Alternative Approaches Considered for Selected Topics
During the Development of 10 CFR Part 53

Over the course of the U.S. Nuclear Regulatory Commission (NRC) staff's extensive public engagement during development of the part 53 draft proposed rule, stakeholders have expressed their perspectives on several key topics within the proposed rule language. The staff is providing this enclosure to the Commission to further explain selected issues, including the rationale for the staff's recommendations within the proposed rule, and possible implications of adopting alternatives within the proposed frameworks. This enclosure discusses the following selected topics:

- the use of the quantitative health objectives (QHOs) from the Commission's Safety Goal Policy Statement[1] as one of several performance standards within Framework A

- the inclusion of requirements in both Framework A and Framework B for a combination of design features and programmatic controls to keep radiation doses to members of the public and plant workers as low as reasonably achievable (ALARA)

- the inclusion of a requirement in Framework A for licensees to implement a facility safety program (FSP) to routinely assess potential changes to plant hazards and consider, when appropriate, risk-reduction measures

- the inclusion of a provision in Framework B providing the alternative evaluation for risk insights (AERI) methodology as an option to including results from probabilistic risk assessments (PRAs) in license applications to the NRC

- the inclusion of provisions in both Framework A and Framework B for the possible use of generally licensed reactor operators (GLROs) as an alternative to the current specific licensing of individual reactor operators by the NRC, with associated design-related justifications

- the inclusion of requirements in both Framework A and Framework B to address a category of events termed "beyond-design-basis events" within the current regulatory structure

- the continued exploration of potential ways to address manufacturing licenses (ML), including whether a holder of a ML could load a manufactured reactor with fuel prior to transport to a licensed location for installation and commercial operation and conduct low-power testing at the manufacturing facility.

Background

Consistent with the Nuclear Energy Innovation and Modernization Act's (Public Law 115-439) direction to the NRC to undertake a rulemaking to develop a technology-inclusive framework for reactor licensing, the NRC staff provided a rulemaking plan to the Commission in

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1 "Safety Goals for the Operations of Nuclear Power Plants; Policy Statement (Republication)" (51 FR 28044, 28046 (Aug. 21, 1986).

SECY-20-0032.[2] The staff's plan for the rulemaking stated that the activity would build on previous agency efforts in the area of risk-informed and technology-inclusive initiatives. For example, the rulemaking plan referred to activities such as those associated with the Licensing Modernization Project (LMP), as described in SECY-19-0117,[3] as an approach to developing performance standards for a risk-informed, performance-based framework. The LMP methodology reflects the evolution of risk-informed initiatives at the NRC; lessons learned from programs such as the Next Generation Nuclear Plant, as well as previous efforts to develop a new regulatory framework, as described in a 2006 advance notice of proposed rulemaking (ANPR).[4] The LMP was a cost-shared initiative led by nuclear utilities and supported by the U.S. Department of Energy (DOE), and it led to development of the methodology detailed in the Nuclear Energy Institute (NEI) industry guidance document NEI 18-04.[5] The NRC staff endorsed NEI 18-04 in Regulatory Guide (RG) 1.233.[6]

The rulemaking plan provided in SECY-20-0032 was guided by the Commission's direction in the staff requirements memorandum (SRM) for SECY-10-0121[7]:

> The Commission reaffirms that the existing safety goals, safety performance expectations, subsidiary risk goals and associated risk guidance (such as the Commission's 2008 Advanced Reactor Policy Statement[8] and Regulatory Guide 1.174[9]), key principles and quantitative metrics for implementing risk-informed decision making, are sufficient for new plants. 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. This flexibility will provide for a more efficient use of NRC resources and allow a fuller focus on issues of true safety significance.

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2 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 (Agencywide Document Access and Management System Accession No. ML19340A056).

3 See 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 (ML18311A264).

4 "Approaches to Risk-Informed and Performance-Based Requirements for Nuclear Power Reactors" (71 FR 26267; May 4, 2006).

5 NEI 18-04, Revision 1, "Risk-Informed Performance-Based Technology-Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," August 2019 (ML19241A472).

6 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," June 2020 (ML20091L698).

7 SRM-SECY-10-0121, "Modifying the Risk-Informed Regulatory Guidance for New Reactors," March 2, 2011 (ML110610166).

8 "Policy Statement on the Regulation of Advanced Reactors (73 FR 60612; October 14, 2008).

9 RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," January 2018 (ML17317A256).

Thus, as reflected in SECY-20-0032, the staff planned to take full advantage of previous initiatives and to use the existing radiation safety standards, safety goals, and other associated risk guidance.

The SRM for SECY-20-0032[10] approved the staff's proposed approach for a rulemaking to develop a voluntary, risk-informed, performance-based, technology-inclusive alternative regulatory framework for licensing of future commercial nuclear plants. As discussed below, the staff built upon previous initiatives and related Commission decisions to form the basis for its approach to the development of Part 53.

The staff considered several alternatives to some key features of the proposed rulemaking as a result of the internal discussions among the NRC staff, numerous interactions with external stakeholders, and feedback from the Advisory Committee on Reactor Safeguards (ACRS). As reflected in the iterations of preliminary proposed rule language, the NRC staff made significant changes in some areas during the development of the proposed rule. For example, some reactor designers preferred a more traditional licensing framework as found 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," because of its similarities to regulatory systems in other countries and standards and guidance issued by the International Atomic Energy Agency. In response to the feedback, the NRC staff developed Framework B to provide a traditional, yet technology-inclusive, option within Part 53. Below, the staff discusses several specific topics frequently raised during interactions with stakeholders and the ACRS.

<u>(1) Use of the Quantitative Health Objectives as Performance Standards in Framework A</u>

<u>Background</u>

Framework A is a risk-informed approach. It builds upon previous initiatives, most notably, the LMP's technology-inclusive guidance for developing the licensing basis for non-light-water reactors (non-LWRs). The Commission found in SRM-SECY-19-0117[11] that the LMP methodology is a reasonable approach for establishing key parts of the licensing basis for licenses, certifications, and approvals for non-light-water reactors. As noted above, in SRM-SECY-20-0032, the Commission approved the rulemaking plan that included the use of the LMP in developing Part 53. The LMP methodology and related proposed regulations in Framework A include the use of PRAs and related performance standards to inform the identification and assessment of licensing-basis events; to establish safety classification and performance criteria for structures, systems, and components (SSCs); and to evaluate the adequacy of defense in depth. The LMP methodology and Framework A consider cumulative plant risks and comparisons to the QHOs. As stated in NEI-18-04, "Having these cumulative risk targets as part of the process provides a mechanism to ensure that the [acceptance criteria for licensing events are] conservatively defined for use as a tool for focusing attention on matters important to managing risks from non-LWRs."[12]

In this area, Framework A differs from both existing regulatory requirements and Framework B by design. The existing regulatory requirements in 10 CFR Part 50 and 10 CFR Part 52 are

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[10] SRM-SECY-20-0032, October 2, 2020 (ML20276A293).

[11] SRM-SECY-19-0117, dated May 26, 2020 (ML20147A504).

[12] NEI-18-04, Rev. 1, at 16 (alterations to quote replace the phrase "F-C Target" with "acceptance criteria for licensing basis events" reflect to differences in terminology between the LMP and Part 53).

sufficient to enable the NRC to make the required findings that the licensing of a commercial nuclear plant will be in accord with the common defense and security and will adequately protect public health and safety. The requirements in these parts reflect the evolution of regulations and the understanding of risks posed by nuclear power plants over decades of experience with light-water-reactor technologies. The regulations address the uncertainties associated with assessing these risks by using a combination of factors, including conservatisms in analyses, plant designs, siting, and emergency planning. The NRC also imposed significant regulatory requirements to address issues such as the performance of emergency cooling systems, reactor protection systems, and electric power systems. The Commission has said on many occasions that it need not specifically define "adequate protection," but that compliance with the existing totality of NRC regulations provides reasonable assurance that adequate protection is maintained. Because Framework B includes the same or similar structure and requirements as 10 CFR Part 50 and 10 CFR Part 52, Framework B provides a basis for the NRC to make its findings on reasonable assurance of adequate protection without the need to establish risk-informed performance standards such as the QHOs.

