnel*.

(i) A description of the completed assessments related to the role of personnel in ensuring safe operations considering the analyses required by § 53.730. These assessments must include the following:

(A) Human factors engineering design requirements of § 53.730(a);

(B) Human system interface design requirements of § 53.730(b);

(C) Concept of operations of § 53.730(c); and

(D) Functional requirements analysis and function allocation of § 53.730(d);

(ii) A description of the program to be used for evaluating and applying operating experience as required by § 53.730(e);

(iii) A staffing plan and supporting analyses as required by § 53.730(f).

(8) *Training, examination, and proficiency programs.*

(i) A description of the training, examination, and proficiency programs required by § 53.730(g); and

(ii) A description of the training programs required by § 53.830.

(9) *Emergency plan*. Emergency plans complying with the requirements of § 53.855.

(i) The emergency plan must include, as applicable, all emergency plan certifications that have been obtained from the State, local, and participating Tribal

governmental agencies with emergency planning responsibilities. The certifications must state that—

(A) The proposed emergency plans are practicable;

(B) These agencies are committed to participating in any further development of the plans, including any required field demonstrations; and

(C) These agencies are committed to executing their responsibilities under the plans in the event of an emergency.

(ii) If certifications cannot be obtained after sustained, good faith efforts by the applicant, then the application must contain information, including a utility plan, sufficient to show that the proposed plans provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency at the site.

(10) *Organization.* A description of the applicant's organizational structure, allocations of responsibilities and authorities, and personnel qualifications requirements for operation.

(11) *Maintenance program*. A description of a maintenance program under § 53.715.

(12) *Quality assurance*. A description of the QAP under § 53.865.

(13) *Radiation protection program*. A radiation protection program description under § 53.850.

(14) *Security program*. A physical security plan that describes how the applicant will comply with § 53.860 (and 10 CFR part 11, if applicable, including the identification and description of jobs as required by § 11.11(a) of this chapter, at the proposed facility). The plan must list tests, inspections, audits, and other means to be used to demonstrate compliance with the requirements of 10 CFR parts 11 and 73, if applicable.

(15) *Safeguards contingency plan*. A safeguards contingency plan in accordance with the criteria set forth in appendix C to 10 CFR part 73. The safeguards contingency

plan must include plans for dealing with threats, thefts, and radiological sabotage, as defined in 10 CFR part 73, relating to the SNM and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license must include the information contained in the applicant's safeguards contingency plan.[1] (Implementing procedures required for this plan need not be submitted for approval.)

(16) *Security training and qualification*. A training and qualification plan that describes how the applicant will demonstrate compliance with the criteria set forth in § 73.100 of this chapter or appendix B to 10 CFR part 73.

(17) *Cybersecurity plan*. A cybersecurity plan in accordance with the criteria set forth in § 73.54 or § 73.110 of this chapter.

(18) *Security, safeguards, and cybersecurity plan implementation*. A description of the implementation of the physical security plan, safeguards contingency plan, training and qualification plan, and cybersecurity plan. Each applicant who prepares a physical security plan, a safeguards contingency plan, a training and qualification plan, or a cybersecurity plan must protect the plans and other related Safeguards Information against unauthorized disclosure in accordance with the requirements of §§ 73.21 and 73.22 of this chapter.

(19) *Fire protection program*. A description of the fire protection program under § 53.875.

(20) *Inservice inspection/inservice testing program*. Descriptions of inservice inspection and inservice testing programs under § 53.880.

(21) [Reserved]

(22) [Reserved]

(23) *General employee training*. A description of the training program required to demonstrate compliance with § 53.830 and its implementation.

(24) *Fitness-for-duty program*. A description of the FFD program under part 26 of this chapter and its implementation.

(25) *Technical specifications*. Proposed technical specifications prepared in accordance with the requirements of § 53.710(a).

(b) If there are SSCs of the plant for which research and development is necessary to confirm the adequacy of their design, a report which documents the resolution of any safety questions associated with such SSCs.

(c) A description of how the performance of each safety design feature has been demonstrated capable of fulfilling functional design criteria considering interdependent effects through either analysis, appropriate test programs, prototype testing, operating experience, or a combination thereof, in accordance with § 53.440(a).

(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) 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.

(4) 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.

(5) 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.

(e) If the COL application references a standard design approval, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the design approval, provided, however, that the FSAR must either include or incorporate by reference the standard design approval FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the characteristics of the site fall within the site parameters specified in the design approval. In addition, the plant-specific information of the PRA, other SREs, or a combination thereof must use the information of the PRA, other SREs, or a combination thereof for the design approval and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that all terms and conditions that have been included in the design approval will be satisfied by the date of issuance of the COL.

(f) If the COL application references a standard design certification, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the standard design certification, provided, however, that the FSAR must either include or incorporate by reference the standard design certification FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the standard design certification. In addition, the plant-specific information of the PRA, other SREs, or a combination thereof must use the information of the PRA, other SREs, or a combination thereof for the standard design certification and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design under § 53.1239(a)(24) have been met.

(3) The FSAR must demonstrate that all requirements and restrictions set forth in the referenced standard design certification rule must be satisfied by the date of issuance of the COL. Any requirements and restrictions set forth in the referenced standard design certification rule that could not be satisfied by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

(g) If the COL application references the use of one or more manufactured reactors licensed under § 53.1270, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the ML, provided, however, that the FSAR must either include or incorporate by reference the ML FSAR and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the ML. In addition, the

plant-specific information of the PRA, other SREs, or a combination thereof must use the information of the PRA, other SREs, or a combination thereof for the manufactured reactor and must be updated to account for site-specific design information and any design changes or departures.

(2) The FSAR must demonstrate that the interface requirements established for the design have been met.

(3) The FSAR must demonstrate that all terms and conditions that have been included in the ML will be satisfied by the date of issuance of the COL. Any terms or conditions of the ML that could not be met by the time of issuance of the COL, must be set forth as terms or conditions of the COL.

(h) Each applicant for a COL under this part must protect Safeguards Information against unauthorized disclosure in accordance with the requirements in §§ 73.21 and 73.22 of this chapter, as applicable.

[1] A physical security plan that contains all the information required in both § 73.55 or § 73.100 of this chapter and appendix C to 10 CFR part 73 demonstrates compliance with the requirement for a contingency plan.

§ 53.1419 Contents of applications for combined licenses; other application content.

(a) In addition to the FSAR, the application must also include the following:

(1) *Environmental report.*

(i) An environmental report either in accordance with § 51.50(c) of this chapter if an LWA under § 53.1130 is not requested in conjunction with the COL application, or in accordance with §§ 51.49 and 51.50(c) of this chapter if an LWA is requested in conjunction with the COL application; or

(ii) If the applicant wishes to request that an LWA under § 53.1130 be issued before issuance of the COL, the information otherwise required by § 53.1130, in accordance with either § 2.101(a)(1) through (a)(4), or § 2.101(a)(9) of this chapter;

(2) *Availability controls (if not included in the FSAR).* A description of the controls on plant operations, including availability controls, to provide reasonable confidence of safe operation and that the configurations and special treatments for SR SSCs and NSRSS SSCs provide the capabilities and reliabilities required to satisfy the safety criteria of § 53.220 if not addressed by Technical Specifications under § 53.1416(a)(25); and

(3) *Inspections, tests, analyses, and acceptance criteria.* The proposed inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must 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, the facility has been constructed and will be operated in conformity with the COL, the provisions of the Act, and the Commission's rules and regulations.

(i) If the application references an early site permit with ITAAC, the early site permit ITAAC must apply to those aspects of the COL which are approved in the early site permit.

(ii) 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 approved in the standard design certification.

(iii) If the application references an ML, the ITAAC contained in the ML must apply to those portions of the facility design which are approved in the ML.

(iv) If the application references an early site permit with ITAAC, a standard design certification, an ML, or a combination thereof, the application may include a notification that a required inspection, test, or analysis in the ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The *Federal Register* notice required by § 53.1422 of this chapter must indicate that the

application includes this notification.

(b) [Reserved]

§ 53.1422 Review of applications.

(a) *Standards for review of applications.* Applications filed under this part will be reviewed according to the standards set out in 10 CFR parts 20, 51, 53, 73, and 140.

(b) *Administrative review of applications; hearings*. 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 hearings on COLs are governed by the procedures contained in 10 CFR part 2.

§ 53.1425 Finality of referenced NRC approvals.

If the application for a COL under this part references an early site permit, standard design certification rule, standard design approval, or ML, issued under this part, the scope and nature of matters resolved for the application and any COL issued are governed by the relevant provisions addressing finality, including §§ 53.1188, 53.1221, 53.1263, and 53.1288.

§ 53.1431 Referral to the Advisory Committee on Reactor Safeguards.

The Commission must refer a copy of the application to the ACRS. The ACRS must report on those portions of the application that concern safety and must apply the standards referenced in § 53.1422, in accordance with the finality provisions in § 53.1425.

§ 53.1434 Authorization to conduct limited work authorization activities.

(a) If the application for a COL under this part does not reference an early site permit which authorizes the holder to perform the activities under § 53.1130(b), the

applicant may not perform those activities without obtaining the separate authorization required by § 53.1130(a). Authorization may be granted only after the presiding officer in the proceeding on the application has made the findings and determination required by § 53.1130(b)(1)(ii) and (b)(1)(iv), and the Director, Office of Nuclear Reactor Regulation makes the determination required by § 53.1130(b)(1)(iii).

(b) If, after an applicant has performed the activities permitted by a LWA issued under § 53.1130, the application for the COL is withdrawn or denied, then the applicant must implement the approved site redress plan.

§ 53.1437 Exemptions, departures, and variances.

(a) An applicant for a COL, or any amendment to a COL, may include in the application a request for an exemption from one or more of the Commission's regulations.

(1) If the request is for an exemption from any part of a referenced standard design certification rule, the Commission may grant the request if it determines that the exemption complies with any exemption provisions of the referenced standard design certification rule, or with § 53.1263 if there are no applicable exemption provisions in the referenced standard design certification rule.

(2) For all other requests for exemptions, the Commission may grant a request if it determines that the exemption complies with § 53.080.

(b) An applicant for a COL who has filed an application referencing an early site permit issued under § 53.1158 may include in the application a request for a variance from one or more site characteristics, design parameters, or terms and conditions of the permit, or from the Site Safety Analysis Report. In determining whether to grant the variance, the Commission must apply the same technically relevant criteria as were applicable to the application for the original or renewed site permit. Once a COL referencing an early site permit is issued, variances from the early site permit will not be

granted for that CP or COL.

(c) An applicant for a COL who has filed an application referencing use of a manufactured reactor may include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor under the ML issued under § 53.1287. The Commission may grant such a request only if it determines that the departure will comply with the requirements of § 53.080, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(d) Issuance of a variance under paragraph (b) of this section or a departure under paragraph (c) of this section is subject to litigation during the COL proceeding in the same manner as other issues material to that proceeding.

§ 53.1440 Issuance of combined licenses.

(a)(1) After conducting a hearing under § 53.1422(b) and receiving the report submitted by the ACRS, the Commission may issue a COL if the Commission finds that—

(i) The applicable standards and requirements of the Act and the Commission's regulations have been met;

(ii) Any required notifications to other agencies or bodies have been duly made;

(iii) There is reasonable assurance that the facility will be constructed and will operate in conformity with the license, the provisions of the Act, and the Commission's regulations;

(iv) The applicant is technically and financially qualified to engage in the activities authorized; however, no finding of financial qualification is necessary for an electric utility applicant for a COL;

(v) Issuance of the license will not be inimical to the common defense and

security or to the health and safety of the public; and

(vi) The findings required by 10 CFR part 51 have been made.

(2) The Commission may also find, at the time it issues the COL, that certain acceptance criteria in one or more of the ITAAC in a referenced early site permit, standard design certification, or ML have been met. This finding will finally resolve that those acceptance criteria have been met, those acceptance criteria will be deemed to be excluded from the COL, and findings under § 53.1452(g) with respect to those acceptance criteria are unnecessary.

(b) The Commission must identify within the COL the inspections, tests, and analyses, including those applicable to emergency planning, that the licensee must perform, and the acceptance criteria that, if met, 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 Act, and the Commission's rules and regulations.

(c) A COL must contain the terms and conditions, including technical specifications, as the Commission deems necessary and appropriate.

§ 53.1443 Finality of combined licenses.

(a) After issuance of a COL, the Commission may not modify, add, or delete any term or condition of the COL, the design of the facility, the ITAAC contained in the license that are not derived from a referenced standard design certification or ML, except under the provisions of § 53.1452 or § 53.1590.

(b) If the COL does not reference a standard design certification, then a licensee 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) under the applicable change processes in § 53.1550.

(c) If the COL references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced standard design certification rule are subject to the applicable change processes in that rule; and

(2) Changes that are not within the scope of the referenced standard design certification rule are subject to the applicable change processes in subpart I of this part, unless they also involve changes to or noncompliance with information within the scope of the referenced standard design certification rule. In these cases, the applicable provisions of this section and the standard design certification rule apply.

(d) [Reserved]

(e) The Commission may issue and make immediately effective any amendment to a COL upon a determination by the Commission that the amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person. The amendment may be issued and made immediately effective in advance of the holding and completion of any required hearing. The amendment will be processed under the procedures specified in § 53.1515.

(f) Any modification to, addition to, or deletion from the terms and conditions of a COL, including any modification to, addition to, or deletion from the inspections, tests, and analyses, or related acceptance criteria contained in the license is a proposed amendment to the license. There must be an opportunity for a hearing on the amendment.

§ 53.1449 Inspection during construction.

(a) *Licensee schedule for inspections, tests, or analyses*. The licensee must submit to the NRC, no later than 1 year after issuance of the COL or at the start of construction as defined at § 53.020, whichever is later, its schedule for completing the inspections, tests, or analyses in the ITAAC. The licensee must submit updates to the ITAAC schedules every 6 months thereafter and, within 1 year of its scheduled date for

initial loading of fuel (or, for a fueled manufactured reactor, within 1 year of its scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), the licensee must submit updates to the ITAAC schedule every 30 days until the final notification is provided to the NRC under paragraph (c)(1) of this section.

(b) *Licensee and applicant conduct of activities subject to ITAAC*. With respect to activities subject to an ITAAC, an applicant for a COL may proceed at its own risk with design and procurement activities, and a licensee may proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any one of the prescribed acceptance criteria are met.

(c) *Licensee notifications*.

(1) *ITAAC closure notification*. The licensee must notify the NRC that prescribed inspections, tests, and analyses have been performed and that the prescribed acceptance criteria are met. The notification must contain sufficient information to demonstrate that the prescribed inspections, test, and analyses have been performed and that the prescribed acceptance criteria are met.

(2) *ITAAC post-closure notifications*. Following the licensee's ITAAC closure notifications under paragraph (c)(1) of this section until the Commission makes the finding under § 53.1452(g), the licensee must notify the NRC, in a timely manner, of new information that materially alters the basis for determining that either inspections, tests, or analyses were performed as required, or that acceptance criteria are met. The notification must contain sufficient information to demonstrate that, notwithstanding the new information, the prescribed inspections, tests, and analyses have been performed as required, and the prescribed acceptance criteria are met.

(3) *Uncompleted ITAAC notification*. If the licensee has not provided, by the date 225 days before the scheduled date for initial loading of fuel (or, for a fueled manufactured reactor, by the date 225 days before the scheduled date for initiating the

removal of the features to prevent criticality required under § 53.620(d)(1)), the notification required by paragraph (c)(1) of this section for all ITAAC, then the licensee must notify the NRC that the prescribed inspections, tests, or analyses for all uncompleted ITAAC will be performed and that the prescribed acceptance criteria will be met prior to operation. The notification must be provided no later than the date 225 days before the scheduled date for initial loading of fuel (or, for a fueled manufactured reactor, no later than the date 225 days before the scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1)), and must provide sufficient information to demonstrate that the prescribed inspections, tests, or analyses will be performed and the prescribed acceptance criteria for the uncompleted ITAAC will be met, including, but not limited to, a description of the specific procedures and analytical methods to be used for performing the prescribed inspections, tests, and analyses and determining that the prescribed acceptance criteria are met.

(4) *All ITAAC complete notification*. The licensee must notify the NRC that all ITAAC are complete.

(d) *Licensee determination of noncompliance with ITAAC*.

(1) In the event that an activity is subject to an ITAAC derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request an exemption from the standard design certification ITAAC, as applicable. A request for an exemption must also be accompanied by a request for a license amendment under subpart I.

(2) In the event that an activity is subject to an ITAAC not derived from a referenced standard design certification and the licensee has not demonstrated that the prescribed acceptance criteria are met, the licensee may take corrective actions to successfully complete that ITAAC or request a license amendment under subpart I.

(e) *NRC inspection, publication of notices, and availability of licensee notifications*. The NRC must ensure that the prescribed inspections, tests, and analyses in the ITAAC are performed.

(1) At appropriate intervals until the last date for submission of requests for hearing under § 53.1452, the NRC must publish notices in the *Federal Register* of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

(2) The NRC must make publicly available the licensee notifications under paragraph (c) of this section. The NRC must, no later than the date of publication of the notice of intended operation required by § 53.1452(a), make publicly available those licensee notifications under paragraph (c) of this section that have been submitted to the NRC at least 7 days before that notice.

§ 53.1452 Operation under a combined license.

(a) The licensee must notify the NRC of its scheduled date for initial loading of fuel no later than 270 days before the scheduled date and must notify the NRC of updates to its schedule every 30 days thereafter.[1] Not less than 180 days before the date scheduled for initial loading of fuel into a plant by a licensee that has been issued a COL under this part, the Commission must publish notice of intended operation in the *Federal Register*.[2] The notice must provide that any person whose interest may be affected by operation of the plant may, within 60 days, request that the Commission hold a hearing on whether the facility as constructed complies, or on completion will comply, with the acceptance criteria in the COL, except that a hearing must not be granted for those ITAAC that the Commission found were met under § 53.1440(a)(2).

(b) A request for hearing under paragraph (a) of this section must show, *prima facie*—

(1) That one or more of the acceptance criteria of the ITAAC in the COL have not

been, or will not be, met; and

(2) The specific operational consequences of nonconformance that would be contrary to providing reasonable assurance of adequate protection of the public health and safety.

(c) The Commission, acting as the presiding officer, must determine whether to grant or deny the request for hearing under the applicable requirements of § 2.309 of this chapter. If the Commission grants the request, the Commission, acting as the presiding officer, must determine whether during a period of interim operation there will be reasonable assurance of adequate protection to the public health and safety. The Commission's determination must consider the petitioner's *prima facie* showing and any answers thereto. If the Commission determines there is such reasonable assurance, it must allow operation during an interim period under the COL.

(d) The Commission, in its discretion, must determine appropriate hearing procedures, whether informal or formal adjudicatory, for any hearing under paragraph (a) of this section, and must state its reasons therefore.

(e) The Commission must, to the maximum possible extent, render a decision on issues raised by the hearing request within 180 days of the publication of the notice provided by paragraph (a) of this section or by the anticipated date for initial loading of fuel into the reactor, whichever is later.

(f) A petition to modify the terms and conditions of the COL will be processed as a request for action under § 2.206 of this chapter. The petitioner must file the petition with the Secretary of the Commission. Before the licensed activity allegedly affected by the petition (fuel loading, low power testing, etc.) commences, the Commission must determine whether any immediate action is required. If the petition is granted, then an appropriate order will be issued. Fuel loading and operation under the COL will not be affected by the granting of the petition unless the order is made immediately effective.

(g) The licensee must not operate the facility until the Commission makes a finding that the acceptance criteria in the COL are met, except for those acceptance criteria that the Commission found were met under § 53.1440(a)(2). If the COL is for a modular design, each reactor unit may require a separate finding as construction proceeds.

(h) After the Commission has made the finding in paragraph (g) of this section, the ITAAC do not, by virtue of their inclusion in the COL, constitute regulatory requirements either for licensees or for renewal of the license; except for the specific ITAAC for which the Commission has granted a hearing under paragraph (a) of this section, all ITAAC expire upon final Commission action in the proceeding. However, subsequent changes to the facility or procedures described in the FSAR (as updated) must comply with the requirements in § 53.1443(e) or (f), as applicable.

[1] For licensees installing fueled manufactured reactors under a COL, the COL holder must instead notify the NRC of its scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) no later than 270 days before the scheduled date and must notify the NRC of updates to its schedule every 30 days thereafter.

[2] For licensees installing fueled manufactured reactors under a COL, the Commission must instead publish notice of intended operation in the *Federal Register* not less than 180 days before the date scheduled for initiating the removal of the features to prevent criticality required under § 53.620(d)(1).

§ 53.1455 Duration of combined license.

A COL is issued for a specified period not to exceed 40 years from the date on which the Commission makes a finding that acceptance criteria are met under § 53.1452(g) or allowing operation during an interim period under the COL under § 53.1452(c).

§ 53.1456 Transfer of a combined license.

A COL may be transferred under § 53.1570.

§ 53.1458 Application for renewal.

The filing of an application for a renewed license must be in accordance with § 53.1595.

§ 53.1461 Continuation of combined license.

Each COL for a facility that has permanently ceased operations continues in effect beyond the expiration date to authorize ownership and possession of the facility until the Commission notifies the licensee in writing that the license is terminated. During this period of continued effectiveness, the licensee must—

(a) Take actions necessary to decommission and decontaminate the facility and continue to maintain the facility, including, where applicable, the storage, control and maintenance of the spent fuel, in a safe condition; and

(b) Conduct activities in accordance with all other restrictions applicable to the facility in accordance with the NRC's regulations and the provisions of the COL for the facility.

§ 53.1470 Standardization of commercial nuclear plant designs: licenses to construct and operate nuclear power reactors of identical design at multiple sites.

(a) Except as otherwise specified in this section, the provisions of this section apply to CP, OL, and COL applications for commercial nuclear plants of identical design (the "common design") under this part.

(b) Each application for a CP, OL, or COL submitted pursuant to this section must be submitted as specified in § 53.1300, § 53.1360, or § 53.1410, respectively, and § 2.101 of this chapter. Each application must state that the applicant wishes to construct a facility identical to a facility proposed for one or more sites other than the applicant's (the "common design"), and the applicant wishes to have the application considered under this section. Each application must list each of the other applications to be treated together under this section or specify that such other applications will be submitted to the NRC within 12 months of submittal of the first application.

(c) Each application must include the information required by the applicable sections of this subpart, provided, however, that the application must identify the

common design, and, if applicable, reference a standard design certification or standard design approval under this part, or the use of a reactor manufactured under this part. The FSAR for each application must either incorporate by reference or include the final safety analysis of the common design, including, if applicable, the FSAR for the referenced standard design certification, standard design approval, or the manufactured reactor.

(d) Each application submitted pursuant to this section must contain an environmental report under § 53.1312(a)(1), § 53.1372(a), or § 53.1419(a)(1), as applicable, that complies with the applicable provisions of 10 CFR part 51, *provided, however*, that the application may incorporate by reference a single environmental report on the environmental impacts of the common design that are applicable to each site.

(e) Upon a determination that each application is acceptable for docketing under § 2.101 of this chapter, each application will be docketed and a notice of docketing for each application will be published in the *Federal Register*, under § 2.104 of this chapter, *provided, however*, that the notice must state that the application will be processed under the provisions of this section and subpart D of 10 CFR part 2. At the discretion of the Commission, a single notice of docketing for multiple applications may be published in the *Federal Register.*

(f) The NRC must prepare an environmental assessment or draft and final environmental impact statements for each of the applications under 10 CFR part 51. Scoping under §§ 51.28 and 51.29 of this chapter for each of the license applications may be conducted simultaneously and joint scoping may be conducted with respect to the environmental issues relevant to the common design. If the applications reference a standard design certification, then the environmental assessment or environmental impact statement for each of the applications must incorporate by reference the standard design certification environmental assessment. If the applications do not reference a

standard design certification, then the NRC must prepare environmental assessments or draft and final supplemental environmental impact statements which address severe accident mitigation design alternatives for the common design, which must be incorporated by reference into the environmental assessment or environmental impact statement prepared for each application. Scoping under §§ 51.28 and 51.29 of this chapter for the supplemental environmental impact statement may be conducted simultaneously and may be part of the scoping for each of the applications.

(g) The ACRS must report on each of the applications as required by the applicable sections of this subpart. Each report must be limited to those safety matters for each application that are not relevant to the common design. In addition, the ACRS must separately report on the safety of the common design, *provided, however*, that the report need not address the safety of a referenced standard design certification or reactor manufactured under this part.

(h) The Commission must designate a presiding officer to conduct the proceeding with respect to the health and safety, common defense and security, and environmental matters relating to the common design and affecting at least two applications. The hearing will be governed by the applicable provisions of subparts A, C, G, L, N, and O of 10 CFR part 2 relating to applications for CPs, OLs, and COLs. The presiding officer must issue a partial initial decision on the common design.

(i) If the design for the power reactor(s) proposed in a particular application is not identical to the others, that application may not be processed under this section and subpart D of 10 CFR part 2.

(j) As used in this section, the design of a nuclear power reactor included in a single referenced Safety Analysis Report means the design of those SSCs important to radiological health and safety and the common defense and security.

Subpart I—Maintaining and Revising Licensing-Basis Information

§ 53.1500 Licensing-basis information.

This subpart provides the requirements for each holder of a license for a commercial nuclear plant licensed under this part to maintain licensing-basis information as defined in § 53.020; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the U.S. Nuclear Regulatory Commission (NRC).

§ 53.1502 Specific terms and conditions of licenses.

(a) Each license issued under this part is subject to the provisions of the Atomic Energy Act of 1954, as amended, (the Act) and to all rules, regulations, and orders of the Commission. The terms and conditions of the license will be subject to amendment, revision, or modification, by reason of amendments of the Act or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Each license issued under this part must be subject to all conditions imposed as a matter of law by sections 401(a)(2) and 401(d) of the Federal Water Pollution Control Act, as amended (33 U.S.C.A. 1341(a)(2) and (d)).

(c) A holder of an operating license (OL) or combined license (COL) under this part may take reasonable action that departs from a license condition or a technical specification included in a license issued under this part in a national security emergency established by a law enacted by the Congress or by an order or directive issued by the President pursuant to statutes or the Constitution of the United States. The authority under this paragraph (c) must be exercised in accordance with law, including section 57e of the Act, and is in addition to the authority granted under § 53.740(h), which remains in effect unless otherwise directed by the Commission during a national security emergency. The authority under this paragraph (c) may be exercised—

(1) When this action is immediately needed to implement national security objectives as designated by the national command authority through the Commission; and

(2) No action consistent with license conditions and technical specifications that can satisfy national security objectives is immediately apparent.

(d)(1) If the NRC 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 (including findings based on requirements of 10 CFR part 50, appendix E, section IV.D.3) and if the deficiencies (including deficiencies based on requirements of 10 CFR part 50, appendix E, section IV.D.3) are not corrected within 4 months of that finding, the Commission will determine whether the facility must be shut down or cease operations until such deficiencies are remedied or whether other enforcement action is appropriate. In determining whether a shutdown or other enforcement action is appropriate, the Commission will take into account, among other factors, whether the licensee can demonstrate to the Commission's satisfaction that the deficiencies in the plan are not significant for the plant in question, or that adequate interim compensating actions have been or will be taken promptly, or that that there are other compelling reasons for continued operation.

(2) If the planning standards for radiological emergency preparedness apply to offsite emergency response plans, or if the planning activities in § 50.160(b)(1)(iv)(B) apply, then the NRC will base its finding on a review of the Federal Emergency Management Agency findings and determinations as to whether State, participating Tribal, and local emergency plans are adequate and capable of being implemented, and on the NRC assessment as to whether the licensee's emergency plans are adequate and capable of being implemented. Nothing in this paragraph (d)(2) must be construed as limiting the authority of the Commission to take action under any other regulation or

authority of the Commission or at any time other than that specified in this paragraph (d)(2).

§ 53.1505 Changes to licensing-basis information requiring prior NRC approval.

(a) Sections 53.1510 through 53.1520 provide the process for a licensee to request and the NRC to issue amendments to licenses, including any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license. Sections 53.1525 and 53.1530 govern proposed changes to a commercial nuclear plant referencing a certified design or manufacturing license (ML).

(b) A licensee may propose changing licensing-basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.

§ 53.1510 Application for amendment of license.

Whenever a holder of a license under this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040, that fully describes the changes desired and, following as far as applicable, the form prescribed for original applications. Applications for amendments involving changes to plant structures, systems, and components (SSCs), programmatic controls, or the role of plant personnel must include an assessment of the changes in relation to the safety requirements in subpart B of this part and the analyses requirements of § 53.450 as applicable, an analysis of whether the amendment involves no significant hazards consideration using the standards in § 53.1520, and a consideration of environmental factors.

§ 53.1515 Public notices; State consultation.

The Commission will use the following procedures for an application requesting an amendment to an OL or COL issued under this part.

(a) *Public notices.*

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 of this chapter an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will

(A) Contain the staff's proposed determination under the standards in § 53.1520;

(B) Provide a brief description of the amendment and of the facility involved;

(C) Solicit public comments on the proposed determination; and

(D) Provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination of no significant hazards consideration unless it receives a request for a hearing on that amendment request.

(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called

for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a commercial nuclear reactor, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration but will publish a notice of issuance under § 2.106 of this chapter providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in a timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a *Federal Register* notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it—

(i)(A) Will either issue a *Federal Register* notice providing notice of an opportunity for hearing and allowing at least 2 weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(1) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106 of this chapter;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter; and

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it and use its normal public notice and comment procedures in paragraph (a)(1) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation*.

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make the names of the Project Manager or other NRC personnel it designated to consult with the State available to the State official designated to consult about its proposed determination. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration.)

(4) The Commission will make a good faith attempt to consult with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official. (Inability to consult with a responsible State official following good faith attempts will not prevent the Commission from making effective a license amendment involving no significant hazards consideration, if the Commission deems it necessary in an emergency situation.)

(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.

(c) *Caveats about State consultation.*

(1) The State consultation procedures in paragraph (b) of this section do not give the State a right—

(i) To veto the Commission's proposed or final determination;

(ii) To a hearing on the determination before the amendment becomes effective; or

(iii) To insist upon a postponement of the determination or upon issuance of the amendment.

(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for commercial nuclear plants.

§ 53.1520 Issuance of amendment.

(a) In determining whether an amendment to a license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses to the extent applicable and appropriate. If the application is for amendment of an OL or COL and involves the material alteration of a commercial nuclear plant, a construction permit (CP) will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a manufactured reactor under this part before its installation at a site, or a COL before the date that the Commission makes the finding under § 53.1452(g), no application for or issuance of a CP is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action—

(1) Under § 2.105 of this chapter before acting thereon; and

(2) As soon as practicable after the application has been docketed.

(b) The Commission will be particularly sensitive to a license amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a commercial nuclear plant).

(c) The Commission may make a final determination, under the procedures in § 53.1515, that a proposed amendment to an OL or a COL for a commercial nuclear plant under this part involves no significant hazards consideration, if operation of the plant in accordance with the proposed amendment would not—

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or

(2) Create the possibility of a new or different kind of an accident from any accident previously evaluated; or

(3) Involve a significant reduction in a margin of safety.

§ 53.1525 Revising certification information within a design certification rule.

(a) A holder of an OL or COL who references a design certification rule issued under this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080 and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

(b) The request for an exemption must be included with any associated license amendment request, which must be requested and processed in accordance with §§ 53.1510, 53.1515, and 53.1520.

(c) Licensees must evaluate changes to the design as described in the Final Safety Analysis Report (FSAR) not involving changes to the certification information using the criteria in § 53.1550.

§ 53.1530 Revising information within a Final Safety Analysis Report associated with a manufacturing license.

(a) The holder of an ML may make changes to the facility or procedures as described in the Final Safety Analysis Report (FSAR) associated with the ML without obtaining a license amendment pursuant to § 53.1510 if the change meets the criteria in § 53.1550(a)(1) and (2) using the specifications in § 53.1550(b). If needed, applications for amending an ML must be submitted and processed in accordance with §§ 53.1510, 53.1515, and 53.1520. In those cases where an ML references a design certification rule, the amendment application from the holder of the ML must also request an exemption from the design certification rule under § 53.1525 if proposing to change one or more elements of the certification information.

(b)(1) The holder of an ML must maintain records of changes to the facility or procedures made without a license amendment under paragraph (a) 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 the criteria in paragraph § 53.1550(a)(2).

(2) The records of changes in the facility must be maintained until the expiration of an ML issued under this part, or the expiration of a renewed license issued under § 53.1295—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

§ 53.1535 Amendments 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.

(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 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 amendment will not be granted.

§ 53.1540 Updating licensing-basis information and determining the need for NRC approval.

(a) Sections 53.1545 through 53.1565 provide the process for a holder of an OL or COL to modify licensing-basis information and to evaluate potential changes to its facilities, procedures, programs, and organizations to determine if NRC approval is required.

(b) Definitions for the purposes of §§ 53.1545 through 53.1565—

Change means a modification or addition to, or removal from, the commercial nuclear plant or procedures that affects a design feature or related functional design criteria, method of performing or controlling the functions of design features, or an evaluation that demonstrates that intended functions will be accomplished.

Departure from a method of evaluation described in the Final Safety Analysis Report (FSAR) (as updated) used in establishing the functional design criteria for safety-related structures, systems, or components or in the safety analyses means—

Changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or

Changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

Facility as described in the FSAR (as updated) means—

The SSCs that are described in the FSAR (as updated),

The design and performance requirements for such SSCs described in the FSAR (as updated), and

The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

Final Safety Analysis Report (as updated) means the FSAR submitted under § 53.1279, § 53.1369 or § 53.1416, as amended and supplemented, and as updated under § 53.1545, as applicable.

Procedures as described in the Final Safety Analysis Report (as updated) means those procedures that contain information described in the FSAR (as updated) such as how SSCs are operated and controlled (including assumed operator actions and response times).

§ 53.1545 Updating Final Safety Analysis Reports.

(a) Each holder of an OL or COL under this part for which the Commission has made the finding under § 53.1452(g) must update the FSAR originally submitted as part of the application for the license every 24 months or more frequently to assure that the information included in the report contains the latest information developed. The submittal must include the effects on the content of the FSAR of—

(1) Changes made to the facility or procedures as described in the FSAR;

(2) Safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment under § 53.1550;

(3) Updates to the probabilistic risk assessment (PRA), other systematic risk evaluations, or a combination thereof required under § 53.450(a);

(4) The cumulative effects of the changes to the facility or procedures on the margins to the safety criteria in §§ 53.210, 53.220, and 53.450(e) since the last FSAR update; and

(5) Analyses of new safety issues performed by or on behalf of the licensee at Commission request.