However, Framework A has developed performance-based requirements as an alternative to the prescriptive requirements in 10 CFR Part 50 and 10 CFR Part 52. Framework A proposes to support the adequate protection finding with a collective set of function-oriented and performance-based requirements. These requirements are intended to ensure that the proposed new regulations provide a level of safety comparable to that required by the existing regulations in Parts 50 and 52. In that respect, the risk-informed performance standards, such as the QHOs, play an important role in Framework A. These standards provide a fixed cumulative risk standard for licensing events ranging from anticipated event sequences to very unlikely event sequences. Without these cumulative risk standards in Framework A, including the QHOs, there would be no equivalent to the collective effects of the prescriptive requirements in Parts 50 and 52 that provide reasonable assurance of adequate protection of public health and safety.

However, it is important to understand that Framework A does not rely on QHOs as standalone criteria for assessing adequate protection. Rather, the QHOs are used as one of several safety criteria in proposed 10 CFR 53.220, "Safety criteria for licensing-basis events other than design-basis accidents." Therefore, the comparison of the calculated cumulative plant risks to the QHOs as a performance standard in Framework A is consistent with the principles of risk-informed integrated decision-making described in RG 1.174.

Moreover, the QHOs have played a critical role in the development of the Commission's regulatory approach related to light- and non-light-water reactors. Several Commission policy statements, including the Advanced Reactor Policy Statement and the Safety Goal Policy Statement, which contains the QHOs, were developed contemporaneously to support a variety of reactor technologies. The development and issuance of NUREG-1860[13] and a proposed risk-informed, technology-inclusive regulatory framework discussed in the ANPR published in 2006 explicitly contemplate the central role of QHOs. NUREG-1860 describes the possible regulatory framework as follows:

> At the highest level, the Framework [referenced in the 2006 ANPR] has been developed from the top down with the safety expectation that future NPPs

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[13] NUREG-1860, "Feasibility Study for a Risk-Informed and Performance-Based Regulatory Structure for Future Plant Licensing," December 2007 (ML073400763).

> [nuclear power plants] are to achieve a level of safety at least as good as that defined by the Quantitative Health Objectives (QHOs) in the Commission's 1986 Safety Goal Policy Statement. This approach is consistent with the Commission's 1986 Policy Statement on Advanced Reactors which states that the Commission expects advanced reactor designs will comply with the Commission's Safety Goal Policy Statement . . . . Possible criteria are then developed, consistent with the QHOs, that utilize a probabilistic approach for defining the licensing basis….

Methodologies similar to those described in NUREG-1860, in which the QHOs play a critical role, were carried forward and included in the licensing strategy developed for the Next Generation Nuclear Plant.[14] Further, the methodology described in LMP-related documents and SECY-19-0117 continued the evolution of risk-informed, performance-based approaches by ensuring the methodology could support a wide range of non-light-water reactor designs.

Moreover, as described in SECY-20-0032, the development of the risk-informed and technology-inclusive approach proposed in Framework A has a long history that includes the application of similar methodologies to several reactor projects. This history provides confidence that the methodology can offer a level of safety for future plants that is equivalent to that afforded by current regulations while also supporting greater operational flexibilities. As described above, the QHOs are an important element of that methodology.

In addition to ensuring that Framework A provides an equivalent level of safety to Parts 50 and 52 and appropriately adapts the LMP approach in NEI-18-04 to the regulations, use of the QHOs furthers the Commission's long-standing policy of using risk insights to improve the agency's regulatory framework. The Commission stated in the introduction of the Safety Goal Policy Statement that the use of the safety goals, including the QHOs, could "lead to a more coherent and consistent regulation of nuclear power plants, a more predictable regulatory process, a public understanding of the regulatory criteria that the NRC applies, and public confidence in the safety of operating plants."

Regarding the use of the QHOs as criteria for adequate protection or as the basis for individual licensing actions, the Commission stated the following in SRM-SECY-89-102[15]:

> The Commission believes that "adequate protection" is a case by case finding based on evaluating a plant and site combination and considering the body of our regulations. Safety goals are to be used in a more generic sense and not to make specific licensing decisions. It is not necessary to create a generic definition of adequate protection, nor is it necessary to amend the Safety Goal Policy Statement in order to provide a direct relationship between the safety goals and the concept of adequate protection.

However, the use of PRAs and the related risk insights, including consideration of the QHOs in NRC decision-making, increased in the years following the issuance of the Safety Goal Policy Statement and SRM-SECY-89-102 as the state of the art for PRA improved through various initiatives and studies. Through the initial 1989 rulemaking, 10 CFR Part 52 required

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[14] "Next Generation Nuclear Plant Licensing Strategy: A Report to Congress", joint DOE and NRC report, August 2008 (ML082290017).

[15] SRM-SECY-89-102, "SECY-89-102—Implementation of the Safety Goals," June 15, 1990 (ML003707881).

applications to include PRAs (10 CFR 52.47(a)(1)(v); 52.79(b) (1989)).[16] By 1999, the NRC issued RG 1.174 and related specific guides on using risk-informed approaches, including comparisons of plant risks to the QHOs, for evaluating individual licensing actions. Risk evaluations and comparisons to the QHOs were also used to support regulatory decisions following the Great Tōhoku Earthquake and Tsunami, which caused the 2011 accident at the Fukushima Dai-Ichi nuclear power plant in Japan. Those decisions included whether to require the expedited transfer of spent fuel from storage pools to dry storage casks[17] and whether to require the installation of engineered filters to the containment venting systems for boiling-water reactors.[18] Placing greater emphasis on the QHOs, as one of several safety standards, to reflect the enhanced role of PRA in Framework A would further this evolution and support the performance-based approach used in lieu of the prescriptive requirements in existing regulations.

Identification and Implications of Alternatives

Stakeholders and the ACRS have frequently raised concerns about the inclusion of the QHOs as one of several performance standards in the regulations proposed for Framework A. The possible alternatives offered by stakeholders include (1) having a cumulative risk standard other than the existing QHOs from the Safety Goal Policy Statement and (2) not having a cumulative risk standard in the regulations.

Alternative Risk Standards

Regarding the first alternative, stakeholder suggestions have included allowing only surrogate risk measures such as core damage frequency (CDF) or large release frequency, both of which have been shown to be conservative approaches to comparing plant risks to the QHOs for light-water reactors. Stakeholders have also proposed developing new safety goals or including the QHOs in guidance rather than in regulations.

Surrogates in lieu of Quantitative Health Objectives

Regarding surrogate risk measures, the preamble to the *Federal Register* notice (FRN) of proposed Part 53 (Enclosure 1) explains that applicants and licensees may choose to use surrogate measures to show that particular designs or plants satisfy the QHO-related safety criteria. This would be similar to the development and use of the light-water-reactor surrogate measures in the 1980s. Such surrogate measures 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.[19] Insofar as such approaches are a conservative way to demonstrate that radiological releases are controlled for a wide spectrum of events, they may also provide confidence that a particular design or commercial nuclear plant satisfies the QHO-related performance standard. However, the CDF and similar risk surrogates apply to LWR technology and may not apply to all Part 53 applications, particularly those proposing to use non-LWR technologies that include some designs in which the fuel is in a

16 54 FR 15372 at 15390, 15393, April 18, 1989.

17 NUREG-2161, "Consequence Study of a Beyond-Design-Basis Earthquake Affecting the Spent Fuel Pool for a U.S. Mark I Boiling Water Reactor," September 2014 (ML14255A365).

18 NUREG-2206, "Technical Basis for the Containment Protection and Release Reduction Rulemaking for Boiling Water Reactors with Mark I and Mark II Containments," March 2018 (ML18065A048).

19 NUREG/BR-0058, draft Revision 5, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," April 2017 (ML17100A480).

molten state during normal operation. The use of surrogates for the QHOs is a possible approach for the proposed Part 53 and is mentioned in NEI 18-04 and RG 1.233 in the context of assessing fission product barriers and showing that those barriers are likely to retain radioactive materials within the facility with a high degree of confidence. The preamble of the FRN discusses the potential use of surrogate measures to demonstrate that a design or commercial nuclear plant satisfies the safety criteria in Framework A.