(b)(1) The licensee must submit revisions containing updated information to the Commission, under § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

(c) Each applicant for or holder of a COL under this part for which the Commission has not made the finding under § 53.1452(g) must submit an update to the FSAR annually by providing the information required in paragraphs (a)(1) through (a)(5) of this section and meeting the requirements of paragraph (b) of this section. Combined license applicants who have requested the NRC to suspend its review of the COL application and COL holders who have informed the NRC that they do not plan to pursue construction need not submit an annual update of the FSAR. If a COL applicant requests that the NRC resume its review, or a COL holder notifies the NRC that the COL holder plans to commence or resume construction, then the COL applicant or holder must submit to NRC an update to its FSAR within 90 days of the request or notification, as applicable, and annually thereafter.

(d) The FSAR (as updated) must be retained by the licensee until the Commission terminates its license.

(e) Each holder of an ML under this part must submit an update of the FSAR every 24 months or more frequently as necessary to facilitate dependent COL or CP

applications. The submittal must include the effects of changes on the content of the FSAR as described in paragraphs (a)(1), (a)(3) through (a)(5), and (b) of this section and safety analyses and evaluations performed by the licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment under § 53.1530.

§ 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 a license amendment pursuant to § 53.1510 only if—

(1) A change to the technical specifications 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, or the revised method of evaluation can be used under an NRC-endorsed consensus code or standard.

(v) Does not result in a change to the safety classification of an SSC 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) [Reserved]

(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)(1) The licensee must maintain records of changes in the facility and procedures made under paragraph (a) 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) 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.

§ 53.1560 Updating program documents included in licensing-basis information.

(a) Each holder under this part of an OL or COL for which the Commission has made the finding under § 53.1452(g) must biennially or more frequently update the program documents submitted as part of an application to obtain or maintain the license to assure that the information included in the documents contains the latest information developed. The submittals must include the effects on the content of the program documents of—

(1) Changes made in the facility, procedures, licensee's organization, or site environs;

(2) Safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.1550;

(3) Analyses of new safety issues performed by or on behalf of the licensee at Commission request; and

(4) Changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to support the requirements in subpart B of this part or other NRC regulations.

(b)(1) The licensee must submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.

(2) The submittal must include—

(i) A certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and

(ii) An identification of changes made under the provisions of § 53.1550 but not previously submitted to the Commission.

(c) The updated program documents must be retained by the licensee until the Commission terminates their license.

§ 53.1565 Evaluating changes to programs included in licensing-basis information.

(a) A licensee may make changes to the facility, procedures, or organizations or address changes to site environs as described in the program documents included in licensing-basis information without obtaining prior NRC approval only if—

(1) A change to the technical specifications incorporated in the license is not required;

(2) An exemption from an NRC regulation is not required; and

(3) The change conforms to program-specific requirements included in regulations in this part, technical specifications, or the NRC-approved program document included and reviewed as part of a license application under subpart H or an amendment under this subpart.

(b) In implementing this section, the program documents (as updated) include changes since submittal of the last updates of the program documents pursuant to § 53.1560.

(c) The provisions in this section do not apply to changes to the program documents when the applicable regulations establish more specific criteria for accomplishing such changes.

(d) To make changes to the facility, procedures, or organizations or to address changes to site environs as described in the program documents included in licensing-basis information for individual programs, the following requirements must be satisfied:

(1) *Quality assurance program—operation*.

(i) Each holder under this part of an OL or COL, after the Commission makes the finding under § 53.1452(g), 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:

(A) The use of a quality assurance (QA) standard approved by the NRC which is more recent than the QA standard in the licensee's QAP at the time of the change;

(B) The use of a QA alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;

(C) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;

(D) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;

(E) The elimination of QAP information that duplicates language in QA regulatory guides and QA standards to which the licensee is committed; and

(F) Organizational revisions that ensure that persons and organizations performing QA functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

(ii) Changes to the QAP description that do reduce the commitments must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(A) Changes made to the QAP description 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 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 to 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 change 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.

(2) *Quality assurance program—siting, construction, and manufacturing*. Each holder of an LWA, early site permit, CP, ML, or COL, before the Commission makes the finding under § 53.1452(g) of this chapter, under this part 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:

(i) 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.

(ii) 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).

(iii) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(iv) 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.

(3) *Emergency preparedness program*.

(i) Definitions for the purpose of paragraph (d)(3) of this section:

(A) *Change* means an action that results in modification or addition to, or removal from, the licensee's emergency plan. All such changes are subject to the provisions of this section except where the applicable regulations establish specific criteria for accomplishing a particular change.

(B) *Emergency plan* means the document(s), prepared and maintained by the licensee, that identify and describe the licensee's methods for maintaining emergency preparedness and responding to emergencies. An emergency plan includes the plan as originally approved by the NRC and all subsequent changes made by the licensee with, and without, prior NRC review and approval under paragraph (d)(3) of this section.

(C) *Emergency planning function* means a capability or resource necessary to prepare for and respond to a radiological emergency.

(D) *Reduction in effectiveness* means 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.

(ii)(A) Except as provided in paragraph (d)(3)(ii)(B) of this section, 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).

(B) A holder of an OL under this part for a commercial nuclear plant consisting of small modular reactors (SMRs) or non-light-water reactors, or a holder of a COL under this part after the Commission makes the finding under § 53.1452(g) for a commercial nuclear plant consisting of either SMRs or non-light-water reactors, must follow and maintain the effectiveness of either an emergency plan that meets the requirements in § 50.160 or an emergency plan that meets the requirements in appendix E to part 50 of this chapter and the planning standards of § 50.47(b).

(iii)(A) Except as provided in paragraph (d)(3)(iii)(B) of this section, the licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet the requirements in appendix E to part 50 of this chapter and the planning standards of § 50.47(b).

(B) A license under this part for a commercial nuclear plant consisting of either SMRs or non-light-water reactors may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the requirements in § 50.160 or the requirements in appendix E to part 50 and the planning standards of § 50.47(b).

(iv) The changes to a licensee’s emergency plan that reduce the effectiveness of the plan as defined in paragraph (d)(3)(i)(D) of this section may not be implemented without prior approval by the NRC. A licensee desiring to make such a change must

submit an application for an amendment to its license. In addition to the filing requirements of §§ 53.1510 and 53.1515, the request must include all emergency plan 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 licensee's emergency plan, as revised, will continue to meet either the requirements in § 50.160 to this chapter or the requirements in appendix E to part 50 of this chapter and the planning standards of § 50.47(b) of this chapter.

(v) The licensee must retain a record of each change to the emergency plan made without prior NRC approval for a period of three years from the date of the change and shall submit, as specified in § 53.040, a report of each such change, including a summary of its analysis, within 30 days after the change is put in effect.

(vi) The licensee must retain the emergency plan and each change for which prior NRC approval was obtained pursuant to paragraph (d)(3)(iv) of this section as a record until the Commission terminates the license for the nuclear power reactor.

(vii)(A) The licensee must provide for the development, revision, implementation, and maintenance of its emergency preparedness program. The licensee must ensure that all program elements are reviewed by persons who have no direct responsibility for the implementation of the emergency preparedness program either—

(1) At intervals not to exceed 12 months; or

(2) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect emergency preparedness, but no longer than 12 months after the change. In any case, all elements of the emergency preparedness program must be reviewed at least once every 24 months.

(B) The review must include an evaluation for adequacy of interfaces with State, participating Tribal, and local governments and of licensee drills, exercises, capabilities, and procedures. The results of the review, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, and retained for a period of 5 years. The part of the review involving the evaluation for adequacy of interface with State, participating Tribal, and local governments must be available to the appropriate State, participating Tribal, and local governments.

(4) *Security programs.*

(i) The licensee must prepare and maintain safeguards contingency plan procedures in accordance with appendix C of part 73 of this chapter for affecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may not make a change that would decrease the safeguard effectiveness of a physical security plan, or guard training and qualification plan, or cybersecurity plan submitted under subpart H or part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan submitted under subpart H or part 73 of this chapter, as applicable, without prior approval of the Commission. A licensee desiring to make such a change must submit an application for amendment to the licensee’s license under §§ 53.1510, 53.1515, and 53.1520.

(ii) The licensee may make changes to the plans referenced in paragraph (d)(4)(i) of this section without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee must maintain records of changes to the plans made without prior Commission approval for a period of 3 years from the date of the change, and must submit, as specified in § 53.040, a report

containing a description of each change within 2 months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee must have—

(A) All safeguards capabilities specified in the safeguards contingency plan available and functional;

(B) Detailed procedures developed according to appendix C to part 73 of this chapter available at the licensee's site; and

(C) All appropriate personnel trained to respond to safeguards incidents as outlined in the plan and specified in the detailed procedures.

(iii) The licensee must provide for the development, revision, implementation, and maintenance of its safeguards contingency plan. The licensee must ensure that all program elements are reviewed by individuals independent of both security program management and personnel who have direct responsibility for implementation of the security program either—

(A) At intervals not to exceed 12 months; or

(B) As necessary, based on an assessment by the licensee against performance indicators, and as soon as reasonably practicable after a change occurs in personnel, procedures, equipment, or facilities that potentially could adversely affect security, but no longer than 12 months after the change. In any case, all elements of the safeguards contingency plan must be reviewed at least once every 24 months.

(iv) The review must include a review and audit of safeguards contingency procedures and practices, an audit of the security system testing and maintenance program, and a test of the safeguards systems along with commitments established for response by local law enforcement authorities. The results of the review and audit, along with recommendations for improvements, must be documented, reported to the licensee’s corporate and plant management, and kept available at the plant for inspection for a period of 3 years.

§ 53.1570 Transfer of licenses.

(a) No commercial nuclear plant license issued under this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.

(b)(1) An application for transfer of a license must include—

(i) As much of the information described in §§ 53.1109, 53.1306, 53.1366, and 53.1413 with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.

(ii) A statement of the purposes for which the transfer of the license is requested, the nature of the transaction necessitating or making desirable the transfer of the license, and an agreement to limit access to Restricted Data or Classified National Security Information pursuant to § 53.1115. The Commission may require any person who submits an application for license pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.

(2) [Reserved]

(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license, if the Commission determines—

(1) That the proposed transferee is qualified to be the holder of the license; and

(2) That transfer of the license is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.

§ 53.1575 Termination of licenses.

(a) When the holder of an OL or COL under this part has determined to permanently cease operations the licensee must, within 30 days, submit a written certification to the NRC, consistent with the requirements of § 53.1070.

(b) Once fuel has been permanently removed from the reactor system, the licensee must submit a written certification to the NRC that meets the requirements of § 53.1070.

(c)(1) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor system, or when a final legally effective order to permanently cease operations has come into effect, the license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor system.

(2) Activities associated with decommissioning will be carried out in accordance with the requirements and procedures in subpart G of this part.

(3) The Commission shall terminate the license if it determines that—

(i) The remaining dismantlement has been performed in accordance with the approved license termination plan required in subpart G of this part; and

(ii) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in subpart E of 10 CFR part 20.

(d) A holder of a CP or COL under this part may request the termination of the license as well as licenses issued by the NRC under parts 30, 40, or 70 of this chapter

prior to plant operations. Such requests may support an immediate NRC approval of the site for unrestricted use.

§ 53.1580 Information requests.

Each licensee under this part must at any time before termination of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.

§ 53.1585 Revocation, suspension, modification of licenses and approvals for cause.

A license or standard design approval issued under this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license or approval on an original application; or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a CP under this part shall be governed by the provisions

of § 53.1342(b); or for violation of, or failure to observe, any of the terms and provisions of the Act, regulations, license, approval, or order of the Commission.

§ 53.1590 Backfitting.

(a)(1) Backfitting means the modification of or addition to systems, structures, components, or design of a facility; or the design approval for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of the commercial nuclear plant license issued under this part.

(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.

(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.

(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriate documented evaluation for its finding, either—

(i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or

(ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or

(iii) That the regulatory action involves defining or redefining what level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission must always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available

concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) The statement of the specific objectives that the proposed backfit is designed to achieve;

(2) The general description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) The potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) The potential impact on radiological exposure of facility employees;

(5) The installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.

(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his or her designee.

§ 53.1595 Renewal.

Licenses may be renewed by the Commission upon expiration of the period of the license.

Subpart J—Reporting and Other Administrative Requirements

§ 53.1600 General information.

Each applicant and licensee under this part must ensure that U.S. Nuclear Regulatory Commission (NRC) inspectors have unfettered access to sites and facilities licensed or proposed to be licensed in § 53.1610, must maintain records and make reports to the NRC in accordance with requirements in §§ 53.1620 through 53.1650, must satisfy financial qualification and reporting requirements in §§ 53.1660 through 53.1700, and must obtain and maintain required financial protections in case of an accident in §§ 53.1720 and 53.1730.

§ 53.1610 Unfettered access for inspections.

(a) Each applicant for or holder of a manufacturing license (ML), operating license (OL), combined license (COL), construction permit (CP), or early site permit must permit inspection, by duly authorized representatives of the Commission, of its records, premises, activities, and of licensed materials in possession or use, related to the license or CP or early site permit as may be necessary to effectuate the purposes of the Atomic Energy Act of 1956, as amended, (the Act) and the Energy Reorganization Act of 1974, as amended.

(b)(1) Each holder of an ML, OL, COL, or CP must, upon request by the Director, Office of Nuclear Reactor Regulation, provide rent-free office space for the exclusive use of the Commission inspection personnel. Heat, air conditioning, light, electrical outlets, and janitorial services must be furnished by each licensee and each holder of a CP. The office must be convenient to and have full access to the facility and must provide the inspectors both visual and acoustic privacy.

(2) For a site or facility with an assigned resident inspector, the space provided must be adequate to accommodate a full-time inspector, a part-time secretary, and transient NRC personnel and must be generally commensurate with other office facilities at the site. For sites or facilities assigned multiple resident inspectors, additional space may be requested. The office space that is provided must be subject to the approval of the Director, Office of Nuclear Reactor Regulation. All furniture, supplies, and communication equipment will be furnished by the Commission.

(3) For a site or facility without an assigned resident inspector, temporary space to accommodate periodic or special inspections must be provided. The office space must be generally commensurate with other office accommodations at the site.

(4) The licensee or permit holder must afford any NRC resident inspector assigned to that site, or other NRC inspectors identified by the Regional Administrator as likely to inspect the facility, immediate unfettered access, equivalent to access provided regular plant employees, following proper identification and compliance with applicable access control measures for security, radiological protection, and personal safety.

(5) The licensee or permit holder must ensure that the arrival and presence of an NRC inspector, who has been properly authorized facility access as described in paragraph (b)(4) of this section, is not announced or otherwise communicated by its employees or contractors to other persons at the facility unless specifically requested by the NRC inspector.

§ 53.1620 Maintenance of records, making of reports.

(a) Each holder of an ML, OL, COL, CP, or early site permit must maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the regulations and orders of the Commission in effectuating the purposes of the Act and the Energy Reorganization Act of 1974, as amended. Reports must be submitted in accordance with § 53.040.

(b) [Reserved]

(c) Records that are required by the regulations in this part, by license condition, or by technical specifications must be retained for the period specified by the appropriate regulation, license condition, or technical specification. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility license or, in the case of an early site permit, until the permit expires.

(d)(1) Records which must be retained under this part may be the original or a reproduced copy or a microform if the reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee must maintain adequate safeguards against tampering with, and loss of records.

(2) If there is a conflict between the Commission's regulations in this part, license condition, or technical specification, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part for such records shall apply unless the Commission, under § 53.080 of this part, has granted a specific exemption from the record retention requirements in the regulations in this part.

(e) Each licensee must notify the Commission as specified in § 53.040 of this part, of successfully completing power ascension testing or startup testing as applicable within 30 calendar days of completing the testing.

§ 53.1630 Immediate notification requirements for operating commercial nuclear plants.

(a) *General requirements.*[1]

(1) Each holder of an OL under this part or a COL under this part after the Commission makes the finding under § 53.1452(g), must notify the NRC Headquarters Operations Center via the Emergency Notification System (ENS) of—

(i) The declaration of any of the Emergency Classes specified in the licensee's approved Emergency Plan; or

(ii) Those non-emergency events specified in paragraph (b) of this section that occurred within 3 years of the date of discovery.

(2) If the ENS is inoperative, the licensee must make the required notifications via commercial telephone service, other dedicated telephone system, or any other method which will ensure that a report is made as soon as practical to the NRC Headquarters Operations Center at the numbers specified in appendix A to part 73 of this chapter.

(3) The licensee must notify the NRC immediately after notification of the appropriate State or local agencies and not later than 1 hour after the time the licensee declares one of the Emergency Classes.

(4) The licensee must activate the data links with the NRC as specified in their emergency plans after declaring an Emergency Class for events of actual or potential substantial degradation of plant safety or security, probable risk to site personnel life, or site equipment damage caused by hostile action. The data links may also be activated by the licensee during emergency drills or exercises if the licensee's computer system has the capability to transmit the exercise data.

(5) When making a report under paragraph (a)(1) of this section, the licensee must identify—

(i) The Emergency Class declared; or

(ii) Paragraph (b)(1), “One-hour reports,” paragraph (b)(2), “Four-hour reports,” or paragraph (b)(3), “Eight-hour reports,” as the paragraph of this section requiring notification of the non-emergency event.

(6) In lieu of submitting a report required under paragraph (b)(2) or (b)(3) of this section through the Emergency Notification System, the licensee may submit the report using other methods, provided the licensee submits the report to the NRC Headquarters Operations Center within the required timeframe and confirms receipt of the report by the NRC.

(b) *Non-emergency events*.

(1) *One-hour reports*. If not reported as a declaration of an Emergency Class under paragraph (a) of this section, the licensee must notify the NRC as soon as practical and in all cases within one hour of the occurrence of any deviation from the plant’s Technical Specifications authorized under § 53.740(h) of this part.

(2) *Four-hour reports*. If not reported under paragraphs (a) or (b)(1) of this section, the licensee must notify the NRC as soon as practical, and in all cases within 4 hours of the occurrence of any of the following:

(i) The initiation of any commercial nuclear plant shutdown required by the plant’s Technical Specifications.

(ii) Any event or condition that results in actuation of the reactor protection system when the reactor is critical except when the actuation results from and is part of a pre-planned sequence during testing or reactor operation.

(iii) [Reserved]

(iv) Any event or condition that results in an unplanned movement of, change of state in, or chemical interaction involving a significant amount of radioactive material within the commercial nuclear plant.

(v) [Reserved]

(3) *Eight-hour reports*. If not reported under paragraphs (a), (b)(1), or (b)(2) of this section, the licensee must notify the NRC as soon as practical and in all cases within 8 hours of the occurrence of any of the following:

(i) Any event or condition that results in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in a condition not analyzed under § 53.450 that significantly degrades plant safety.

(ii) [Reserved]

(iii) [Reserved]

(iv) [Reserved]

(v) Any event that results in a major loss of emergency assessment capability, offsite response capability, or offsite communications capability (e.g., significant portion of control room indication, ENS, or offsite notification system).

(c) *Follow-up notification*: With respect to the notifications made under paragraphs (a) and (b) of this section, in addition to making the required initial notification, each licensee, must during the course of the event—

(1) Immediately report:

(i) Any further degradation in the level of safety of the plant or other worsening plant conditions, including those that require the declaration of any of the Emergency Classes, if such a declaration has not been previously made, or

(ii) Any change from one Emergency Class to another, or

(iii) A termination of the Emergency Class.

(2) Immediately report:

(i) The results of ensuing evaluations or assessments of plant conditions,

(ii) The effectiveness of response or protective measures taken, and

(iii) Important information related to plant behavior that is not understood.

(3) Maintain an open, continuous communication channel with the NRC Headquarters Operation Center upon request by the NRC.

[1] Other requirements for immediate notification of the NRC by licensed operating commercial nuclear plants are contained elsewhere in this chapter, in particular §§ 20.1906, 20.2202, 72.216, 73.77, and 73.1200 of this chapter.

§ 53.1640 Licensee event report system.

(a) *Reportable events*.

(1) Each commercial nuclear plant licensee holding an OL under this part or a COL under this part after the Commission makes the finding under § 53.1452(g), must submit a Licensee Event Report (LER) for any event of the type described in this paragraph (a) within 60 days after discovery of the event. In the case of an invalid actuation reported under § 53.1640(a)(2), other than automatic reactor shutdown when the reactor is critical, the licensee may, at its option, provide a telephone notification to the NRC Operations Center within 60 days after discovery of the event instead of submitting a written LER. Unless otherwise specified in this section, the licensee must report an event if it occurred within 3 years of the date of discovery regardless of the plant mode or power level, and regardless of the significance of the structure, system, or component that initiated the event.

(2) The licensee must report—

(i)(A) The completion of any commercial nuclear plant shutdown required by the plant's Technical Specifications.

(B) Any operation or condition which was prohibited by the plant's Technical Specifications except when—

(1) The Technical Specification is administrative in nature;

(2) The event consisted solely of a case of a late surveillance test where the oversight was corrected, the test was performed, and the equipment was found to be capable of performing its specified safety functions; or

(3) The Technical Specification was revised prior to discovery of the event such that the operation or condition was no longer prohibited at the time of the event.

(C) Any deviation from the plant's Technical Specifications authorized under § 53.740(h).

(ii) Any event or condition that resulted in—

(A) The condition of the commercial nuclear plant, including its principal safety barriers, being seriously degraded; or

(B) The commercial nuclear plant being in a condition not analyzed under § 53.450 that significantly degrades plant safety.

(iii) Any natural phenomena or other external condition that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the commercial nuclear plant.

(iv) Any event or condition that resulted in inadvertent operation of any structures, systems, and component classified as safety-related (SR) for an identified safety function under § 53.460 or the unplanned sole reliance on an SR system for those systems that are in constant operation, except when—

(A) The actuation resulted from and was part of a pre-planned sequence during testing; or

(B) The actuation was invalid and—

(*1*) Occurred while the system was properly removed from service; or

(*2*) Occurred after the safety function had been already completed.

(v) Any event or condition that could have prevented the fulfillment of the safety functions identified under § 53.230.

(vi) Events covered in paragraph (a)(2)(v) of this section may include one or more procedural errors, equipment failures, and/or discovery of design, fabrication, construction, and/or procedural inadequacies. However, individual component failures need not be reported pursuant to paragraph (a)(2)(v) of this section if any other equipment was operable and available to perform the required safety function.

(vii)(A) Any event or condition that as a result of a single cause could have prevented the fulfillment of any of the safety functions identified under § 53.230.

(B) Events covered in paragraph (a)(2)(vii)(A) of this section may include cases of procedural error, equipment failure, and/or discovery of a design, analysis, fabrication, construction, and/or procedural inadequacy. However, licensees are not required to report an event pursuant to paragraph (a)(2)(vii)(A) of this section if the event results from—

(*1*) A shared dependency among trains or channels that is a natural or expected consequence of the approved plant design; or

(*2*) Normal and expected wear or degradation.

(viii)(A) Any airborne radioactive release that, when averaged over a time period of 1-hour, resulted in airborne radionuclide concentrations in an unrestricted area that exceeds 20 times the applicable concentration limits specified in appendix B to 10 CFR part 20, table 2, column 1.

(B) Any liquid effluent release that, when averaged over a time period of 1-hour, exceeds 20 times the applicable concentrations specified in appendix B to 10 CFR part 20, table 2, column 2, at the point of entry into the receiving waters (i.e., unrestricted area) for all radionuclides except tritium and dissolved noble gases.

(ix) Any event that posed an actual threat to the safety of the commercial nuclear plant or significantly hampered site personnel in the performance of duties necessary for the safe operation of the plant, including fires, toxic gas releases, or radioactive releases.

(b) *Contents*. The LER must contain—

(1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

(2)(i) A clear, specific narrative description of what occurred so that knowledgeable readers conversant with the design of commercial nuclear plants, but not familiar with the details of a particular plant, can understand the complete event.

(ii) The narrative description must include the following specific information as appropriate for the particular event:

(A) Plant operating conditions before the event.

(B) Status of systems, structures, or components that were inoperable at the start of the event and that contributed to the event.

(C) Dates and approximate time of the occurrences.

(D) The cause of each component or system failure or personnel error, if known.

(E) The failure mode, mechanism, and effect of each failed component, if known.

(F) [Reserved]

(G) For failures of components with multiple functions, include a list of systems or secondary functions that were also affected.

(H) For failure that rendered a component or system classified as SR or non-safety-related but safety-significant inoperable, an estimate of the elapsed time from the discovery of the failure until the component or system was returned to service.

(I) The method of discovery of each component or system failure or procedural error.

(J) For each human performance related root cause, the licensee must discuss the cause(s) and circumstances.

(K) Automatically and manually initiated safety system responses.

(L) The manufacturer and model number (or other identification) of each component that failed during the event.

(3) An assessment of the safety consequences and implications of the event. This assessment must include—

(i) The availability of systems or components that could have performed the same function as the components and systems that failed during the event, and

(ii) For events that occurred when the reactor was shut down, the availability of systems or components that are needed to shut down the reactor and maintain safe shutdown conditions, remove residual heat, control the release of radioactive material, or mitigate the consequences of an accident.

(4) A description of any corrective actions planned as a result of the event, including those to reduce the probability of similar events occurring in the future.

(5) Reference to any previous similar events at the same plant that are known to the licensee.

(6) The name and contact information of a person within the licensee's organization who is knowledgeable about the event and can provide additional information concerning the event and the plant's characteristics.

(c) *Supplemental information*. The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for

supplemental information will be made in writing and the licensee must submit, as specified in § 53.040, the requested information as a supplement to the initial LER.

(d) *Submission of reports*. Licensee Event Reports must be prepared on NRC Form 366 and submitted to the NRC, as specified in § 53.040.

(e) *Report legibility*. The reports and copies that licensees are required to submit to the Commission under the provisions of this section must be of sufficient quality to permit legible reproduction and micrographic processing.

§ 53.1645 Reports of radiation exposure to members of the public.

(a) Each holder of an OL, and each holder of a COL after the Commission has made the finding under § 53.1452(g), must submit radiological reports as required by 10 CFR part 20, as well as an Annual Radioactive Effluent Release Report and an Annual Radiological Environmental Operating Report. The Annual Radioactive Effluent Release Report must specify the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents and an estimate of the dose received by the maximally exposed member of the public in an unrestricted area from effluents and direct radiation from contained sources during the previous calendar year. The Annual Radiological Environmental Operating Report must provide data on measurable levels of radiation and radioactive materials in the environment, must include an evaluation of the relationship between quantities of radioactive material released in effluents and resultant radiation doses to individuals from principal pathways of exposure, and must include the results of environmental monitoring during the previous calendar year. These reports must also include any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public. The reports must be submitted as specified in § 53.040 by May 15 of each successive year. If the total effective dose equivalent to members of the public in unrestricted areas during the reporting period is greater than the design objectives

established under § 53.425, the report must specify the causes for exceeding the design objective and describe any corrective actions. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

(b) If during any calendar quarter the radiation exposure to a member of the public in the unrestricted areas, calculated on the same basis as the respective design objective exposure, exceeds one-half of the annual design objective exposure, the licensee must submit a report as specified in § 53.040. The report shall specify the causes for exceeding one-half the annual design objective exposure in a quarter and describe corrective actions that the licensee will take to maintain radiation exposure to levels within the design objectives for the remainder of the year. The report shall be submitted within 30 days from the end of the quarter when one-half of the annual design objective exposure was exceeded.

§ 53.1650 Facility information and verification.

(a) In response to a written request by the Commission, each applicant for a CP or license and each recipient of a CP or a license must submit facility information, as described in § 75.10 of this chapter, on International Atomic Energy Agency (IAEA) Design Information Questionnaire forms and site information on DOC/NRC Form AP-A and associated forms;

(b) As required by the Additional Protocol, must submit location information described in § 75.11 of this chapter on DOC/NRC Form AP-1 and associated forms; and

(c) Must permit verification thereof by the IAEA and take other action as necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

§ 53.1660 Financial requirements.

Sections 53.1670 through 53.1700 set out the requirements and procedures related to financial qualifications and related reporting requirements.

§ 53.1670 Financial qualifications.

Except for an electric utility applicant for a license to operate a commercial nuclear plant, an applicant for a CP, OL, or COL under this part must appear to be financially qualified for the activities for which the permit or license is sought.

§ 53.1680 [Reserved]

§ 53.1690 Licensee's change of status; financial qualifications.

(a) An electric utility licensee holding an OL or COL (including a renewed license) for a commercial nuclear plant, no later than seventy-five (75) days prior to ceasing to be an electric utility in any manner not involving a license transfer under § 53.1399 or § 53.1456 must provide the NRC with the financial qualifications information that would be required for obtaining an initial OL under this part. The financial qualifications information must address the first full 5 years of operation after the date the licensee ceases to be an electric utility.

(b)(1) Any holder of a license issued under this part must notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against—

(i) The licensee;

(ii) An entity (as 11 U.S.C. 101(14) defines that term) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as 11 U.S.C. 101(2) defines that term) of the licensee.

(2) This notification must indicate—

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

§ 53.1700 Creditor regulations.

(a) Pursuant to section 184 of the Act, the Commission consents, without individual application, to the creation of any mortgage, pledge, or other lien upon any facility not owned by the United States which is the subject of a license or upon any leasehold or other interest in such facility; provided—

(1) That the rights of any creditor so secured may be exercised only in compliance with and subject to the same requirements and restrictions as would apply to the licensee pursuant to the provisions of the license, the Act, and regulations issued by the Commission under the Act; and

(2) That no creditor so secured may take possession of the facility pursuant to the provisions of this section prior to either the issuance of a license from the Commission authorizing such possession or the transfer of the license.

(b) Any creditor so secured may apply for transfer of the license covering such facility by filing an application for transfer of the license under § 53.1570. The Commission will act upon such application under subpart I of this part.

(c) Nothing contained in this regulation shall be deemed to affect the means of acquiring, or the priority of, any tax lien or other lien provided by law.

(d) As used in this section—

(1) *License* includes any license under this part, which may be issued by the Commission with regard to a facility.

(2) *Creditor* includes, without implied limitation, the trustee under any mortgage, pledge or lien on a facility made to secure any creditor, any trustee or receiver of the facility appointed by a court of competent jurisdiction in any action brought for the benefit of any creditor secured by such mortgage, pledge or lien, any purchaser of such facility at the sale thereof upon foreclosure of such mortgage, pledge, or lien or upon exercise of any power of sale contained therein, or any assignee of any such purchaser.

(3) *Facility* includes, but is not limited to, a site which is the subject of an early site permit under this part, and a reactor manufactured under an ML under this part.

§ 53.1710 Financial protection.

Sections 53.1720 and 53.1730 set out the requirements and procedures related to licensees obtaining and maintaining insurance to cover stabilization and decontamination activities in the event of an accident and financial protection in accordance with part 140, “Financial Protection Requirements and Indemnity Agreements,” of this chapter.

§ 53.1720 Insurance required to stabilize and decontaminate plant following an accident.

Each commercial nuclear plant licensee under this part must take reasonable steps to obtain insurance available at reasonable costs and on reasonable terms from private sources or to demonstrate that it possesses an equivalent amount of protection covering the licensee's obligation, in the event of an accident at the licensee's commercial nuclear reactor, to stabilize and decontaminate the plant and the plant site at which such an accident may occur, provided that—

(a) The insurance required by this section must have a minimum coverage limit for each commercial nuclear plant site of $1.06 billion, an amount based on plant-specific estimates of costs to stabilize and decontaminate a plant, or whatever amount of insurance is generally available from private sources, whichever is less. The required insurance must clearly state that, as and to the extent provided in paragraph (d)(1) of this section, any proceeds must be payable first for stabilization of the plant and next for decontamination of the plant and the plant site. If a licensee's coverage falls below the required minimum, the licensee must within 60 days take all reasonable steps to restore its coverage to the required minimum. The required insurance may, at the option of the

licensee, be included within policies that also provide coverage for other risks, including, but not limited to, the risk of direct physical damage.

(b)(1) With respect to policies issued or annually renewed, the proceeds of such required insurance must be dedicated, as and to the extent provided in this paragraph (b), to reimbursement or payment on behalf of the insured of reasonable expenses incurred or estimated to be incurred by the licensee in taking action to fulfill the licensee's obligation, in the event of an accident at the licensee's plant, to ensure that the plant is in, or is returned to, and maintained in, a safe and stable condition and that radioactive contamination is removed or controlled such that personnel exposures are consistent with the occupational exposure limits in 10 CFR part 20. These actions must be consistent with any other obligation the licensee may have under this chapter and must be subject to paragraph (d) of this section. As used in this section, an "accident" means an event that involves the release of radioactive material from its intended place of confinement within the commercial nuclear plant such that there is a present danger of release off site in amounts that would pose a threat to the public health and safety.

(2) The stabilization and decontamination requirements set forth in paragraph (d) of this section must apply uniformly to all insurance policies required under this section.

(c) The licensee shall report to the NRC on April 1 of each year the current levels of this insurance or financial security it maintains and the sources of this insurance or financial security.

(d)(1) In the event of an accident at the licensee's plant, whenever the estimated costs of stabilizing the licensed plant and of decontaminating the plant and the plant site exceed one tenth of the minimum insurance under paragraph (a) of this section, the proceeds of the insurance required by this section must be dedicated to and used, first, to ensure that the licensed plant is in, or is returned to, and can be maintained in, a safe and stable condition so as to prevent any significant risk to the public health and safety

and, second, to decontaminate the plant and the plant site in accordance with the licensee's cleanup plan as approved by order of the Director, Office of Nuclear Reactor Regulation. This priority on insurance proceeds must remain in effect for 60 days or, upon order of the Director, for such longer periods, in increments not to exceed 60 days except as provided for activities under the cleanup plan required in paragraphs (d)(3) and (d)(4) of this section, as the Director may find necessary to protect the public health and safety. Actions needed to bring the plant to and maintain the plant in a safe and stable condition may include one or more of the following, as appropriate:

(i) Shutdown of the reactor(s) and other processes at the plant;

(ii) Establishment and maintenance of long-term cooling with stable decay heat removal;

(iii) Maintenance of sub-criticality;

(iv) Control of radioactive releases; and

(v) Securing of structures, systems, or components to minimize radiation exposure to onsite personnel or to the offsite public or to facilitate later decontamination or both.