However, the staff's perspective is that the primary drawback of considering only surrogate measures in the rule is that such an approach would be difficult to make technology-inclusive. Because Part 53 would be available for use by a wide range of reactor technologies, including some that lack a traditional containment or a solid core, surrogate risk measures would need to be specific to individual reactor designs or technologies. This approach could therefore blend technology-specific performance standards into an otherwise technology-inclusive framework. Therefore, retaining the QHOs in the rule text, with an option to develop surrogates, preserves the technology-inclusive nature of Framework A.

Development of New Safety Goals

Regarding new safety goals, some stakeholders have suggested that including a cumulative risk measure within Framework A is appropriate, but the NRC should consider revising the current Safety Goal Policy Statement. In developing the Part 53 rulemaking plan approved by the Commission and the draft proposed rule, the NRC staff sought to leverage previous initiatives and existing safety goals, safety performance expectations, subsidiary risk goals, and associated risk guidance, and did not identify a need to revise the current Safety Goal Policy Statement. This approach for using the existing safety goals is consistent with the Commission decisions in SRM-SECY-10-0121 and SRM-SECY-12-010.[20] This approach also reflects the substance of the QHOs, which are based on the Commission's qualitative safety goals to ensure that nuclear power plant operations (1) will not introduce significant additional risk to human life and health and (2) will present a level risk to human life and health that is comparable to or lower than the risk posed by viable, competing technologies for producing electricity. Because the QHOs are based in part on overall societal acceptance of risk, as opposed to a level of risk chosen by the NRC, developing alternate safety goals would present a substantial regulatory challenge. Moreover, revisiting the existing QHOs as part of the rulemaking would significantly lengthen the time needed to develop and publish Part 53.

Include No Cumulative Risk Measure in the Regulations

Some stakeholders suggested implementing the Safety Goal Policy Statement (possibly including the QHOs) through guidance instead of incorporating it into regulations. This approach would mean that the two frameworks consider the issue of cumulative plant risk in basically the same way. However, the two frameworks differ in the role played by the assessment of the cumulative plant risk estimated by PRAs. Under Framework B, the collective regulations that follow the same structure as 10 CFR Part 50 and 10 CFR Part 52 are presumed to provide a reasonable assurance of adequate protection of public health and safety. The assessment of the QHOs under Framework B is largely confirmatory and is used as a vehicle to potentially identify risk insights. For Framework A, reasonable assurance of adequate protection of public health and safety is provided through compliance with performance standards, including the QHOs, which establish an equivalent level of safety as the deterministic regulations in

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[20] SRM-SECY-12-0110 – Consideration of Economic Consequences Within the U.S. Nuclear Regulatory Commission's Regulatory Framework, dated March 20, 2013 (ML13079A055).

10 CFR Part 50 and 10 CFR Part 52. The implications of omitting the QHOs from Framework A would be that other requirements would need to be developed to ensure an integrated set of regulations, compliance with which would provide reasonable assurance of adequate protection of public health and safety. The NRC decision-making process on applications under proposed Framework A would also be integrated, similar to that provided by the methodology in RG 1.174. An alternative to including the QHOs in the regulations might be to require specific assessment or analysis criteria for licensing-basis events other than design-basis accidents in 10 CFR 53.450(e) in Framework A. Previous efforts by the NRC or others to develop such criteria (considering both event frequency and consequences) have been based largely on the existing QHOs.

The NRC staff proposes including in the FRN for the proposed rule a specific request for comments on the topic of including the QHOs in Part 53.

(2) ALARA Requirements for Radiation Doses to the Public and Workers

Background

The ALARA requirements in Part 53 are consistent with current NRC regulations which for decades have required reactor applicants and licensees to consider ALARA principles. The Atomic Energy Commission (AEC) added ALARA-related requirements in both 10 CFR Part 20, "Standards for Protection Against Radiation," and 10 CFR Part 50. The basic requirements and philosophy supporting them are little changed to this day. The ALARA-related requirements address both occupational exposures and public doses. The original rule text in § 20.1(c) explained the following:[21]

> In accordance with recommendations of the Federal Radiation Council, approved by the President, persons engaged in activities under licenses issued by the Atomic Energy Commission pursuant to the Atomic Energy Act of 1954, as amended, should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in this part as practicable. The term "as far below the limits specified in this part as practicable" means as low as is practicably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and in relation to the utilization of atomic energy in the public interest.

In addition to the 10 CFR Part 20 requirements, the AEC added specific requirements to limit the dose to members of the public from nuclear power reactors. Specifically, 10 CFR 50.34a, "Design objectives for equipment to control releases of radioactive material in effluents - nuclear power reactors," was incorporated into the regulations in 1970 (35 FR 18387, Dec. 3, 1970) and in § 50.34a(a) included the following requirements:

> An application for a permit to construct a nuclear power reactor shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including expected operational occurrences. In the

21 AEC, Final Rule, "Control of Releases of Radioactivity to the Environment" (35 FR 18387, December 3, 1970).

case of an application filed on or after January 2, 1971, the application shall also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas as low as practicable. The term "as low as practicable" as used in this part means as low as is practicably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and in relation to the utilization of atomic energy in the public interest.

Five years later, the NRC issued 10 CFR Part 50, Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents" (40 FR 19442, May 5, 1975). In the 1975 original version of Appendix I, Section I, the Commission stated that "[d]esign objectives and limiting conditions for operation conforming to the guidelines of [Appendix I] shall be deemed a conclusive showing of compliance with the "as low as practicable" requirement of 10 CFR 50.34a and 10 CFR 50.36a."

The NRC revised 10 CFR Part 20 in 1991[22] and maintained requirements related to ALARA in 10 CFR 20.1101(b), "Radiation protection programs," which states the following:

The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

At the time of the above changes to 10 CFR Part 20, 10 CFR 50.34a, and Appendix I to 10 CFR Part 50, the only applications for nuclear power plants involved those for construction permits and operating licenses under 10 CFR Part 50. Guidance regarding the content of applications[23] from the 1970s to the current day describes expected information for preliminary and final safety analysis reports to address the design and programmatic measures to maintain public and occupational doses ALARA.

Following promulgation of these regulations, as the NRC developed additional regulations, guidance, and policies, ALARA remained an important element of the agency's approach to protecting the public and workers. That position was reinforced in the Advanced Reactor Policy Statement (original version and subsequent updates), which specifically referenced "designs that reduce potential radiation exposures to plant personnel as a desirable attribute that could assist in establishing the acceptability or licensability of a proposed advanced reactor design." As with other attributes identified in the Advanced Reactor Policy Statement, it is beneficial to consider ALARA early in the design phase to identify design features that could be included to prevent or mitigate problems rather than relying solely on operational programs.

The NRC subsequently developed and issued an alternative licensing framework in 10 CFR Part 52 that included a process for resolving design issues by certifying standard designs by rulemaking (54 FR 15372, April 18, 1989). The original requirement captured in 10 CFR 52.47, "Contents of applications," for the content of applications for standard design certifications stated the following:

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22 NRC Final Rule (56 FR 23359, May 21, 1991)

23 RG 1.70, Revision 2, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," September 1975 (ML010610289).

> (a) The requirements of this paragraph apply to all applications for design certification. (1) An application for design certification must contain:
>
> (i) The technical information which is required of applicants for construction permits and operating licenses by 10 CFR Part 20, Part 50 and its appendices, and Parts 73 and 100, and which is technically relevant to the design and not site-specific….

10 CFR 52.47 (1989); 54 FR at 15,390-91. The above requirement provided an equivalent to the application-related requirements for construction permits and operating licenses pertaining to facility design within the scope of the standard plant, i.e., included requirements to provide information on how plant designs achieve keeping doses to the public and workers ALARA. A similar stipulation provided the required content of applications for combined licenses by referring to the regulations in § 52.47 and additional requirements for operating license applications in § 50.34. 10 CFR 52.79(b) (1989); 54 FR at 15,392.