(2) The licensee must inform the Director, Office of Nuclear Reactor Regulation in writing when the plant is and can be maintained in a safe and stable condition so as to prevent any significant risk to the public health and safety. Within 30 days after the licensee informs the Director that the plant is in this condition, or at such earlier time as the licensee may elect or the Director may for good cause direct, the licensee must prepare and submit a cleanup plan for the Director's approval. The cleanup plan must identify and contain an estimate of the cost of each cleanup operation that will be required to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for

authority to decommission the reactor and to surrender the license voluntarily. Cleanup operations may include one or more of the following, as appropriate:

(i) Processing any contaminated materials generated by the accident and by decontamination operations to remove radioactive materials;

(ii) Decontamination of surfaces inside the plant buildings to levels consistent with the Commission's occupational exposure limits in 10 CFR part 20, and decontamination or disposal of equipment;

(iii) Decontamination or removal and disposal of internal parts, damaged fuel from the reactor coolant or fuel systems, or related process or waste systems; and

(iv) Cleanup of the reactor coolant or fuel systems or related process or waste systems.

(3) Following review of the licensee's cleanup plan, the Director will order the licensee to complete all operations that the Director finds are necessary to decontaminate the reactor sufficiently to permit the licensee either to resume operation of the reactor or to apply to the Commission under subpart G of this part for authority to decommission the reactor and to surrender the license voluntarily. The Director must approve or disapprove, in whole or in part for stated reasons, the licensee's estimate of cleanup costs for such operations. Such order may not be effective for more than one year, at which time it may be renewed. Each subsequent renewal order, if imposed, may be effective for not more than 6 months.

(4) Of the balance of the proceeds of the required insurance not already expended to place the plant in a safe and stable condition under paragraph (b)(1) of this section, an amount sufficient to cover the expenses of completion of those decontamination operations that are the subject of the Director's order must be dedicated to such use, provided that, upon certification to the Director of the amounts expended previously and from time to time for stabilization and decontamination and

upon further certification to the Director as to the sufficiency of the dedicated amount remaining, policies of insurance may provide for payment to the licensee or other loss payees of amounts not so dedicated, and the licensee may proceed to use in parallel (and not in preference thereto) any insurance proceeds not so dedicated for other purposes.

§ 53.1730 Financial protection requirements.

Commercial nuclear plant licensees must satisfy the applicable provisions of part 140, “Financial Protection Requirements and Indemnity Agreements,” of this chapter.

Subparts K and L [Reserved]

Subpart M—Enforcement

§ 53.9000 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended (the Act);

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued under those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(ii) Section 206 of the Energy Reorganization Act of 1974, as amended;

(iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Act.

§ 53.9010 Criminal penalties.

(a) Section 223 of the Act provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 53 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in 10 CFR part 53 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 53.000, 53.015, 53.020, 53.040, 53.080, 53.090, 53.100, 53.110, 53.120, 53.600, 53.725, 53.726, 53.735, 53.760, 53.775, 53.790, 53.795, 53.820, 53.910, 53.1000, 53.1050, 53.1100, 53.1103, 53.1106, 53.1109, 53.1112, 53.1115, 53.1118, 53.1120, 53.1121, 53.1124, 53.1140, 53.1144, 53.1146, 53.1149, 53.1155, 53.1158, 53.1164, 53.1170, 53.1173, 53.1176, 53.1179, 53.1188, 53.1200, 53.1206, 53.1209, 53.1210, 53.1212, 53.1215, 53.1218, 53.1221, 53.1230, 53.1236, 53.1239, 53.1241, 53.1242, 53.1245, 53.1248, 53.1251, 53.1254, 52.1257, 52.1260, 53.1263, 53.1270, 53.1276, 53.1279, 53.1282, 53.1285, 53.1286, 53.1287, 53.1288, 53.1291, 53.1293, 53.1295, 53.1300, 53.1306, 53.1309, 53.1312, 53.1315, 53.1318, 53.1324, 53.1330, 53.1333, 53.1336, 53.1348, 53.1360, 53.1366, 53.1369, 53.1372, 53.1375, 53.1381, 53.1384, 53.1387, 53.1390, 53.1396, 53.1401, 53.1405, 53.1410, 53.1416, 53.1419, 53.1422, 53.1425, 53.1431, 53.1437, 53.1440, 53.1443, 53.1452, 53.1455, 53.1456, 53.1458, 53.1461, 53.1470, 53.1500, 53.1510, 53.1515, 53.1520, 53.1525, 53.1530, 53.1535, 53.1540, 53.1560, 53.1585, 53.1590, 53.1595, 53.1600, 53.1660, 53.1670, 53.1700, 53.1710, 53.1730, 53.9000, 53.9010.

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

134. The authority citation for 10 CFR part 70 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57(d), 108, 122, 161, 182, 183, 184, 186, 187, 193, 223, 234, 274, 1701 (42 U.S.C. 2071, 2073, 2077(d), 2138, 2152, 2201, 2232, 2233, 2234, 2236, 2237, 2243, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161).

Section 70.21(g) also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

Section 70.31 also issued under Atomic Energy Act sec. 57(d) (42 U.S.C. 2077(d)).

Sections 70.36 and 70.44 also issued under Atomic Energy Act sec. 184 (42 U.S.C. 2234).

Section 70.81 also issued under Atomic Energy Act secs. 186, 187 (42 U.S.C. 2236, 2237).

Section 70.82 also issued under Atomic Energy Act sec. 108 (42 U.S.C. 2138).

§ 70.20a [Amended]

135. In § 70.20a, in paragraph (b) add the number “53,” in sequential order.

§ 70.22 [Amended]

136. In § 70.22, wherever it may appear, remove the phrase “part 50” and add in its place the phrase “part 50 or part 53”.

137. In § 70.24, revise paragraphs (d)(1) and (d)(2) to read as follows:

§ 70.24 Criticality accident requirements.

* * * * *

(d)(1) The requirements in paragraphs (a) through (c) of this section do not apply to a holder of a construction permit or operating license for a nuclear power reactor issued under part 50 or part 53 of this chapter or a combined license issued under part 52 or part 53 of this chapter, if the holder complies with the requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440, as applicable.

(2) An exemption from § 70.24 held by a licensee who thereafter elects to comply with requirements of paragraph (b) of 10 CFR 50.68 or paragraph (m)(2) of 10 CFR 53.440 does not exempt that licensee from complying with any of the requirements in § 50.68 or § 53.440(m) of this chapter but will be ineffective so long as the licensee elects to comply with § 50.68(b) or § 53.440(m)(2) of this chapter, as applicable.

§ 70.32 [Amended]

138. In § 70.32, in paragraph (c)(1) introductory text, remove the phrase “part 50 of this chapter” and add in its place the phrase “part 50 or part 53 of this chapter”; and in paragraph (d) remove the phrase “or § 70.34 of this chapter, as appropriate.” and add in its place the phrase “, § 70.34, or § 53.1510 of this chapter, as appropriate.”.

139. In § 70.50, revise paragraph (d) to read as follows:

§ 70.50 Reporting requirements.

* * * * *

(d) The provisions of § 70.50 do not apply to licensees subject to § 50.72 or § 53.1630 of this chapter. They do apply to those 10 CFR parts 50 or 53 licensees possessing material licensed under 10 CFR part 70 that are not subject to the notification requirements in § 50.72 or § 53.1630 of this chapter.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

140. The authority citation for 10 CFR part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear

Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

141. In § 72.3, revise the definition for "*Independent spent fuel storage installation or ISFSI"* to read as follows:

§ 72.3 Definitions.

* * * * *

Independent spent fuel storage installation or ISFSI means a complex designed and constructed for the interim storage of spent nuclear fuel, solid reactor-related GTCC waste, and other radioactive materials associated with spent fuel and reactor-related GTCC waste storage. An ISFSI which is located on the site of another facility licensed under this part or a facility licensed under part 50 or part 53 of this chapter and which shares common utilities and services with that facility or is physically connected with that other facility may still be considered independent.

* * * * *

142. In § 72.30, revise paragraph (e)(5) to read as follows:

§ 72.30 Financial assurance and recordkeeping for decommissioning.

* * * * *

(e) * * *

(5) In the case of licensees who are issued a power reactor license under part 50 or part 53 of this chapter or ISFSI licensees who are an electric utility, as defined in part 50 or part 53 of this chapter, with a specific license issued under this part, the methods of § 50.75(b), (e), and (h) or § 53.1010, § 53.1040, § 53.1045(b), and § 53.1060 of this chapter, as applicable. In the event that funds remaining to be placed into the licensee's ISFSI decommissioning external sinking fund are no longer approved for recovery in rates by a competent rate making authority, the licensee must make changes to provide

financial assurance using one or more of the methods stated in paragraphs (e)(1) through (4) of this section.

* * * * *

143. In § 72.32, revise paragraph (c)(2) to read as follows:

§ 72.32 Emergency plan.

* * * * *

(c) * * *

(2)(i) Located within the exclusion area as defined in 10 CFR part 100, of a nuclear power reactor licensed for operation by the Commission, the emergency plan that meets 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 shall be deemed to satisfy the requirements of this section.

(ii) Located within the exclusion area, as defined in 10 CFR part 53, of a commercial nuclear plant licensed for operation by the Commission, the emergency plan that meets 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 shall be deemed to satisfy the requirements of this section.

* * * * *

§ 72.40 [Amended]

144. In § 72.40, in paragraph (c) remove the phrase “under part 50 of this chapter,” and add in its place the phrase “under part 50 or part 53 of this chapter,”.

145. In § 72.75, revise paragraph (i)(1)(ii) to read as follows:

§ 72.75 Reporting requirements for specific events and conditions.

* * * * *

(i) * * *

(1) * * *

(ii) Licensees issued a general license under § 72.210, after the licensee has placed spent fuel on the ISFSI storage pad (if the ISFSI is located inside the collocated protected area, for a reactor licensed under part 50 or part 53 of this chapter) or after the licensee has transferred spent fuel waste outside the reactor licensee's protected area to the ISFSI storage pad (if the ISFSI is located outside the collocated protected area, for a reactor licensed under part 50 or part 53 of this chapter).

* * * * *

§ 72.184 [Amended]

146. In § 72.184, in paragraph (a) remove the phrase “under part 50 of this chapter” and add in its place the phrase “under part 50 or part 53 of this chapter”.

147. Revise § 72.210 to read as follows:

§ 72.210 General license issued.

A general license is hereby issued for the storage of spent fuel in an independent spent fuel storage installation at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50, part 52, or part 53.

148. In § 72.212, revise paragraph (b)(8) to read as follows:

§ 72.212 Conditions of general license issued under § 72.210.

* * * * *

(b) * * *

(8) Before use of the general license, determine whether activities related to storage of spent fuel under this general license involve a change in the facility Technical Specifications or require a license amendment for the facility pursuant to § 50.59(c) or § 53.1550 of this chapter. Results of this determination must be documented in the evaluations made in paragraph (b)(5) of this section.

* * * * *

149. In § 72.218, revise paragraphs (a) and (b) to read as follows:

§ 72.218 Termination of licenses.

(a) The notification regarding the program for the management of spent fuel at the reactor required by § 50.54(bb) or § 53.1060 of this chapter must include a plan for removal of the spent fuel stored under this general license from the reactor site. The plan must show how the spent fuel will be managed before starting to decommission systems and components needed for moving, unloading, and shipping this spent fuel.

(b) An application for termination of a reactor operating license issued under 10 CFR part 50 and submitted under § 50.82 of this chapter, or a combined license issued under 10 CFR part 52 and submitted under § 52.110 of this chapter, or a reactor operating or combined license under 10 CFR part 53 and submitted under § 53.1070 of this chapter must contain a description of how the spent fuel stored under this general license will be removed from the reactor site.

* * * * *

PART 73—PHYSICAL PROTECTION OF PLANTS AND MATERIALS

150. The authority citation for 10 CFR part 73 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 147, 149, 161, 161A, 170D, 170E, 170H, 170I, 223, 229, 234, 1701 (42 U.S.C. 2073, 2167, 2169, 2201, 2201a, 2210d, 2210e, 2210h, 2210i, 2273, 2278a, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Section 73.37(b)(2) also issued under sec. 301, Pub. L. 96-295, 94 Stat. 789 (42 U.S.C. 5841 note).

151. In § 73.1, revise paragraph (b)(1)(i) to read as follows:

§ 73.1 [Amended]

* * * * *

(b) * * *

(1) * * *

(i) The physical protection of production and utilization facilities licensed under part 50, part 52, or part 53 of this chapter,

* * * * *

152. In § 73.2, revise introductory text and paragraph (a) to read as follows:

§ 73.2 Definitions.

As used in this part:

(a) Terms defined in parts 50, 52, 53, 70, and 95 of this chapter have the same meaning when used in this part.

* * * * *

153. In § 73.8, revise paragraph (b) to read as follows:

§ 73.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 73.5, 73.15, 73.17, 73.20, 73.21, 73.24, 73.25, 73.26, 73.27, 73.37, 73.40, 73.45, 73.46, 73.50, 73.54, 73.55, 73.56, 73.57, 73.58, 73.60, 73.67, 73.70, 73.72, 73.73, 73.74, 73.77, 73.100, 73.110, 73.120, 73.1200, 73.1205, 73.1210, 73.1215, and appendices B and C to this part.

* * * * *

154. In § 73.50, revise the introductory text to read as follows:

§ 73.50 Requirements for physical protection of licensed activities.

Each licensee who is not subject to § 73.51, but who possesses, uses, or stores formula quantities of strategic special nuclear material that are not readily separable from other radioactive material and which have a total external radiation level in excess of 1 gray (100 rad) per hour at a distance of 1 meter (3.3 feet) from any accessible surfaces without intervening shielding other than at a nuclear reactor facility licensed under part 50, part 52, or part 53 of this chapter, shall comply with the following:

* * * * *

155. In § 73.55, revise paragraphs (a)(4) and (6), (b)(8) and (9)(ii)(C), (c)(6), (i)(4)(iii), (l)(1) and (7)(ii), (p)(1)(i) and (ii), and (r)(2) and (r)(4)(iii) to read as follows:

§ 73.55 Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage.

(a) * * *

(4) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter or holders of a combined license under the provisions of part 52 or part 53 of this chapter shall implement the requirements of this section before fuel is allowed onsite (protected area).

* * * * *

(6) Applicants for an operating license under the provisions of part 50 or part 53 of this chapter, or holders of a combined license under the provisions of part 52 or part 53 of this chapter that do not reference a standard design certification or reference a standard design certification issued after May 26, 2009, shall meet the requirement of § 73.55(i)(4)(iii).

(b) * * *

(8) The licensee shall establish, maintain, and implement a cyber security program in accordance with § 73.54 or § 73.110, as applicable.

(9) * * *

(ii) * * *

(C) The cyber security program described in § 73.54 or § 73.110, as applicable; and

* * * * *

(c) * * *

(6) Cyber Security Plan. The licensee shall establish, maintain, and implement a Cyber Security Plan that describes how the criteria set forth in § 73.54 or § 73.110, as applicable, will be implemented.

* * * * *

(i) * * *

(4) * * *

(iii) Applicants for an operating license under the provisions of part 50 of this chapter, or holders of a combined license under the provisions of part 52 of this chapter, or licensees under part 53 of this chapter that elect to demonstrate compliance with § 73.55, consistent with § 53.860(a)(2) of this chapter, shall construct, locate, protect, and equip both the central and secondary alarm stations to the standards for the central alarm station contained in this section. Both alarm stations shall be equal and redundant, such that all functions needed to satisfy the requirements of this section can be performed in both alarm stations.

* * * * *

(l) * * *

(1) Commercial nuclear power reactors licensed under 10 CFR part 50, part 52, or part 53 and authorized to use special nuclear material in the form of MOX fuel assemblies containing up to 20 weight percent PuO_2 shall, in addition to demonstrating compliance with the requirements of this section, protect un-irradiated MOX fuel assemblies against theft or diversion as described in this paragraph (l).

* * * * *

(7) * * *

(ii) Additional measures for the physical protection of un-irradiated MOX fuel assemblies containing greater than 20 weight percent PuO_2 shall be determined by the

Commission on a case-by-case basis and documented through license amendment in accordance with § 50.90 or § 53.1510 of this chapter.

* * * * *

(p) * * *

(1) * * *

(i) Under § 50.54 paragraphs (x) and (y) or § 53.740(h) of this chapter, the licensee may suspend any security measures under this section in an emergency when this action is immediately needed to protect the public health and safety and no action consistent with license conditions and technical specifications that can provide adequate or equivalent protection is immediately apparent. This suspension of security measures must be approved as a minimum by a licensed senior operator or a generally licensed reactor operator, as applicable, before taking this action.

(ii) During severe weather when the suspension of affected security measures is immediately needed to protect the personal health and safety of security force personnel and no other immediately apparent action consistent with the license conditions and technical specifications can provide adequate or equivalent protection. This suspension of security measures must be approved, as a minimum, by a licensed senior operator or a generally licensed reactor operator, as applicable, with input from the security supervisor or manager, before taking this action.

* * * * *

(r) * * *

(2) The licensee shall submit proposed alternative measure(s) to the Commission for review and approval under § 50.4 and § 50.90, or § 53.040 and § 53.1510 of this chapter, before implementation.

* * * * *

(4) * * *

(iii) Based on comparison of the costs of the alternative measures to the costs of demonstrating compliance with the Commission's requirements using the essential elements of § 50.109 or § 53.1590 of this chapter, the costs of fully demonstrating compliance with the Commission's requirements are not justified by the protection that would be provided.

156. In § 73.56, revise paragraph (a)(3) to read as follows:

§ 73.56 Personnel access authorization requirements for nuclear power plants.

(a) * * *

(3) Each applicant for an operating license under the provisions of part 50 of this chapter, each holder of a combined license under the provisions of part 52 of this chapter, and applicants for an operating license or holders of a combined license under part 53 of this chapter who do not demonstrate compliance with 10 CFR 73.100(a)(1)(i) shall implement the requirements of this section before fuel is allowed on site (protected area).

* * * * *

157. In § 73.57, revise paragraph (a)(3) to read as follows:

§ 73.57 Requirements for criminal history records checks of individuals granted unescorted access to a nuclear power facility, a non-power reactor, or access to Safeguards Information.

(a) * * *

(3) Before receiving its operating license under 10 CFR part 50 or part 53 or before the Commission makes its finding under § 52.103(g) or § 53.1452(g) of this chapter, each applicant for a license to operate a nuclear power reactor (including an applicant for a combined license) or a non-power reactor may submit fingerprints for those individuals who will require unescorted access to the nuclear power facility or non-power reactor facility.

* * * * *

158. In § 73.58, revise paragraph (a) to read as follows:

§ 73.58 [Amended]

(a) Each operating nuclear power reactor licensee with a license issued under part 50, part 52, or part 53 of this chapter shall comply with the requirements of this section.

* * * * *

159. In § 73.67, revise introductory text of paragraphs (d) and (f) to read as follows:

§ 73.67 Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance.

* * * * *

(d) *Fixed site requirements for special nuclear material of moderate strategic significance.* Each licensee who possesses, stores, or uses quantities and types of special nuclear material of moderate strategic significance at a fixed site or contiguous sites, except as allowed by paragraph (b)(2) of this section and except those who are licensed to operate a nuclear power reactor pursuant to part 50 or part 53, provided that the special nuclear material is located within a protected area and protected under § 73.55 or § 73.100, shall:

* * * * *

(f) *Fixed site requirements for special nuclear material of low strategic significance.* Each licensee who possesses, stores, or uses special nuclear material of low strategic significance at a fixed site or contiguous sites, except those who are licensed to operate a nuclear power reactor pursuant to part 50 or part 53, provided that the special nuclear material is located within a protected area and protected under § 73.55 or § 73.100, shall:

* * * * *

160. In § 73.77, revise paragraphs (a), (b)(1), (c)(6) and (7) to read as follows:

§ 73.77 Cybersecurity event notifications.

(a) Each licensee subject to the provisions of § 73.54 or § 73.110 shall notify the NRC Headquarters Operations Center via the Emergency Notification System (ENS), under paragraph (c) of this section:

(1) Within one hour after discovery of a cyberattack that adversely impacted:

(i) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that compromised support systems and equipment resulting in adverse impacts to safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(ii) Safety, security, and emergency preparedness functions performed by digital assets that prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter, or security functions performed by digital assets necessary for implementing the physical security requirements in § 53.860(a) of this chapter.

(2) Within 4 hours:

(i) After discovery of a cyberattack that could have caused an adverse impact to:

(A) Safety-related or important-to-safety functions, security functions, or emergency preparedness functions (including offsite communications); or that could have compromised support systems and equipment, which if compromised, could have adversely impacted safety, security, or emergency preparedness functions within the scope of § 73.54; or,

(B) Safety, security, and emergency preparedness functions performed by digital assets that prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter, or security functions performed by

digital assets necessary for implementing the physical security requirements in § 53.860(a) of this chapter.

(ii) After discovery of a suspected or actual cyberattack initiated by personnel with physical or electronic access to digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(iii) After notification to a local, State, or other Federal agency (e.g., law enforcement, Federal Bureau of Investigation (FBI), etc.) of an event related to the licensee's implementation of their cybersecurity program for digital computer and communication systems and networks within the scope of § 73.54 or § 73.110 that does not otherwise require a notification under paragraph (a) of this section.

(3) Within 8 hours after receipt or collection of information regarding observed behavior, activities, or statements that may indicate intelligence gathering or pre-operational planning related to a cyberattack against digital computer and communication systems and networks within the scope of § 73.54 or § 73.110.

(b) *Twenty-four hour recordable events.*

(1) The licensee shall use the site corrective action program to record vulnerabilities, weaknesses, failures and deficiencies in their § 73.54 or § 73.110 cybersecurity program within 24 hours of their discovery.

* * * * *

(c) * * *

(6) *Declaration of emergencies*. Notifications made to the NRC for the declaration of an emergency class shall be performed in accordance with § 50.72 or § 53.1630 of this chapter, as applicable.

(7) *Elimination of duplication*. Separate notifications and reports are not required for events that are also reportable under §§ 50.72 and 50.73 or §§ 53.1630 and 53.1640

of this chapter. However, these notifications should also indicate the applicable § 73.77 reporting criteria.

* * * * *

161. Add Subpart J—Security Requirements at Commercial Nuclear Plants and §§ 73.100 through 73.120 to read as follows:

Subpart J—Security Requirements at Commercial Nuclear Plants

§ 73.100 Technology-inclusive requirements for physical protection of licensed activities at commercial nuclear plants against radiological sabotage.

(a) *Introduction*.

(1) Each licensee that is licensed to operate a commercial nuclear plant under part 53 of this chapter and elects to implement the requirements of this section must identify achievable target sets in accordance with paragraph (b)(5) of this section and develop, implement, and maintain a physical protection program under the following requirements:

(i) Each licensee that demonstrates no achievable target sets exist in accordance with paragraph (b)(5) of this section, and does not credit any active measures (e.g., operator action, mitigative action, detection, assessment, armed response) in making that demonstration, is exempt from the remaining requirements of this section.

(ii) Each licensee that demonstrates no achievable target sets exist in accordance with paragraph (b)(5) of this section, and credits active measures in making that demonstration, must implement the requirements of this section through its physical security plan, training and qualification plan, safeguards contingency plan, and cybersecurity plan, referred to collectively hereafter as ‘‘security plans,” before initial fuel load into the reactor (or, for a fueled manufactured reactor, before initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter); for such licensees, the requirements of paragraphs (b)(2) through (4) of this section will be

deemed satisfied if the physical protection program is designed to ensure that the credited active measures will be implemented in response to threats up to and including the design-basis threat of radiological sabotage.

(iii) Each licensee that demonstrates achievable target sets exist, in accordance with paragraph (b)(5) of this section, must implement the requirements of this section through its physical security plan, training and qualification plan, safeguards contingency plan, and cybersecurity plan, referred to collectively hereafter as ‘‘security plans,” before initial fuel load into the reactor (or, for a fueled manufactured reactor, before initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter).

(2) The security plans must identify, describe, and account for site-specific conditions that affect the licensee’s capability to satisfy the requirements of this section.

(b) *General performance objective and requirements*.

(1) The licensee must establish, implement, and maintain a physical protection program and a security organization, which will have as their objective to provide reasonable assurance that activities involving special nuclear material are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

(2) To satisfy the general performance objective of paragraph (b)(1) of this section, the physical protection program must protect against the design-basis threat of radiological sabotage as stated in § 73.1. Specifically, the licensee must—

(i) Ensure that the physical protection program capabilities to protect against the design-basis threat of radiological sabotage are maintained at all times; and

(ii) Provide defense in depth in achieving performance requirements through the integration of engineered systems, administrative controls, and management measures.

(3) The physical protection program must be designed to prevent the release of

radionuclides from any source from exceeding the dose reference values defined in § 53.210 of this chapter.

(4) The physical protection program must be designed and implemented to achieve and maintain the reliability and availability of structures, systems, and components (SSCs) required for demonstrating compliance with the following performance requirements at all times:

(i) *Intrusion detection*. The licensee must be capable of detecting attempted and actual unauthorized access to interior and exterior areas containing SSCs needed to implement safety and security functions.

(ii) *Intrusion assessment*. The licensee must be capable of timely assessment for determining the cause of a detected intrusion.

(iii) *Security communication*. The licensee must be capable of continuous security communications. Communication systems must account for design-basis threats that can interrupt or interfere with continuity or integrity of communications.

(iv) *Security response*. The physical protection program must be designed to provide timely security response to interdict and neutralize adversary attacks up to and including the design-basis threat of radiological sabotage. The physical protection program must be designed to provide layers of security response, with each layer assuring that a single failure does not result in the loss of capability to neutralize the design-basis threat adversary. Structures, systems, and components relied on for delay functions must be designed to allow for timely security responses to adversary attacks with adequate defense in depth.

(A) The security response may rely on the use of onsite responders, law enforcement or other offsite armed responders, or a combination thereof, to fulfill the interdiction and neutralization functions required by paragraph (b)(4)(iv) of this section. A

licensee relying entirely or partially on law enforcement or other offsite armed responders must—

(*1*) Maintain the capability to detect, assess, interdict, and neutralize threats as required by paragraphs (b)(4)(i), (b)(4)(ii), and (b)(4)(iv) of this section;

(*2*) Provide adequate delay to enable law enforcement or other offsite armed responders to fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*3*) Provide necessary information about the facility and make available periodic training to law enforcement or other offsite armed responders who will fulfill the interdiction and neutralization functions for threats up to and including the design-basis threat of radiological sabotage;

(*4*) Fully describe in the safeguards contingency plan the role that law enforcement or other offsite armed responders will play in the licensee's protective strategy. The description must provide sufficient detail to enable the NRC to determine that the licensee's physical protection program provides reasonable assurance of adequate protection against threats up to and including the design-basis threat of radiological sabotage; and

(*5*) Identify criteria and measures to compensate for the degradation or absence of law enforcement or other offsite armed responders and propose suitable compensatory measures that meet the requirements of paragraph (h)(3) of this section to address this degradation.

(B) For licensees relying entirely or partially on law enforcement responders to fulfill the interdiction and neutralization functions required by paragraph (b)(4)(iv) of this section, the training and qualification requirements related to armed response personnel in paragraphs (c) and (e) of this section do not apply to law enforcement responders. The licensee shall continue to satisfy the performance evaluation requirements in

paragraph (g) of this section for all armed response personnel, including law enforcement.

(v) *Protecting against land and waterborne vehicle bomb assaults*. The licensee must be capable of protecting the plant against the design-basis threat vehicle bomb assault. The methods that are relied on to protect against a design-basis threat land vehicle and waterborne vehicle bomb assault must be designed to protect the reactor building and structures containing safety- or security-related systems, and components from explosive effects.

(vi) *Access control portals*. The licensee must be capable of detecting and denying unauthorized access to persons and pass-through of contraband materials (e.g., weapons, incendiary devices, explosives) to protected areas.

(5) The licensee must identify and document complete and accurate target sets in accordance with the following:

(i) Preventative operator actions may be credited as target set elements when: sufficient time to implement exists; environmental conditions allow operator actions to be completed successfully; adversary interference is precluded; all equipment required for operator actions is available, dedicated, staged, and maintained; approved procedures exist specific to the task being performed; and training is maintained for proficiency of the credited operator action.

(ii) The identification of target sets must not assume the success of the security organization; except that licensees may consider delay provided by the security organization when assessing the availability of operator actions.

(iii) The licensee must consider cyberattacks in the identification of target sets.

(iv) The licensee must further identify achievable target sets through a site-specific analysis. Achievable target sets are those that are within the capabilities of the design-basis threat adversary to compromise, destroy, or render non-functional; cannot

be mitigated after adversary interference is precluded and prior to a release of radionuclides exceeding dose reference values defined in 10 CFR 53.210; and, if defeated, result irreversibly in exceedance of the dose reference values in 10 CFR 53.210.

(v) The licensee must document and maintain the process used to identify achievable target sets, to include the site-specific analyses and methodologies used to determine and group the target set equipment or elements, including elements not contained in a protected or vital area.

(vi) The licensee must implement a process for the oversight of target set equipment and systems to ensure that changes to the configuration of the identified equipment and systems are considered in the licensee's protective strategy. Where appropriate, changes must be made to documented target sets.

(vii) The licensee must maintain records in accordance with paragraph (j) of this section and, in addition, must maintain site-specific analyses until submittal of the licensee’s certifications required by § 53.1070 of this chapter.

(6) The licensee must identify and analyze site-specific conditions, including achievable target sets, that may affect the physical protection program needed to implement the requirements of this section. The licensee must account for these conditions in demonstrating compliance with the requirements of this section.

(7) The licensee must establish, implement, and maintain a performance evaluation program to assess the effectiveness of the licensee’s implementation of the physical protection program to protect against the design-basis threat of radiological sabotage.

(8) The licensee must establish, implement, and maintain an access authorization program under § 73.56, and must describe the program in the physical security plan.

(9) The licensee must establish, implement, and maintain a cybersecurity program under § 73.54 or § 73.110 and must describe the program in the cybersecurity plan.

(10) The licensee must establish, implement, and maintain an insider mitigation program and must describe the program in the physical security plan.

(i) The insider mitigation program must monitor the initial and continuing trustworthiness and reliability of individuals granted or retaining unescorted access or unescorted access authorization to a protected or vital area, and implement defense-in-depth methodologies to minimize the potential for an insider (active, passive, or both) to adversely affect, either directly or indirectly, the licensee's capability to protect against radiological sabotage.

(ii) The insider mitigation program must integrate elements of—

(A) The access authorization program under § 73.56 or § 73.120;

(B) The fitness-for-duty program under 10 CFR part 26;

(C) The cybersecurity program under § 73.54 or § 73.110; and

(D) The physical protection program under this section.

(11) The licensee must have the capability to track, trend, correct, and prevent recurrence of failures and deficiencies in the implementation of the requirements of this section.

(12) Implementation of security plans and associated procedures must be coordinated with other onsite plans and procedures to preclude conflict during both normal and emergency conditions and ensure the adequate management of the safety and security interface.

(13)(i) The licensee must ensure that the firearms background check requirements of § 73.17 of this part are met for all members of the security organization whose official duties require access to covered weapons or who inventory enhanced

weapons.

(ii) The provisions of this paragraph (b)(13) are only applicable to licensees subject to this section that are also subject to the firearms background check provisions of § 73.17 of this part.

(c) *Security organization*. The licensee must establish and maintain a security organization that is staffed, trained, qualified, and equipped to implement the physical protection program under the requirements of this section.

(1) The licensee must establish a management system for maintaining and implementing security policies and procedures to implement the requirements of this section and the security plans.

(2) Implementing procedures must document the conduct of security operations, security design and configuration controls, maintenance, training and qualification, and contingency responses.

(3) The licensee must—

(i) Establish a process for the approval of designs, policies, processes, and procedures and changes by the individual with overall responsibility for the physical protection program; and

(ii) Ensure that revisions and changes to the physical protection program and implementing policies, processes, and procedures satisfy the requirements of this section.

(4) The licensee must retain, in accordance with § 73.70, all analyses, assessments, calculations, and descriptions of the technical basis for demonstrating compliance with the performance requirements of paragraph (b) of this section. The licensee must protect these records in accordance with the requirements for protecting safeguards information in §§ 73.21 and 73.22.

(5) The licensee may not permit any individual to implement any part of the

physical protection program unless the individual has been trained, equipped, and qualified to perform their assigned duties and responsibilities in accordance with the training and qualification plan.

(d) *Search requirements*. The licensee must establish and implement searches of individuals, vehicles, and materials to detect and prevent the introduction into the protected area of firearms, explosives, incendiary devices, or other items and material which could be used to commit radiological sabotage.

(e) *Training and qualification program*. The licensee must establish and maintain a training and qualification program that ensures personnel who are responsible for the physical protection of the facility against radiological sabotage are able to effectively perform their assigned security-related job duties for implementing the requirements of this section and must describe the program in the training and qualification plan.

(f) *Security reviews*. The licensee must establish and implement security reviews to assess the effectiveness of the implementation of the physical protection program. Security reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the onsite physical protection program.

(1) The licensee must review each element of the physical protection program at a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions. The objective of these reviews must be maintaining effective implementation of the engineered and administrative controls required to achieve the physical protection program functions and the management system required to implement programs and requirements in this section.

(2) The licensee must establish and perform self-assessments to ensure the effective implementation of the physical protection program functions of detection,

assessment, communication, delay, and interdiction and neutralization to protect against the design-basis threat of radiological sabotage. The licensee must perform design verification and assessments of the capabilities of active and passive engineering systems relied on to protect against the design-basis threat.

(3) Reviews of the security program must include, but are not limited to, an audit of the effectiveness of the physical protection program, security plans, implementing procedures, cybersecurity programs, safety/security interface activities, the testing, maintenance, and calibration program, and response commitments by local, State, and Federal law enforcement authorities.

(4) The results and recommendations of the onsite physical protection program reviews, management's findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(g) *Performance evaluation*. Licensee performance evaluations must include methods appropriate and necessary to assess, test, and challenge the integration of the physical protection program's functions to protect against the design-basis threat, including measures to protect against cyberattack and engineered systems designed to protect against the design-basis threat standalone ground vehicle bomb attack.

(1) The licensee must establish the frequencies for performance evaluations commensurate with the security significance of the physical protection program.

(2) The licensee must document processes and procedures for implementing the performance evaluations. The licensee must maintain records, including results, findings, and corrective actions identified during the performance evaluations.