The NRC revised 10 CFR Part 52 in 2007,[24] including adding more specific requirements for the content of applications. With the increased specificity in Part 52, the regulations made distinctions between the contents of applications for different purposes (e.g., early site permits, design certifications, and combined licenses). These revisions included information related to the design of a nuclear power plant that would be referenced in a subsequent license application. The 10 CFR Part 52 rulemaking added the following paragraph in 10 CFR 50.34a to address ALARA at the design stage for applications for design certifications, design approvals, and manufacturing licenses:

> (e) Each application for a design approval, a design certification, or a manufacturing license under part 52 of this chapter shall include:
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> (1) A description of the equipment for the control of gaseous and liquid effluents and for the maintenance and use of equipment installed in radioactive waste systems, under paragraph (a) of this section; and
>
> (2) The information required in paragraph (b)(2) of this section.
>
> * Where the reference to paragraph (a) captures the design information to be provided in the application for a construction permit.

The requirements in the revised 10 CFR Part 52 more clearly state the ALARA requirements for public doses and plant effluents for applications under Part 52. The more specific requirements in 10 CFR Part 52 for design certifications in 10 CFR 52.47 did not include a specific reference to ALARA-related requirements for occupational exposure. However, applications and NRC reviews continued to include design measures to keep occupational exposures ALARA by citing the requirements of 10 CFR Part 20, guidance such as RG 8.8,[25] and NUREG-0800[26] section 12.2, “Radiation Sources,” and section 12.3-12.4, “Radiation Protection Design

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[24] NRC, Final Rule, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (72 FR 49352, August 28, 2007).

[25] RG 8.8, Revision 2, “Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be as Low as Is Reasonably Achievable,” March 1977 (ML13350A225).

[26] NUREG-0800, Rev. 6, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition,” March 2007 (ML070810350).

Features." The continuity in the agency's approach to addressing ALARA for design certifications is reflected in applications and staff safety evaluation reports for all design certifications issued by the NRC.

Framework A includes two requirements addressing normal operations. First, it would include metrics that establish a level of safety or a backstop based on current 10 CFR Part 20 limits on doses to members of the public or contamination of unrestricted areas once a plant is licensed and operating. Second, it would include requirements equivalent to those in 10 CFR Part 20 and 10 CFR 50.34a that a combination of design features and programmatic controls be established such that estimated doses to members of the public are maintained ALARA. Framework A allows flexibility in the specific combination of design features and programmatic controls that will be proposed for a specific design. However, Framework A maintains the expectation that ALARA will be addressed at the design stage and not just through programmatic controls during plant operation.

The ALARA requirements in 10 CFR 50.34a, Appendix I to 10 CFR Part 50 for light-water reactor effluents, and 10 CFR Part 20 allow applicants and licensees to consider the state of technology, the economics of improvements in relation to benefits to public health and safety, and other societal and socioeconomic considerations when developing design features and programmatic controls to limit the release of radionuclides. These same considerations apply to the proposed requirements in Part 53, which also emphasize that ALARA would be achieved with an appropriate consideration of potential costs. Subpart C, "Design and Analysis Requirements," of Part 53 provides a technology-inclusive performance goal to serve the purpose of Appendix I in 10 CFR Part 50. The inclusion of the proposed performance goal in Subpart C reinforces the concept that the purpose of the regulations is to maintain doses ALARA and not to require continuous dose reductions without due consideration of the associated costs. That said, the proposed Part 53 requirements related to ALARA in combination with the established regulations in Part 20, including references to the U.S. Environmental Protection Agency (EPA) regulations in 40 CFR Part 190, will ensure that public doses resulting from the normal operation of commercial nuclear plants are well below the limit of 0.1 rem per year.[27]

Other sections in proposed Framework A would provide for the protection of plant workers. The requirements for occupational exposures follow a similar approach to that of the proposed sections for protection of the public, with (1) references to 10 CFR Part 20 limits on occupational exposures and (2) ALARA-related provisions afforded by a combination of design features and programmatic controls. The need to give special consideration to limiting occupational exposures during all phases of the life cycle of future commercial nuclear plants is especially important, given the wide variety of potential reactor technologies and designs that could be licensed under Framework A of Part 53.

Equivalent requirements are included in Framework B but organized differently. They are found in regulations governing the contents of applications in Subpart R, "Licenses, Certifications, and Approvals," and operational programs in Subpart P, "Requirements for Operation." In recognition of the historical challenges associated with addressing ALARA requirements in the various stages of design and operation of nuclear reactors, the staff plans to develop guidance to incorporate performance-based approaches for addressing ALARA requirements, especially

[27] 40 CFR 190.10, "Standards for normal operations," states that "operations covered by this subpart [uranium fuel cycle, including power plants] shall be conducted in such a manner as to provide reasonable assurance that: (a) The annual dose equivalent does not exceed 25 millirems to the whole body…."

for NRC review of design features under Part 53. The staff is currently developing guidance in this regard to support potential near-term applications for non-LWR designs under Parts 50 and 52 under the Advanced Reactor Content of Applications Project (ARCAP). The ALARA-related guidance appears in ARCAP Interim Staff Guidance (ISG) for chapter 9, "Control of Routine Plant Radioactive Effluents, Plant Contamination and Solid Waste," and ARCAP ISG for chapter 10, "Control of Occupational Dose," on the NRC's Advanced Reactors website.[28] The staff anticipates that it would update this guidance to support Part 53, if the Commission approves Part 53, as the requirements proposed for both Frameworks A and B align with current Part 50 and 52 requirements.

Identification and Implications of Alternatives

Remove ALARA Requirements Related to Plant Design

Some stakeholders have suggested deleting the ALARA-related requirements in Subpart B, "Technology-Inclusive Safety Requirements," and Subpart C, "Design and Analysis Requirements," in Framework A and equivalent requirements in Framework B that apply to the design of commercial nuclear plants. Under such a proposal, the regulatory responsibility to minimize doses to the public and plant workers under ALARA principles would be assigned solely to the holders of operating licenses or combined licenses for commercial nuclear plants under Part 53, through the radiation protection program requirements in Subparts F and P, both titled "Requirements for Operation," and the related requirements in 10 CFR Part 20.

The staff's view is that maintaining the need to consider ALARA during the design stage would comport with the policies underlying ALARA. This is because relatively small design changes may be identified during the design process that could significantly reduce public or occupational exposure without great expense, whereas implementing those (or equivalent) changes during operation may prove much more costly or cost-prohibitive. Moreover, as explained above, such an approach would be inconsistent with the existing requirements in 10 CFR Part 50 and 10 CFR Part 52 that are based on ALARA principles involving a combination of design features and programmatic controls—from which the proposed requirements in Part 53 were taken. In addition to introducing technical and philosophical differences between the proposed Part 53 and the current requirements under 10 CFR Part 50 and 10 CFR Part 52, the removal of requirements for design--related applications such as standard design certifications to address ALARA principles could introduce internal inconsistencies between a combined license application supported by a design certification and either a construction permit or a standalone combined license application, for which some design-related ALARA considerations would likely be introduced through the 10 CFR Part 20 regulations.

The staff has proposed including a specific request in the FRN for the proposed rule for comments on the topic of how to best keep doses to the public and workers ALARA.

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[28] Preliminary versions of chapters 9 and 10 (both dated July 6, 2021) are available under ML21189A033 and ML21189A035, respectively.

(3) Inclusion of Requirements for Facility Safety Programs in Framework A[29]

Background

The proposed requirements in Framework A to periodically update the PRA and to address the possible differences between the plant as modeled in the analyses and the performance history of SSCs represent a significant change from the relatively static analyses and prescriptive compliance verifications used in many of the requirements in 10 CFR Part 50 and 10 CFR Part 52. The proposed requirements in Framework A for an FSP would complement requirements in Subpart C, which include performing and updating PRAs. PRAs are a major part of the design and licensing of commercial nuclear plants under Framework A – and are more central to the safety analysis than they are under Parts 50 and 52 or Framework B. This Framework A approach therefore presents an opportunity to continue to leverage insights from the PRA during operations. Such insights may be valuable in evaluating changes, managing risks, and improving the relationship between the NRC's licensing and oversight programs. For example, the PRA plays an innovative role in the evaluation of plant changes under Subpart I, "Maintaining and Revising Licensing Basis Information," in Framework A, which may provide licensees greater flexibility.