(h) *Maintenance, testing, and calibration and corrective actions*.

(1) The licensee must ensure that security SSCs, including supporting systems, are inspected, tested, and calibrated for operability and performance at intervals

necessary and sufficient to meet the requirements of this section.

(2) The licensee must implement corrective actions to ensure resolution of identified vulnerabilities and deficiencies to meet the requirements of this section.

(3) The licensee must establish and implement timely compensatory measures for degraded or inoperable security SSCs to meet the requirements of this section. Compensatory measures must provide a level of protection that is equivalent to the protection that was provided prior to the degradation or inoperability of the security structures, systems, or components.

(4) The licensee must document processes and procedures and maintain records for implementing the corrective actions, compensatory measures, and maintenance, inspection, testing, and calibration of security SSCs.

(i) *Suspension of security measures*.

(1) The licensee may suspend implementation of affected requirements of this section in accordance with § 53.740(h) of this chapter under the following conditions:

(i) In an emergency, when action is immediately needed to protect the public health and safety; and

(ii) During severe weather, when the suspension of affected security measures is immediately needed to protect the personal health and safety of personnel.

(2) Suspended security measures must be reinstated as soon as conditions permit.

(3) The suspension of security measures must be reported and documented in accordance with the provisions of §§ 73.1200 and 73.1205.

(j) *Records*.

(1) The Commission may inspect, copy, retain, and remove all reports, records, and documents required to be kept by Commission regulations, orders, or license conditions, whether the reports, records, and documents are kept by the licensee or a

contractor.

(2) The licensee must maintain all records required to be kept by Commission regulations, orders, or license conditions, until the Commission terminates the license for which the records were developed and must maintain superseded portions of these records for at least 3 years after the record is superseded, unless otherwise specified by the Commission.

(3) If a contracted security force is used to implement the onsite physical protection program, the licensee's written agreement with the contractor must be retained by the licensee as a record for the duration of the contract.

(4) Review and audit reports must be available for inspection, for a period of 3 years.

§ 73.110 Technology-inclusive requirements for protection of digital computer and communication systems and networks.

(a) Each licensee that is licensed to operate a commercial nuclear plant under 10 CFR part 53 and elects to implement the requirements of this section must establish, implement, and maintain a cybersecurity program that is commensurate with the potential consequences resulting from cyberattacks, up to and including the design-basis threat as described in § 73.1. The cybersecurity program must provide reasonable assurance that digital computer and communication systems and networks are adequately protected against cyberattacks that are capable of causing the following consequences:

(1) Adversely impacting the safety, security, and emergency preparedness functions performed by digital assets that prevent a postulated fission product release resulting in offsite doses exceeding the values in § 53.210 of this chapter.

(2) Adversely impacting the security functions performed by digital assets necessary for implementing the physical security requirements in § 53.860(a) of this

chapter.

(b) To protect digital computer and communication systems and networks associated with the functions described in paragraphs (a)(1) and (2) of this section, the licensee must—

(1) Analyze the potential consequences resulting from cyberattacks on digital computer and communication systems and networks and identify those assets that must be protected to demonstrate compliance with paragraph (a) of this section; and

(2) Implement the cybersecurity program in accordance with paragraph (d) of this section.

(c) The licensee must protect the systems and networks identified in paragraph (b)(1) of this section in a manner that is commensurate with the potential consequences resulting from cyberattacks that:

(1) Adversely impact the integrity or confidentiality of data and/or software;

(2) Deny access to systems, services, and/or data; and

(3) Adversely impact the operation of systems, networks, and associated equipment.

(d) The cybersecurity program must be designed in a manner that is commensurate with the potential consequences resulting from cyberattacks through the following steps:

(1) Implement security controls to protect the assets identified under paragraph (b)(1) of this section from cyberattacks, commensurate with their safety and security significance;

(2) Apply and maintain defense-in-depth protective strategies to ensure the capability to detect, delay, respond to, and recover from cyberattacks capable of causing the consequences identified in paragraph (a) of this section;

(3) Mitigate the adverse effects of cyberattacks capable of causing the

consequences identified in paragraph (a) of this section; and

(4) Ensure that the functions of protected assets identified under paragraph (b)(1) of this section are not adversely impacted due to cyberattacks.

(e) The licensee must implement the following requirements in a manner that is commensurate with the potential consequences resulting from cyberattacks:

(1) As part of the cybersecurity program, the licensee must comply with the requirements in § 73.54(d)(1), (2), and (4), and must ensure that modifications to assets, identified under paragraph (b)(1) of this section are evaluated before implementation to ensure that the cybersecurity performance objectives identified in paragraph (a) of this section are maintained.

(2) The licensee must establish, implement, and maintain a cybersecurity plan that implements the cybersecurity program requirements of this section.

(i) The cybersecurity plan must describe how the requirements of this section will be implemented and must account for the site-specific conditions that affect implementation.

(ii) The cybersecurity plan must include measures for incident response and recovery for cyberattacks. The cybersecurity plan must include the analysis identified under paragraph (b)(1) of this section and describe how the licensee will—

(A) Apply and maintain defense-in-depth protective strategies as required in paragraph (d)(2) of this section;

(B) Maintain the capability for timely detection and response to cyberattacks;

(C) Mitigate the consequences of cyberattacks;

(D) Correct exploited vulnerabilities; and

(E) Restore affected systems, networks, and/or equipment affected by cyberattacks.

(3) The licensee must develop and maintain written policies and implementing procedures to implement the cybersecurity plan. Policies, implementing procedures, and other supporting technical information used by the licensee need not be submitted for Commission review and approval as part of the cybersecurity plan but are subject to inspection by NRC staff on a periodic basis.

(4) The licensee must establish and implement cybersecurity reviews to assess the effectiveness of the implementation of the cybersecurity program.

(i) The licensee must review each element of the cybersecurity program at a frequency commensurate with the importance or significance to safety of plant operations to ensure timely identification and documentation of vulnerabilities, improvements, and corrective actions.

(ii) Cybersecurity reviews must be performed by individuals independent of those personnel responsible for program management and any individual who has direct responsibility for implementing the cybersecurity program.

(iii) The licensee must establish and perform self-assessments to ensure the effective implementation of the cybersecurity program.

(iv) The results and recommendations of the cybersecurity program reviews, management’s findings regarding program effectiveness, and any actions taken as a result of recommendations from prior program reviews, must be documented in a report and must be maintained in an auditable form and available for inspection.

(5) The licensee must retain all records and supporting technical documentation required to demonstrate compliance with the requirements of this section as a record until the Commission terminates the license for which the records were developed and must maintain superseded portions of these records for at least three (3) years after the record is superseded, unless otherwise specified by the Commission.

§ 73.120 Access authorization program for commercial nuclear plants.

(a) *Introduction and scope*. Each applicant for an operating license or a holder of a combined license under 10 CFR part 53 must establish, maintain, and implement an access authorization program before initial fuel load into the reactor (or, for a fueled manufactured reactor, before initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter). The requirements in this section apply to applicants and licensees who demonstrate compliance with 10 CFR 73.100(a)(1)(i).

(b) *Applicability*.

(1) The following individuals must be subject to an access authorization program under this section:

(i) Any individual to whom a licensee intends to grant unescorted access to a commercial nuclear plant protected area, vital area, or controlled access area where licensed material is used or stored;

(ii) Any individual whose duties and responsibilities permit the individual to take actions by electronic means, either on site or remotely, that could adversely impact the licensee's or applicant’s operational safety, security, or emergency preparedness;

(iii) Any individual who has responsibilities for implementing a licensee's or applicant's protective strategy, including armed security force officers, alarm station operators, and tactical response team leaders but not including Federal, State, or local law enforcement personnel; and

(iv) The licensee or applicant access authorization program reviewing official or contractor or vendor access authorization program reviewers.

(2) The licensee or applicant may subject other individuals, including employees of a contractor or a vendor who are designated in access authorization program procedures, to an access authorization program that demonstrates compliance with the requirements of this section.

(c) *General performance objectives and requirements*. Each licensee's or

applicant's access authorization program under this section must demonstrate that the individuals who are specified in paragraph (b) of this section are trustworthy and reliable, such that they do not constitute an unreasonable risk to public health and safety or the common defense and security. The licensee's access authorization program must maintain the capabilities for demonstrating compliance with the following performance requirements:

(1) *Background investigation*.

(i)(A) Licensees and applicants must ensure that any individual seeking initial unescorted access or to maintain unescorted access is subject to a background investigation.

(B) Background investigations must include the program elements contained under § 37.25 of this chapter and must also include a credit history evaluation.

(ii) Background investigations must include fingerprinting and an FBI identification and criminal history records check in accordance with § 37.27 of this chapter.

(iii) Licensees must have the informed and signed consent of the subject individual to initiate a background investigation. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. A signed consent must be obtained prior to any reinvestigation. The subject individual may withdraw his or her consent at any time. Licensees must inform the individual that—

(A) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

(B) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(2) *Behavioral observation*. Licensees, applicants, contractors, and vendors must ensure the access authorization program includes provisions that the individuals specified in paragraph (b) of this section are subject to behavioral observation.

(i) Each person subject to behavioral observation must communicate to the licensee or applicant observed behaviors or activities of individuals that may constitute an unreasonable risk to the health and safety of the public and common defense and security.

(ii) Behavioral observation must include visual observation, in person or remotely by video, to detect and promptly report to plant supervision any concerns arising from behavioral observation, including, but not limited to, concerns related to any questionable behavior patterns or activities of others.

(3) *Self-reporting of legal actions*. Licensees or applicants must inform personnel who are granted and who maintain unescorted access of their responsibilities to self-report to plant supervision legal actions taken by a law enforcement authority or court of law against the individual that could result in incarceration or a court order or that requires a court appearance, including but not limited to an arrest, an indictment, the filing of charges, or a conviction, but excluding minor civil actions or misdemeanors such as parking violations or speeding tickets, for any individual who has applied for unescorted access or who maintains unescorted access.

(4) *Unescorted access*. Licensees or applicants must grant unescorted access only after the licensee has verified an individual is trustworthy and reliable. A list of persons currently approved for unescorted access to a protected area, vital area, or controlled access area must be maintained at all times. Unescorted access determinations must be reviewed annually by the reviewing official. Licensees and applicants must complete an FBI criminal history record check update for each individual maintaining unescorted access, within 10 years of the last review.

(5) *Termination of unescorted access.* Licensees and applicants must promptly terminate unescorted access when this access is no longer required or a reviewing official determines an individual is no longer trustworthy and reliable in accordance with this section.

(6) *Determination basis for access*.

(i) The licensee's or applicant's reviewing official must determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access based on an evaluation of all of the information collected to demonstrate compliance with the requirements of this section.

(ii) Licensees and applicants must provide individuals subject to this section, prior to any final adverse determination, the right to complete, correct, and explain information obtained as a result of the licensee's background investigation pursuant to § 37.23(g) of this chapter.

(iii) The licensee's or applicant's reviewing officials are the only individuals authorized to make unescorted access determination decisions. Each licensee or applicant must name one or more individuals to be reviewing officials pursuant to the requirements of § 37.23(b)(2) of this chapter.

(7) *Review procedures*. Review procedures must be established in accordance with § 37.23(f) of this chapter, to include provisions for the notification in writing of individuals who are denied unescorted access or who are unfavorably terminated.

(8) *Protection of information*. Licensees, applicants, contractors, or vendors must establish and maintain a system of files and procedures in accordance with § 37.31 of this chapter, to ensure personal information is not disclosed to unauthorized persons.

(9) *Access authorization reviews and corrective action*. Licensees and applicants must develop, implement, and maintain procedures for conduct of access authorization reviews and corrective actions in accordance with § 37.33 of this chapter to ensure the

continuing effectiveness of the access authorization program and to ensure that the access authorization program and program elements are in compliance with the requirements of this section. Each licensee and applicant must be responsible for the continuing effectiveness of the access authorization program, including access authorization program elements that are provided by the contractors or vendors, and the access authorization programs of any of the contractors or vendors that are accepted by the licensee or applicant.

(10) *Records.* Licensees, applicants, and contractors or vendors must document the processes and procedures for maintaining records used or created to establish an individual's trustworthiness and reliability or to document access determinations. Licensees, applicants, and contractor or vendors must—

(i) Retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access;

(ii) Retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, retain the superseded material for 3 years after the record is superseded; and

(iii) Retain the list of persons approved for unescorted access for 3 years after the list is superseded or replaced. Records maintained in any database(s) must be available for NRC review.

162. In § 73.1200, revise paragraphs (a) introductory text, (c)(1) introductory text, (e)(1) introductory text, (e)(4), (g)(1) introductory text, (o)(5)(i) and (o)(6)(i), (r), and (s) to read as follows:

§ 73.1200 Notification of physical security events.

(a) *15-minute notifications—facilities*. Each licensee subject to the provisions of § 73.20, § 73.45, § 73.46, § 73.51, § 73.55, or § 73.100 must notify the NRC Headquarters Operations Center, as soon as possible but within 15 minutes after—

* * * * *

(c) * * *

(1) Each licensee subject to the provisions of § 73.20, § 73.45, § 73.46, § 73.50, § 73.51, § 73.55, § 73.60, § 73.67, or § 73.100 must notify the NRC Headquarters Operations Center as soon as possible but no later than 1 hour after the time of discovery of the following significant facility security events involving—

* * * * *

(e) * * *

(1) Each licensee subject to the provisions of § 73.20, § 73.45, § 73.46, § 73.50, § 73.51, § 73.55, § 73.60, § 73.67, or § 73.100 must notify the NRC Headquarters Operations Center within 4 hours after time of discovery of the following facility security events involving—

* * * * *

(4) For licensees subject to the provisions of § 73.55 or § 73.100 of this part, an event involving the licensee's suspension of security measures.

* * * * *

(g) * * *

(1) Each licensee subject to the provisions of § 73.20, § 73.45, § 73.46, § 73.50, § 73.51, § 73.55, § 73.60, § 73.67, or § 73.100 must notify the NRC Headquarters Operations Center within 8 hours after time of discovery of the following facility security program failures involving—

* * * * *

(o) * * *

(5) * * *

(i) Licensees must establish the requested continuous communications channel once the licensee has completed other required notifications under this section, § 50.72 of this chapter, appendix E to part 50 of this chapter, § 53.1630 of this chapter, § 70.50 of this chapter; or § 72.75 of this chapter; as appropriate.

* * * * *

(6) * * *

(i) Licensees must establish the requested continuous communications channel once the licensee or the movement control center has completed other required notifications under this section, § 50.72 of this chapter, appendix E to part 50 of this chapter, § 53.1630 of this chapter, § 70.50 of this chapter; § 72.75 of this chapter; or requested assistance from the LLEA, as appropriate.

* * * * *

(r) *Declaration of emergencies*. Licensees notifying the NRC of the declaration of an emergency class must do so in accordance with §§ 50.72, 53.1630, 63.73, 70.50, and 72.75 of this chapter, as applicable.

(s) *Elimination of duplication*. Licensees with notification obligations under paragraphs (a) through (h), (m), and (n) of this section and §§ 50.72, 53.1630, 63.73, 70.50, and 72.75 of this chapter may notify the NRC of events in a single communication. This communication must identify each regulation under which the licensee is reporting.

* * * * *

163. In § 73.1205, revise paragraph (b)(2) to read as follows:

§ 73.1205 Written follow-up reports of physical security events.

* * * * *

(b) * * *

(2) * * *

(i) Licensees subject to § 50.73 or § 53.1640 of this chapter must prepare the written follow-up report on NRC Form 366.

(ii) Licensees not subject to § 50.73 or § 53.1640 of this chapter must prepare the written follow-up report in a letter format.

* * * * *

164. In § 73.1210, revise paragraphs (a)(1) and (b)(3)(i) to read as follows:

§ 73.1210 Recordkeeping of physical security events.

(a) * * *

(1) Licensees with facilities or shipment activities subject to the provisions of § 73.20, § 73.25, § 73.26, § 73.27, § 73.37, § 73.45, § 73.46, § 73.50, § 73.51, § 73.55, § 73.60, § 73.67, or § 73.100, must record the physical security events and conditions adverse to security that are specified in paragraphs (c) through (f) of this section.

* * * * *

(b) * * *

(3) * * *

(i) Licensees must record these physical security events and conditions adverse to security in either a stand-alone safeguards event log or as part of the licensee's corrective action program, as specified under the applicable quality assurance program provisions of parts 50, 52, 53, 60, 63, 70, and 72 of this chapter, or both.

* * * * *

165. In § 73.1215, revise paragraph (d)(1) to read as follows:

§ 73.1215 Suspicious activity reports.

* * * * *

(d) * * *

(1) For licensees subject to the provisions of § 73.20, § 73.45, § 73.46, § 73.50, § 73.51, § 73.55, § 73.60, § 73.67, or § 73.100, the licensees must report activities they assess are suspicious. Examples include, but are not limited to, the following:

* * * * *

166. In appendix B to part 73, revise *Definitions* introductory text to read as follows:

Appendix B to Part 73—General Criteria for Security Personnel

* * * * *

Definitions

Terms defined in parts 50, 53, 70, and 73 of this chapter have the same meaning when used in this appendix.

* * * * *

PART 74—MATERIAL CONTROL AND ACCOUNTING OF SPECIAL NUCLEAR MATERIAL

167. The authority citation for 10 CFR part 74 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 161, 182, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2201, 2232, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

168. In § 74.31, revise paragraph (a) introductory text to read as follows:

§ 74.31 Nuclear material control and accounting for special nuclear material of low strategic significance.