The FSP would require the licensee to periodically assess possible risk-reduction measures considering technology changes, economic costs, operating experience, and new or revised hazard information. Other sections within Framework A address managing risk to meet the regulations and ensure consistency with the analyses performed in accordance with Subpart C.[30] The FSP would supplement these actions. The FSP requires continuing assessments in areas such as external hazards and considering when cost-effective risk-reduction measures would be appropriate. The FSP requirement for continuing assessment of external hazards is a departure from the current practice under Parts 50 and 52, in which the staff monitors the magnitude of external hazards and addresses information showing an increased hazard with affected licensees. Under Part 53, however, the FSP provision would require each licensee to proactively address such information. This aspect of the FSP is similar to the requirement in 10 CFR 70.62(c)(1)(iv), which applies to licensees authorized to possess a critical mass of special nuclear material.

The staff modeled the FSP proposal for Framework A on 10 CFR 70.62, "Safety program and integrated safety analysis,"[31] and regulations issued by other Federal agencies such as the DOE, U.S. Department of Transportation, and the EPA. Thus, the FSP would provide a flexible, performance-based approach to address possible changes in the risks associated with commercial nuclear plants. When fully considered as part of an overall regulatory regime, the FSP could enable an optimization of NRC oversight programs and more focused operating

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29 The proposed rule does not include an FSP requirement in Framework B, but a similar section could be developed. The staff proposes including in the FRN a request for comments on the use of FSPs in both frameworks.

30 Examples include 10 CFR 53.710, "Maintaining capabilities and availability of structures, systems, and components," and 10 CFR 53.715, "Maintenance, repair, and inspection programs."

31 The regulation at 10 CFR 70.62(a) states, "(1) Each licensee or applicant shall establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. The safety program may be graded such that management measures applied are graded commensurate with the reduction of the risk attributable to that item. Three elements of this safety program; namely, process safety information, integrated safety analysis, and management measures,…."

experience and hazard assessment programs.[32, 33] While the FSP may require additional effort from licensees, it would also provide more flexibility in addressing changes to a facility's risk profile than do current processes.

The proposed regulation provides criteria for considering risk-reduction measures when performing periodic assessments under the FSP. The proposal includes an entry condition for considering risk reduction, below which licensees would not need to conduct further evaluations. If the entry condition is satisfied, the licensee would perform a further assessment using a cost-benefit process to determine whether to implement a change. The NRC staff would prepare guidance to define appropriate factors, which would likely be similar to existing guidance for regulatory analyses in NUREG/BR-0058 (including the dollars-per-person rem conversion factor) and evaluating severe accident mitigation alternatives under 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions." The goal for establishing criteria for considering risk reduction measures is that the entry criteria are low enough to initiate the process when appropriate but high enough to avoid unnecessary analyses. The proposed use of person-rem values as part of the criteria supports cost-benefit assessments and introduces a consideration of broader societal impacts that is not provided by the calculation of doses to hypothetical individuals, as is done in the analyses required under Subpart C.

The proposed requirements include programmatic controls to develop, implement, and maintain the FSP by developing an FSP plan. FSP plans are used to document the details of how assessments are performed; the licensee's overall safety philosophy and safety culture, as discussed in the Commission's Safety Culture Policy Statement (76 FR 34773; June 14, 2011); the required participants and training; and the periodic reviews of the effectiveness of the FSP. The NRC would review FSP plans as part of licensing reviews for operating licenses or combined licenses. Updates and revisions to FSP plans would be submitted at least every 24 months but would not be subject to NRC review and approval unless a proposed change to an FSP plan requires an exemption from Subpart F.

Identification and Implications of Alternatives

Removal of Provisions for Facility Safety Programs

Some stakeholders have suggested that the NRC exclude the FSP requirement from Framework A in favor of a more traditional approach in which the NRC reviews possible changes to external hazards, possible insights from operating experience, and other factors potentially increasing risk. Under this approach, the NRC would use requests for information, analyses of potential backfits, and regulatory actions (e.g., orders or rulemakings) to change

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32 As an example, an FSP could increase flexibility during initial licensing because it may aid the agency in resolving difficult technical issues by providing assurance that new information and, when appropriate, possible risk reduction measures are being routinely assessed in a dynamic nature. Likewise, knowledge that new information is routinely considered as part of FSPs could be considered when assessing the need to issue generic letters or bulletins requiring licensees to provide information to the NRC on certain matters.

33 There are some similarities between the FSP proposal and Recommendation 2.2 in the report "Recommendations for Enhancing Reactor Safety in the 21st Century: The Near-Term Task Force Review of Insights from the Fukushima Dai-Ichi Accident," dated July 12, 2011 (ML111861807). While ultimately the NRC did not impose that recommendation on licensees through the agency's backfit process and instead the NRC expanded its internal programs, Part 53 provides an opportunity to improve the management of risks for future plants with limited effort given the routine updating of the PRAs. Moreover, existing facilities covered by Recommendation 2.2 were not licensed with the robust PRA required by Framework A; therefore, an FSP-type program may not have proven as valuable for those facilities.

plant design or operation (when justified). The FSP could then be deleted and the traditional approach adopted with few other changes to Framework A. Another possible approach to address the elimination of the proposed FSP provisions could involve assessing how other requirements might capture changes to risk information. For example, the NRC could revise Subpart I regarding changes to facilities described in safety analysis reports by expanding the definitions to include the hazards addressed by the design.

The proposed FSP concept shifts some of the routine responsibility for assessing new risk insights to licensees. However, the FSP provides flexibility in how licensees consider and address new information within programs such as routine PRA updates versus responding to NRC inquiries and other regulatory actions. Licensees under Framework A must routinely update their PRAs, which necessarily requires the consideration of new information on revised hazards or other contributors. Thus, deleting the FSP and maintaining NRC's programs in such areas may lead to duplication of efforts because licensees would need to update their PRAs in accordance with NRC-approved consensus codes and standards but would not be responsible for considering measures to address increased risks (similar to current requirements). In the absence of an FSP, the NRC, having the primary role of ensuring new risk insights are assessed and, when appropriate, incorporated into regulatory requirements, would also need to implement the traditional programs related to operating experience, hazard assessments, inspections, and safety issues.

The staff has proposed including in the FRN for the proposed rule a specific request for comments on the topic of FSPs.

(4) Alternate Evaluation for Risk Insights in Framework B

Background

Under the initial drafts of Framework B, commercial nuclear plant applicants would have been required to develop PRAs for use in a confirmatory role as part of their risk evaluation. In response to stakeholder views that a PRA may not be necessary for all designs (particularly very small reactors), the staff developed the AERI as an alternative approach. Framework B, as included in this proposed rule, would require applicants for standard design approvals, standard design certifications, manufacturing licenses, construction permits, operating licenses, and combined licenses to include a description of a risk evaluation and its results in the safety analysis report. Framework B also includes specific design rules and the establishment of principal design criteria to ensure that safety criteria are met.

Using the AERI approach would allow applicants to demonstrate that specified entry conditions are met, thereby ensuring that postulated bounding events result in limited offsite consequences. When used in a confirmatory role for risk evaluation during initial licensing, an AERI would be expected to provide results that are comparable to the results from a PRA, specifically (1) a demonstrably conservative risk estimate for comparison against the Commission's QHOs, (2) a search for severe accident vulnerabilities, (3) a qualitative identification of risk insights, and (4) an assessment of defense-in-depth adequacy.

The proposed use of PRA as one approach to develop a risk evaluation is equivalent to existing requirements in 10 CFR Part 52 for standard design approvals, standard design certifications, manufacturing licenses, and combined licenses, and to proposed requirements in 10 CFR Part 50 for construction permits and operating licenses, as discussed in an ongoing rulemaking.[34] The proposed Part 53 use of AERI in lieu of a PRA, provided that specified entry conditions are met, is consistent with the Commission's policy statement on the use of PRA in regulatory activities.[35] The PRA policy statement noted the following:

> …not all of the Commission's regulatory activities lend themselves to a risk analysis approach that utilizes fault tree methods. In general, a fault tree method is best suited for power reactor events that typically involve complex systems…. Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate.

The proposed AERI entry conditions require analyses to show limited radiological consequences from postulated bounding events for the proposed design. The entry condition sets a maximum consequence (dose) criterion at the maximally exposed location between the exclusion area boundary and 10 miles beyond the exclusion area boundary. If this criterion is met for the bounding postulated event, then the Commission's safety goals will be met without the need to estimate the likelihood of individual event sequences. The proposed AERI entry conditions would not be safety or siting criteria but rather would only be used to determine which applicants could develop an AERI in lieu of a PRA.

<u>Identification and Implications of Alternatives</u>

The primary alternative to not including the AERI provision in the proposed Framework B would be to require all future plants licensed under Framework B of Part 53, as well as 10 CFR Part 50 and 10 CFR Part 52, to be supported by a PRA. Some stakeholders contend that performing and maintaining PRAs would be an undue burden for applicants for some plant designs for which it may be possible to show limited consequences, even for bounding-type events. Removing the AERI provision could therefore unnecessarily add to the cost of developing and operating certain smaller reactor designs. The most likely candidates for using an AERI are microreactors, which take advantage of both inherent and passive systems to perform key safety functions.

The staff has proposed including in the FRN for the proposed rule a specific request for comments on having AERI as an option in Framework B and on the criteria proposed for allowing use of the AERI approach.

<u>(5) Provisions for Generally Licensed Reactor Operators</u>

<u>Background</u>

Including provisions for GLROs is a transformational proposal within both Part 53 frameworks, and, as such there is not a direct parallel between the proposed requirements in Part 53 and 10 CFR Part 50 and 10 CFR Part 52. The proposed 10 CFR 53.800, "Facility licenses for self-reliant-mitigation facilities," in Subpart F establishes two new classes of facilities (defined as either an "interaction-dependent mitigation" facility or a "self-reliant-mitigation" facility) for which

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[34] See SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)," June 6, 2022 (ML21159A055).

[35] Final Policy Statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622, August 16, 1995).

an applicant could apply for a license under either Framework A or B. Those facilities classified as "self-reliant-mitigation" facilities would employ GLROs. The proposed regulations include entrance criteria for "self-reliant-mitigation" facilities related to whether reactor operators have a role in maintaining and fulfilling safety functions at the facility. For those designs, generally licensed reactor operators would perform duties under the provisions of a general license that would be effective without filing an application with the Commission or the issuance of licensing documents to a particular person. The requirements for generally licensed reactor operators incorporate greater flexibility, consistent with the modified operator role in safety at self-reliant-mitigation facilities.

This approach builds on the recognition that staffing, operator qualifications, and human factors engineering each represent interconnected areas that should be approached in an integrated manner. For example, the proposed Part 53 includes specific technical requirements associated with human factors engineering, human-system interface design, concept of operations, functional requirements analysis, and function allocation. These requirements in turn help to determine appropriate staffing plans and the roles and responsibilities of plant personnel. These requirements would ensure that the expected reduced reliance on human actions for reactor designs with the attributes described in the Advanced Reactor Policy Statement is achieved in a deliberative manner that continues to provide defense in depth and protect public health and safety.

The proposed Part 53 sections in Subpart F provide an integrated methodology to assess safety functions and the role of human actions. The methodology is used to determine the numbers and responsibilities of various plant staff, including reactor operators. Building on these insights, Subpart F introduces the possible use of GLROs as an alternative to the current licensing of reactor operators under 10 CFR Part 55, "Operators' Licenses."

<u>Identification and Implications of Alternatives</u>

The possible alternatives offered by stakeholders to the staff's proposal generally fall into three categories. First, some stakeholders propose retaining a pathway for licensing specifically licensed operators and senior operators under Part 53 but eliminating an allowance for GLROs. Second, some stakeholders propose eliminating both the specifically licensed operator framework and provisions for GLROs from Part 53, relying instead on the existing 10 CFR Part 55 (with modifications). Finally, some stakeholders suggest eliminating both the specifically licensed operator framework and provisions for GLROs from Part 53 and employing new guidance documents to facilitate using 10 CFR Part 55 as it is, concurrent with the use of regulatory exemptions where appropriate.

Regarding the first alternative, the staff's view is that the GLRO proposal in the proposed rule addresses power reactor designs that may not warrant the regulatory burden and attendant costs associated with a traditional licensing program because a careful analysis of that facility design has demonstrated that operators would not have a credible influence on public health and safety outcomes. While still an operator licensing program, the GLRO pathway offers substantial reductions in costs for NRC staff review and oversight in connection with operator licensing. Eliminating the GLRO pathway in light of this consideration may result in the imposition of significant long-term operating costs upon facility licensees without any improvement in facility safety commensurate with those costs.

Regarding the second alternative, the above reasoning regarding the GLRO pathway would also apply. Beyond that, this alternative would require modifying the existing 10 CFR Part 55 requirements for operator licensing to enable comparable flexibilities to those afforded under the proposed rule language of Part 53. Such a modification would take a large effort. For example, as 10 CFR Part 55 governs the licensing of operators at all existing power and nonpower reactors, any such undertaking must be approached carefully to manage potential impacts for the existing domestic reactor fleet.

Finally, with regard to the third alternative, the previously discussed considerations also apply. In this case, in addition, the use of new guidance for, and regulatory exemptions from, the existing requirements of 10 CFR Part 55 must also be considered. A key driver behind the proposed flexibilities for reactor operator and senior reactor operator licensing programs at future commercial nuclear plants under proposed Part 53 is that such programs must accommodate a wide variety of technologies and diverse concepts of operations. A primary type of guidance document currently used for operator licensing is technology-specific knowledge and ability catalogs that are published by the NRC as NUREG-series documents. Therefore, implementation of this alternative approach would mean that, at a minimum, the agency would need to generate knowledge and ability catalogs to account for each new technology and associated concept of operations under Part 53. Furthermore, to be able to provide catalogs to support the cold licensing of operators before facility startup, guidance development efforts would need to begin several years in advance of anticipated startup. This would be resource intensive and, if guidance for licensing operators is not available in sufficient time, this could impact timeliness of new facility operation. An additional implication of this alternative is that it would likely necessitate requests for exemptions from existing regulatory requirements.

The staff proposes including in the FRN for the proposed rule a specific request for comments on the topic of allowing GLROs.

(6) Consideration of "Beyond-Design-Basis Events" (BDBEs)

Background

Both frameworks in the proposed Part 53 include provisions to analyze certain design-basis accidents to help establish requirements for safety-related SSCs and provisions to analyze other events to achieve goals such as ensuring defense in depth is provided by plant equipment, human actions, and programmatic controls. The introduction and consideration of events beyond those traditionally included in the transient and accident analysis sections of safety analysis reports (e.g., Chapter 15) began under the AEC and has continued to evolve over the subsequent decades. The following discussion of the history of considering BDBEs was provided in the NRC's Near-Term Task Force report following the accident at the Fukushima Nuclear Plant in Japan.[36, 37]

> Design-basis events became a central element of the safety approach almost 50 years ago when the U.S. Atomic Energy Commission (AEC) formulated the idea of requiring safety systems to address a prescribed set of anticipated operational

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[36] Recommendations for Enhancing Reactor Safety in the 21st Century – The Near-Term Task Force Review of Insights from the Fukushima Dai-ichi Accident," July 12, 2011 (ML112510271)

[37] The subsequent actions taken by the NRC in response to the accident at Fukushima Dai-ichi included requests for information, requirements needed to provide reasonable assurance of adequate protection of public health and safety, and requirements to provide substantial enhancements in safety and justified in terms of cost. Similar to the NRC actions following the terrorist attacks of September 11, 2001, the post-Fukushima requirements imposed to maintain reasonable assurance of adequate protection involved licensees developing and implementing flexible mitigating strategies for the specific BDBEs identified in the applicable order or rule in lieu of adding specific design basis events or safety-related SSCs.