(a) *General performance objectives*. Each licensee who is authorized to possess and use more than one effective kilogram of special nuclear material of low strategic significance, excluding sealed sources, at any site or contiguous sites subject to control by the licensee, other than a production or utilization facility licensed pursuant to part 50,

part 53, or part 70 of this chapter, or operations involved in waste disposal, shall implement and maintain a Commission-approved material control and accounting system that will achieve the following objectives:

* * * * *

169. In § 74.41, revise paragraph (a) introductory text to read as follows:

§ 74.41 Nuclear material control and accounting for special nuclear material of moderate strategic significance.

(a) *General performance objectives*. Each licensee who is authorized to possess special nuclear material (SNM) of moderate strategic significance or SNM in a quantity exceeding one effective kilogram of strategic special nuclear material in irradiated fuel reprocessing operations other than as sealed sources and to use this material at any site other than a nuclear reactor licensed pursuant to part 50 or part 53 of this chapter; or as reactor irradiated fuels involved in research, development, and evaluation programs in facilities other than irradiated fuel reprocessing plants; or an operation involved with waste disposal, shall establish, implement, and maintain a Commission-approved material control and accounting (MC&A) system that will achieve the following performance objectives:

* * * * *

170. In § 74.51, revise paragraph (a) introductory text to read as follows:

§ 74.51 Nuclear material control and accounting for strategic special nuclear material.

(a) *General performance objectives*. Each licensee who is authorized to possess five or more formula kilograms of strategic special nuclear material (SSNM) and to use such material at any site, other than a nuclear reactor licensed pursuant to part 50 or 53 of this chapter, an irradiated fuel reprocessing plant, an operation involved with waste disposal, or an independent spent fuel storage facility licensed pursuant to part 72 of this

chapter shall establish, implement, and maintain a Commission-approved material control and accounting (MC&A) system that will achieve the following objectives:

* * * * *

PART 75—SAFEGUARDS ON NUCLEAR MATERIAL – IMPLEMENTATION OF SAFEGUARDS AGREEMENTS BETWEEN THE UNITED STATES AND THE INTERNATIONAL ATOMIC ENERGY AGENCY

171. The authority citation for 10 CFR part 75 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 63, 103, 104, 122, 161, 223, 234, 1701 (42 U.S.C. 2073, 2093, 2133, 2134, 2152, 2201, 2273, 2282, 2297f); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Section 75.4 also issued under Nuclear Waste Policy Act secs. 135 (42 U.S.C. 10155, 10161).

172. In § 75.4, revise the second paragraph of the introductory text and the definition for “Facility” to read as follows:

§ 75.4 Definitions.

* * * * *

Unless otherwise defined in this section, the terms defined in §§ 40.4, 50.2, 53.020, and 70.4 of this chapter have the same meaning when used in this part.

* * * * *

Facility means:

(6) Any plant or location where the possession of more than 1 effective kilogram of nuclear material is licensed pursuant to 10 CFR part 40, 50, 53, 60, 61, 63, 70, 72, 76, or 150 of this chapter or an Agreement State license.

* * * * *

PART 95—FACILITY SECURITY CLEARANCE AND SAFEGUARDING OF NATIONAL SECURITY INFORMATION AND RESTRICTED DATA

173. The authority citation for 10 CFR part 95 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 145, 161, 223, 234 (42 U.S.C. 2165, 2201, 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note; E.O. 10865, as amended, 25 FR 1583, 3 CFR, 1959–1963 Comp., p. 398; E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298.

174. In § 95.5, revise the definition for "*License*" to read as follows:

§ 95.5 Definitions.

* * * * *

License means a license issued under 10 CFR part 50, 52, 53, 54, 60, 63, 70, or 72.

* * * * *

§ 95.39 [Amended]

175. In § 95.39(a), remove "part 52" and add in its place "part 52 or part 53."

PART 140—FINANCIAL PROTECTION REQUIREMENTS AND INDEMNITY AGREEMENTS

176. The authority citation for 10 CFR part 140 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 170, 223, 234 (42 U.S.C. 2201, 2210, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

177. In § 140.2, revise paragraphs (a)(1) and (2) to read as follows:

§ 140.2 Scope.

(a) * * *

(1) To each person who is an applicant for or holder of a license issued under 10 CFR part 50, 52, 53, or 54 to operate a nuclear reactor, and

(2) With respect to an extraordinary nuclear occurrence, to each person who is an applicant for or holder of a license to operate a production facility or a utilization facility (including an operating license issued under part 50 or part 53 of this chapter and a combined license under part 52 or part 53 of this chapter), and to other persons indemnified with respect to the involved facilities.

* * * * *

178. Revise § 140.10 to read as follows:

§ 140.10 Scope.

This subpart applies to each person who is an applicant for or holder of a license issued under 10 CFR part 50, 53 or 54 to operate a nuclear reactor, or is the applicant for or holder of a combined license issued under 10 CFR part 52, 53, or 54, except licenses held by persons found by the Commission to be Federal agencies or nonprofit educational institutions licensed to conduct educational activities. This subpart also applies to persons licensed to possess and use plutonium in a plutonium processing and fuel fabrication plant.

179. In § 140.11, revise paragraph (b) to read as follows:

§ 140.11 Amounts of financial protection for certain reactors.

* * * * *

(b) In any case where a person is authorized under 10 CFR part 50, 52, 53, or 54 to operate two or more nuclear reactors at the same location, the total primary financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such primary financial protection covers all reactors at the location.

180. In § 140.12, revise paragraph (c) to read as follows:

§ 140.12 Amount of financial protection required for other reactors.

* * * * *

(c) In any case where a person is authorized under 10 CFR part 50, 52, 53, or 54 to operate two or more nuclear reactors at the same location, the total financial protection required of the licensee for all such reactors is the highest amount which would otherwise be required for any one of those reactors; provided, that such financial protection covers all reactors at the location.

* * * * *

181. Revise § 140.13 to read as follows:

§ 140.13 Amount of financial protection required of certain holders of construction permits and combined licenses.

Each holder of a 10 CFR part 50 or 10 CFR part 53 construction permit, or a holder of a combined license under part 52 or part 53 of this chapter before the date that the Commission had made the finding under § 52.103(g) or § 53.1452(g) of this chapter, who also holds a license under part 70 of this chapter authorizing ownership, possession and storage only of special nuclear material at the site of the nuclear reactor for use as fuel in operation of the nuclear reactor after issuance of either an operating license under 10 CFR part 50 or 53, or a combined license under 10 CFR part 52 or 53, shall, during the period before issuance of a license authorizing operation under 10 CFR part 50 or 53, or the period before the Commission makes the finding under § 52.103(g) or § 53.1452(g) of this chapter, as applicable, have and maintain financial protection in the amount of $1,000,000. Proof of financial protection shall be filed with the Commission in the manner specified in § 140.15 before issuance of the license under part 70 of this chapter.

182. In § 140.20, revise paragraphs (a)(1)(i) and (ii) to read as follows:

§ 140.20 Indemnity agreements and liens.

(a) * * *

(1)(i) The effective date of the license (issued under part 50 or part 53 of this chapter) authorizing the licensee to operate the nuclear reactor involved; or

(ii) The date that the Commission makes the finding under § 52.103(g) or § 53.1452(g) of this chapter; or

* * * * *

PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

183. The authority citation for 10 CFR part 150 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 81, 83, 84, 122, 161, 181, 223, 234, 274 (42 U.S.C. 2014, 2201, 2231, 2273, 2282, 2021); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); Nuclear Waste Policy Act of 1982, secs. 135, 141 (42 U.S.C. 10155, 10161); 44 U.S.C. 3504 note.

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under Atomic Energy Act secs. 11e(2), 81, 83, 84 (42 U.S.C. 2014e(2), 2111, 2113, 2114).

Section 150.14 also issued under Atomic Energy Act sec. 53 (42 U.S.C. 2073).

Section 150.15 also issued under Nuclear Waste Policy Act sec. 135 (42 U.S.C. 10155, 10161).

Section 150.17a also issued under Atomic Energy Act sec. 122 (42 U.S.C. 2152).

Section 150.30 also issued under Atomic Energy Act sec. 234 (42 U.S.C. 2282).

184. In § 150.15, revise paragraphs (a)(7)(iii) and (a)(8) to read as follows:

§ 150.15 Persons not exempt.

(a) * * *

(7) * * *

(iii) Greater than Class C (GTCC) waste, as defined in part 72 of this chapter, in an ISFSI or an MRS licensed under part 72 of this chapter; the GTCC waste must originate in, or be used by, a facility licensed under part 50, part 52, or part 53 of this chapter.

(8) Greater than Class C waste, as defined in part 72 of this chapter, that originates in, or is used by, a facility licensed under part 50, part 52, or part 53 of this chapter and is licensed under part 30 and/or part 70 of this chapter.

* * * * *

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

185. The authority citation for 10 CFR part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

186. In § 170.3, revise the definitions for "*Manufacturing License,"* "*Part 55 Reviews,"* "*Power reactor,"* and "*Special projects"* to read as follows:

§ 170.3 Definitions.

* * * * *

Manufacturing license means a license under subpart F of part 52 of this chapter or subpart H of part 53 of this chapter to manufacture a nuclear power reactor(s) to be operated at sites not identified in the license application.

* * * * *

Part 55 Reviews as used in this part means those services provided by the Commission to administer requalification and replacement examinations and tests for reactor operators licensed under 10 CFR part 55 or part 53 of the Commission's regulations and employed by part 50 or part 53 licensees. These services also include related items such as the preparation, review, and grading of the examinations and tests.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy licensed by the Commission under the authority of section 103 or subsection 104b of the Act, and under the provisions of § 50.21(b), § 50.22, or part 53 of this chapter.

* * * * *

Special projects means specific services provided by the Commission for which fees are not otherwise specified in this chapter. This includes, but is not limited to, contested hearings on licensing actions directly related to U.S. Government national security initiatives (as determined by the NRC), topical report reviews, early site reviews, waste solidification activities, activities related to the tracking and monitoring of shipment of classified matter, services provided to certify licensee, vendor, or other private industry personnel as instructors for 10 CFR part 55 or part 53 reactor operators, reviews of financial assurance submittals that do not require a license amendment, reviews of responses to Confirmatory Action Letters, reviews of uranium recovery licensees' land-use survey reports, and reviews of § 50.71 or § 53.1545 of this chapter Final Safety Analysis Reports. Special projects does not include activities otherwise exempt from fees under this part. It also does not include those contested hearings for which a fee exemption is granted in § 170.11(a)(2), including those related to individual plant security modifications.

* * * * *

187. In § 170.12, revise paragraph (d)(1)(v) to read as follows:

§ 170.12 Payment of fees.

* * * * *

(d) * * *

(1) * * *

(v) 10 CFR 50.71 or 53.1545 Final Safety Analysis Reports;

* * * * *

§ 170.21 [Amended]

188. In § 170.21, in footnote 1 remove the phrase “(e.g., 10 CFR 50.12, 10 CFR 73.5)” and add in its place the phrase “(e.g., 10 CFR 50.12, 10 CFR 53.080, 10 CFR 73.5)”.

189. Revise § 170.41 to read as follows:

§ 170.41 Failure by an applicant or licensee to pay prescribed fees.

If the Commission determines that an applicant or a licensee has failed to pay a prescribed fee required in this part, the Commission will not process any application and may suspend or revoke any license or approval issued to the applicant or licensee. The Commission may issue an order with respect to licensed activities that the Commission determines to be appropriate or necessary to carry out the provisions of this part, parts 30, 31, 32 through 35, 40, 50, 53, 61, 70, 71, 72, 73, and 76 of this chapter, and of the Act.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

190. The authority citation for 10 CFR part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2215; 44 U.S.C. 3504 note.

191. Revise § 171.3 to read as follows:

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a test reactor or research reactor issued under part 50 of this chapter, and to any person holding an operating license for a power reactor licensed under 10 CFR part 50 or part 53, or a combined license issued under 10 CFR part 52 or part 53, that has provided notification to the U.S. Nuclear Regulatory Commission (NRC) that the licensee has successfully completed power ascension testing. The regulations in this part also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program approval, and to a Government agency as defined in this part. Notwithstanding the other provisions in this section, the regulations in this part do not apply to uranium recovery and fuel facility licensees until after the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license.

192. In § 171.5, revise the definitions for "*Operating license*," and "*Power reactor*" to read as follows:

§ 171.5 Definitions.

* * * * *

Operating license means having a license issued under § 50.57 or § 53.1387 of this chapter. It does not include licenses that only authorize possession of special nuclear material after the Commission has received a request from the licensee to amend its licensee to permanently withdraw its authority to operate or the Commission has permanently revoked such authority.

* * * * *

Power reactor means a nuclear reactor designed to produce electrical or heat energy and licensed by the Commission under the authority of section 103 or subsection 104b of the Atomic Energy Act of 1954, as amended, and under the provisions of § 50.21(b) or § 50.22, or part 53 of this chapter.

* * * * *

193. In § 171.15, revise paragraphs (a), (b)(2)(iii), (c)(1), and (d)(1) to read as follows:

§ 171.15 Annual fees: Non-power production or utilization licenses, reactor licenses, and independent spent fuel storage licenses.

(a) Each person holding an operating license for one or more non-power production or utilization facilities under 10 CFR part 50 that has provided notification to the NRC of the successful completion of startup testing; each person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license under 10 CFR part 52, or an operating license or combined license for a commercial nuclear plant under 10 CFR part 53, that has provided notification to the NRC of the successful completion of power ascension testing; each person holding a 10 CFR part 50 or part 52, power reactor license, or a 10 CFR part 53 commercial nuclear plant license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a 10 CFR part 72 license who does not hold a 10 CFR part 50, part 52, or part 53 license and provides notification under § 72.80(g) of this chapter, shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph (a) does not apply to test or research reactors exempted under § 171.11(b).

(b) * * *

(2) * * *

(iii) Generic activities required largely for NRC to regulate power reactors (e.g., updating part 50, part 52, or part 53 of this chapter, operating the Incident Response Center, new reactor regulatory infrastructure). The base annual fee for operating power reactors does not include generic activities specifically related to reactor decommissioning.

(c)(1) The FY 2025 annual fee for each power reactor holding a 10 CFR part 50 or part 53 operating license or combined license issued under 10 CFR part 52 or part 53 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 or part 53 operating license, or a 10 CFR part 52 or part 53 combined license, is $326,000.

* * * * *

(d)(1) Each person holding an operating license for an SMR issued under 10 CFR part 50 or part 53, or a combined license issued under 10 CFR part 52 or part 53, that has provided notification to the NRC of the successful completion startup testing, shall pay the annual fee for all licenses held for an SMR site. The annual fee will be determined using the cumulative licensed thermal power rating of all SMR units and the bundled unit concept, during the fiscal year in which the fee is due. For a given site, the use of the bundled unit concept is independent of the number of SMR plants, the number of SMR licenses issued, or the sequencing of the SMR licenses that have been issued.

* * * * *

194. In § 171.17, revise paragraphs (a) introductory text, (a)(1)(ii), and (a)(2) to read as follows:

§ 171.17 Proration.

* * * * *

(a) *Reactors*, 10 CFR part 72 licensees who do not hold 10 CFR part 50, 10 CFR part 52, or 10 CFR part 53 licenses, and materials licenses with annual fees of $100,000 or greater for a single fee category. The NRC will base the proration of annual fees for terminated and downgraded licenses on the fee rule in effect at the time the action is official. The NRC will base the determinations on the proration requirements under paragraphs (a)(2) and (3) of this section.

(1) * * *

(ii) The annual fees for new licenses for non-power production or utilization facilities, 10 CFR part 72 licensees who do not hold 10 CFR part 50, part 52, or part 53 licenses, and materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY, that are subject to fees under this part and are granted a license to operate on or after October 1 of a FY, are prorated on the basis of the number of days remaining in the FY. Thereafter, the full annual fee is due and payable each subsequent FY.

(2) *Terminations*. The base operating power reactor annual fee for operating reactor licensees or the annual fee for small modular reactor licensees, who have requested amendment to withdraw operating authority permanently during the FY will be prorated based on the number of days during the FY the license was in effect before docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel or when a final legally effective order to permanently cease operations has come into effect. The spent fuel storage/reactor decommissioning annual fee for reactor licensees who permanently cease operations and have permanently removed fuel from the site during the FY will be prorated on the basis of the number of days remaining in the FY after docketing of both the certifications of permanent cessation of operations and permanent removal of fuel from the site. The spent fuel storage/reactor decommissioning annual fee will be prorated for those

10 CFR part 72 licensees who do not hold a 10 CFR part 50, part 52, or part 53 license who request termination of the 10 CFR part 72 license and permanently cease activities authorized by the license during the FY based on the number of days the license was in effect before receipt of the termination request. The annual fee for materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY will be prorated based on the number of days remaining in the FY when a termination request or a request for a possession-only license is received by the NRC, provided the licensee permanently ceased licensed activities during the specified period. The annual fee for non-power production or utilization facilities will be prorated based on the number of days remaining in the FY when the authorization to operate the facility has been permanently removed from the license during the FY.

* * * * *

Dated: March 25, 2026.

For the Nuclear Regulatory Commission.

Tomas Herrera,
Acting Secretary of the Commission.