> occurrences and postulated accidents. In addition, the design-basis requirements for nuclear power plants included a set of external challenges including seismic activity and flooding from various sources. That approach and its related concepts of design-basis events and design bases were used in licensing the current generation of nuclear plants in the 1960s and 1970s.
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> Frequently, the concept of design-basis events has been equated to adequate protection, and the concept of beyond-design-basis events has been equated to beyond adequate protection (i.e., safety enhancements). This vision of adequate protection has typically only led to requirements addressing beyond-design-basis concerns when they were found to be associated with a substantial enhancement in safety and justified in terms of cost.
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> Starting in the 1980s and continuing to the present, the NRC has maintained the design-basis approach and expanded it to address issues of concern. The NRC added requirements to address each new issue as it arose but did not change the fundamental concept of design-basis events or the list of those events; nor did the NRC typically assign the concept of adequate protection to these changes. …

The terminology related to nuclear plant licensing and relationships between the design basis (as defined in 10 CFR 50.2 for SSCs), design-basis events (as defined for LWRs by the application of the GDC), beyond-design-basis accidents or events, and the general licensing basis for a plant has a lengthy, complicated regulatory history.[38] This history arose from the AEC's reticence in identifying a distinction among those requirements necessary for adequate protection and those desirable for safety enhancement. Rather than risk omitting an element of adequate protection from its requirements, the AEC structured its regulations to reflect concepts such as margin and defense in depth to minimize residual uncertainty as to whether compliance would result in adequate protection of the public health and safety.[39] Accordingly, the AEC initially limited the scope of the design basis to those matters necessary to achieve high confidence that operation would assure adequate protection of public health and safety. Nonetheless, the distinctions between event categories by both the AEC and NRC have often related to matters such as the justification for the requirements (i.e., adequate protection or safety enhancement) and the associated safety classification of SSCs, and not whether the events influenced the overall design of nuclear power plants.[40] The most often cited examples of requirements that went beyond the original "design basis" for plants are the regulations pertaining to anticipated transients without scram (ATWS) (10 CFR 50.62) and station blackout (10 CFR 50.63). These rules involved imposing regulatory requirements that resulted in changes to plant designs to prevent and mitigate scenarios categorized as BDBEs. Likewise, the requirements in Parts 50 and 52 addressing severe accidents (termed "class 9" accidents in earlier AEC terminology) involved significant changes to proposed plant designs. However,

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38 Additional background information related to establishing the design basis for SSCs and addressing various events and conditions is provided in references such as Appendix B to Nuclear Energy Institute (NEI) 97-04, "Design Bases Program Guidelines," (ML003771698), RG 1.186, "Guidance and Examples for Identifying 10 CFR 50.2 Design Basis," (ML003754825) and SECY-15-0168, "Recommendations on Issues Related to Implementation of a Risk Management Regulatory Framework," dated December 18, 2015 (ML15302A135).

39 This history also gave rise to the concept that compliance with Commission regulations would presumptively provide adequate protection to the public health and safety.

40 Justification for new requirements, however, should not be conflated with the status of SSC design being covered in or beyond the design basis. For example, some elements of LWR design required in the design basis by the General Design Criteria in Part 50, Appendix A, are not "adequate protection" requirements.

consistent with the general approach in place since the 1970s, the SSCs associated with the example BDBEs were not categorized as safety related and licensees were afforded flexibility in how the SSCs are maintained. Calling the events subject to these regulations "beyond the design basis" is a misnomer insofar as the regulations establish requirements for SSC design or human action that an application must describe.

Applicants and licensees for new reactor designs are required under Parts 50 and 52 to address specific BDBEs developed for the operating fleet that have been incorporated into NRC regulations (e.g., ATWS and station blackout). In addition, the Commission has placed additional requirements on new applicants and licensees to address potential severe accidents and potential impacts by large commercial aircraft.[41] As reflected in both the Commission's Severe Accident Policy Statement and Advanced Reactor Policy Statement, an important consideration in designing and licensing new reactor designs is recognizing that safety improvements can be made because of knowledge gained through operating experience, advances in technology, and the ability to incorporate risk-reduction measures into the design process. The increased use of passive safety features and the development of approaches to address the regulatory treatment of non-safety systems is an example of how the design attributes resulted in a change in NRC requirements and practices.[42] The Commission's policy statements and past actions recognize that the initial plant design process provides the best opportunity to address risks from a wide spectrum of possible events and identify the most cost-effective combination of design features, staffing, and programmatic controls to resolve issues.

While maintaining most of the historical distinctions and treatment of BDBEs in Part 53, the staff is proposing to use some different terminology to help clarify the requirements and to avoid possible use of similar terms with different definitions from those in Parts 50 and 52.

- In Framework A, the staff refers to event categories that extend from benign to severe based on estimated frequencies from PRAs as anticipated event sequences, unlikely event sequences, and very unlikely event sequences. The names of these categories differ from those in NEI 18-04[43] to avoid using terms such as design-basis events that have a different meaning in Parts 50 and 52 and in Framework B. The licensing-basis event category of design-basis accident (DBA) is maintained in Framework A because it is generally consistent with the historical use of such events to determine the needed performance requirements for safety-related SSCs. However, Framework A refers to the performance requirements for safety-related SSCs as functional design criteria and avoids using the term "design basis" because of the specific meaning of the terminology in Parts 50 and 52 and in Framework B. The analysis of DBAs in Framework A provides for selecting safety-related SSCs and determining functional design criteria for those SSCs.

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41 Examples include § 52.47(a)(23) that requires applicants for design certifications for LWRs to provide a description of design features for the prevention and mitigation of severe accidents and § 52.47(a)(28) that requires those applicants to provide the information required by § 50.150, "Aircraft impact assessment."

42 See NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Section 19.3, "Regulatory Treatment of Non-Safety Systems for Passive Advanced Light Water Reactors," (ML12128A405).

43 The licensing basis events in NEI 18-04 that are assessed using PRA methods are categorized according to event frequencies as anticipated operational occurrences, design-basis events, and beyond-design-basis events. In addition, NEI 18-04 includes DBAs as a category of licensing basis events and describes them as being similar to the traditional or deterministic analyses of DBAs performed under Parts 50 and 52.

The overall control of risks posed by commercial nuclear plants under Framework A would be provided by the analyses of and measures taken for both DBAs and other licensing-basis events, including very unlikely event sequences. This differs somewhat from the traditional deterministic approach in Part 50 wherein design-basis events, including DBAs, provide bounding assessments, incorporate standard design rules such as assumptions related to single failures, and define conservative performance requirements for safety-related SSCs. The consideration of very unlikely event sequences in Framework A supports a flexible approach for determining special treatments of SSCs, important human actions, and needed programmatic controls to address risk-significant events and ensure overall defense in depth. In addition, giving due consideration to potential risks to public health and safety beyond the DBAs is necessary to ensure, per the Commission's "Policy Statement on the Regulation of Advanced Reactors," that commercial nuclear plants licensed under Framework A are at least as safe as those previously licensed by the NRC. Therefore, as described in NEI 18-04 and related references, the need to include an event category for very unlikely event sequences (or what has been termed BDBEs) is an essential element of the specific risk-informed approach provided by Framework A.

- Framework B is similar to Parts 50 and 52 in terms of identifying and categorizing postulated initiating events as anticipated operational occurrences or DBAs for systematically evaluating engineered systems. Framework B also includes specific provisions to address the Commission's Severe Accident Policy Statement.[44] The deterministic process for identifying and analyzing events used in Framework B is well-established as a means to provide a reasonably comprehensive assessment of challenges to a design and establish requirements for safety-related SSCs. However, decades of operating experience and research throughout the world have shown there are limitations associated with such an approach. In particular, the approach may not adequately address some challenges due to overreliance on a single analysis, design function or feature within the analysis, or considerations resulting from common cause failure from a single initiating event. Therefore, to address safety concerns not captured by either the design-basis events or severe accident provisions, a proposed requirement (§ 53.4730(a)(5)(iv)) is included in Framework B for applicants to identify and assess additional licensing-basis events. This terminology was chosen to avoid the confusion with prior use of the term "BDBEs" in existing regulations and in initial iterations of preliminary draft proposed rule language for Part 53.[45] The requirements in Framework B provide a level of safety comparable to existing regulations by referring to recognized initiators such as ATWS and station blackout from LWR experience and calling for additional assessments to ensure the approach is technology inclusive. The proposed requirements are consistent with the NRC's historical practices in that SSCs provided to mitigate additional licensing-basis events need not be classified as safety related but must have appropriate treatments identified to ensure these SSCs function as specified in the analyses. Framework B also includes a proposed section (§ 53.4420) that is analogous to 10 CFR 50.155, "Mitigation of beyond-design-basis events," for

44 The need to address severe accidents is included in existing requirements in Part 52 (e.g., 52.47(a)(23)) and in proposed requirements for part 50 CPs and OLs as discussed in SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150 AI66)," dated June 6, 2022 (ADAMS Accession No. ML21159A055).

45 Additional licensing-basis events are similar to and largely serve the same purpose as design extension conditions (DEC) included in international standards such as IAEA SSR-2/1, "Safety of Nuclear Power Plants: Design." The use of "additional" or "extension" more accurately reflects how these types of events are considered in the design of nuclear power plants than does the current phrase "BDBE."

applicants to assess and demonstrate the ability to mitigate beyond-design-basis external hazards causing loss of safety functions.

Identification and Implication of Alternatives

Stakeholders and the ACRS have asked questions and offered suggestions about how the two frameworks in the proposed Part 53 address BDBEs and on related issues such as safety classifications for SSCs. One suggestion has been that consideration of BDBEs not be required when determining design attributes of plant SSCs but instead be addressed by requiring mitigating strategies similar to those developed under 10 CFR 50.155 for nuclear power reactors to address beyond-design-basis external events from natural phenomena with concurrent losses of all alternating current power and access to normal heat sinks. The suggestions received in this area did not address how other requirements for BDBEs that influenced the development of 10 CFR 50.155, such as station blackout, should be addressed, or how other BDBEs, such as ATWS, could be addressed without affecting the design of plant SSCs. Given that neither proposed framework in Part 53 prescribes how to address very unlikely event sequences (Framework A) or additional licensing-basis events (Framework B), applicants might be able to use mitigating strategies, portable equipment, and offsite assistance to address one or more events that would fall into the typical BDBE categories. However, the acceptability of relying solely on mitigating strategies for all BDBEs would only be possible if plant attributes affecting the timing and consequences of such events support such an approach. The NRC's past and ongoing review of advanced reactor designs has not included a design that proposed to address all BDBEs, or could likely justify addressing all BDBEs, using only mitigating strategies similar to those developed for LWRs under the post-Fukushima orders and 10 CFR 50.155.

The staff has not identified a viable alternative to the consideration of very unlikely event sequences in Framework A, which is an integral part of the methodology used to determine special treatment requirements for non-safety-related but safety-significant SSCs (possibly including those used for a mitigating strategies approach), human actions, and programmatic controls, all of which contribute to assessing the adequacy of defense in depth. Likewise in Framework B, the staff has not identified a viable alternative to a systematic assessment of additional licensing-basis events to address safety concerns not captured by either the design-basis events or severe accident provisions included in the proposed regulations. As with existing assessments of some passive plant designs, Framework B would allow, where appropriate, SSCs to be considered to address both additional licensing-basis events and mitigating strategies (proposed § 53.4420).

(7) Additional Issues Related to Manufacturing Licenses

The proposed Part 53 addresses construction and manufacturing requirements in Subparts E and O, "Construction and Manufacturing Requirements," for Framework A and B, respectively. The proposed language for construction-related activities largely reflects current requirements in 10 CFR Part 50 without fundamental changes. The proposed requirements for manufacturing activities largely mirror those for construction-related activities and are largely equivalent to those in 10 CFR Part 52. Although the staff updated the proposed requirements for manufacturing licenses somewhat, the staff is not yet proposing significant changes in this area.

During development of the proposed Part 53, the staff considered requirements related to allowing an ML holder to load a manufactured, unlicensed reactor module with fuel in the manufacturing facility prior to its transport to a licensed location for installation and commercial operation. The staff also considered requirements related to the manufacturing licensee's ability to conduct low-power testing of the unlicensed reactor module at the manufacturing facility. This work reflects the staff's recognition that some future reactor deployment models include the concept of fabricating a number of small reactors (i.e., microreactors) in a single facility prior to their deployment at sites under a combined license (COL). Because further refinement of these approaches to address MLs is needed, the staff has not included either proposal (i.e., fuel load at the manufacturing facility or fuel load and low-power testing at the manufacturing facility) in the proposed Part 53 text. However, to continue regulatory development of requirements that would apply to these deployment models, the proposed preamble includes detailed questions on these topics. The staff anticipates that responses to these questions could support future regulatory activity in these areas, if warranted.

The staff recognizes that some of the deployment strategies for a "manufactured reactor" include loading fuel at the manufacturing facility, which would constitute a "manufactured reactor module." Therefore, the staff is considering whether a module could be configured with, for example, at least two independent mechanisms, each of which is sufficient to prevent criticality during its loading and storage. This would involve consideration of applicable requirements for the storage of, movement of, and loading of fuel into the manufactured reactor module within the manufacturing facility as well as applicability of the Atomic Energy Act of 1954, as amended (AEA) requirements related to manufacturing, producing, transferring, acquiring, possessing, using, importing, or exporting any utilization facility, including where applicable inspections, tests, analyses, and acceptance criteria.

Additional considerations include how to address the fuel loading operations. For example, should the following be in place prior to the receipt of special nuclear material (SNM): (1) radiation monitoring instrumentation and alarms; (2) measures to prevent criticality accidents which satisfy the requirements in §§ 70.61 and 70.64 and measures to detect potential criticality accidents in accordance with proposed § 53.440(m); (3) appropriate procedures, equipment, and personnel qualified for the fuel loading; (4) physical security programs; and (5) material control and accounting programs. Also, the staff is contemplating whether any loading or unloading of fresh fuel into a manufactured reactor module and any changes to the configuration of reactivity-related systems would need to be performed by a certified fuel handler demonstrating compliance with the requirements in Subpart F.

Additionally, the staff is considering what requirements are needed related to an application for a ML that includes the installation of fuel at the factory. Considerations include requirements for fueling operations; protections to prevent criticality and otherwise ensure the safety of workers and the public during the manufacture, storage, and transport of each manufactured reactor module; and a description of the safety program and integrated safety analysis like that required by Subpart H of Part 70.

Likewise, the staff is considering how to address the transfer of authorities and responsibilities for the manufactured reactor module from the holder of the ML to the holder of the COL for the installation site and controls to demonstrate compliance with the requirements to address the receipt, storage, and loading of SNM into a manufactured reactor module, including an fitness for duty program, a radiation protection program, an information security program, a physical security program, a fire protection program, an emergency plan, and a plant staff training program.

Separately, the staff also considered including provisions to support the low-power nuclear physics testing of manufactured reactor modules in the manufacturing facility. For example, the staff considered whether combined licenses could be issued to the holders of a manufacturing license to support low-power (<1% rated thermal power) nuclear physics testing of manufactured reactor modules within the manufacturing facility prior to the modules being transported to and incorporated into a commercial nuclear plant for the purpose of energy production.

If an ML holder could accomplish low-power nuclear physics testing by applying for a COL under Subparts H or R, many of the applicable requirements would likely be unnecessary, given the reduced risk profile posed by such activities. Therefore, one approach could be to promulgate a regulation that would provide that applicants for a COL to support low-power nuclear physics testing of manufactured reactor modules demonstrate compliance with all COL requirements in Subparts H and R unless otherwise noted. Examples of requirements that could be relaxed or modified to support applications for low-power testing at ML facilities are described in the specific question in the preamble.

Given the complexity posed by these issues, the staff recommends including detailed questions on these topics in Enclosure 1, Section VII, Specific Requests for Comments. The staff anticipates that responses to these questions may facilitate development of additional provisions for Part 53 in the future to address these topics or to determine other appropriate regulatory action.