

Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing

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EXECUTIVE SUMMARY

The U.S. Nuclear Regulatory Commission (NRC) is considering updating and aligning its regulations for nuclear power plant application reviews under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” and Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants.” The NRC has prepared this regulatory basis to explain:

- why the existing regulations, policies, or, in a few cases, guidance documents, need to be revised to address identified regulatory issues;
- how a change in the regulations or guidance can resolve the issues;
- why alternatives to rulemaking (or sometimes guidance) are not suitable;
- the scientific, policy, legal, or technical information that supports the decision to undertake rulemaking or change guidance;
- backfitting and issue finality considerations, as appropriate;
- stakeholder interactions in developing the technical portion of the regulatory basis, and stakeholder views, to the extent known;
- how the recommended changes will support the NRC’s Strategic Plan goals; and
- any limitations on the scope and quality of the regulatory basis, such as known uncertainties in the data or methods of analysis.

The NRC concludes that there is sufficient basis to proceed with rulemaking and guidance development to address the alignment of regulatory requirements associated with Parts 50 and 52 and the incorporation of lessons learned from new power reactor licensing reviews.

The staff’s recommended alternatives would result in net averted costs to industry and the NRC of approximately \$18 million (7 percent net present value [NPV]) and \$29.6 million (3 percent NPV), respectively, making the overall potential rulemaking cost beneficial.

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ACRONYMS AND INITIALISMS

ABWR	advanced boiling water reactor
AC	acceptance criterion
ACRS	Advisory Committee on Reactor Safeguards
ADAMS	Agencywide Documents Access and Management System
AEA	Atomic Energy Act of 1954, as amended
ALWR	advanced light water reactor
AP1000	Advanced Passive 1000 (reactor design)
AP600	Advanced Passive 600 (reactor design)
APR1400	Advanced Power Reactor 1400 (reactor design)
ASME	American Society of Mechanical Engineers
ATWS	anticipated transients without scram
BPV	Boiler and Pressure Vessel
CAA	controlled access area
CAS	Commission-approved simulator
CFR	<i>Code of Federal Regulations</i>
COL	combined license
CP	construction permit
DC	design certification
DCA	design certification application
DCD	design control document
DCR	design certification rule
DG	draft regulatory guide
EA	environmental assessment
EAL	emergency action level
ECCS	emergency core cooling system
EM	evaluation model
EP	emergency preparedness / planning
EPA	U.S. Environmental Protection Agency
EPZ	emergency planning zone
ETE	evacuation time estimate
ESBWR	Economic Simplified Boiling Water Reactor
ESP	early site permit
ESRP	Environmental Standard Review Plan
FDA	final design approval
FEMA	Federal Emergency Management Agency
FFD	fitness for duty

FR	<i>Federal Register</i>
FRN	<i>Federal Register</i> notice
FSAR	final safety analysis report
FSER	final safety evaluation report
FTE	full-time equivalent (employee)
FY	fiscal year
GDC	general design criterion
GI	generic issue
GSi	generic safety issue
ITA	inspection, test, or analysis
ITAAC	inspections, tests, analyses, and acceptance criteria
JPM	job performance measure
LAR	license amendment request
LERF	large early release frequency
LOCA	loss of coolant accident
LRF	large release frequency
LWA	limited work authorization
LWR	light water reactor
MD	Management Directive
ML	manufacturing license
MRO	medical review officer
NEI	Nuclear Energy Institute
NPV	net present value
NRC	U.S. Nuclear Regulatory Commission
OCA	owner-controlled area
OL	operating license
OLA	operating license application
OSC	operational support center
PA	protected area
PAG	protective action guide
PAR	protective action recommendation
PDI	potentially disqualifying information or potentially disqualifying fitness-for-duty information
PERT	program evaluation and review technique
PRA	probabilistic risk assessment
PRS	plant-referenced simulator
PSAR	preliminary safety analysis report

PWV	post-work verification
RA	Regional Administrator
RAI	request for additional information
rem	roentgen equivalent man
RG	regulatory guide
RIS	regulatory issue summary
SAMDA	severe accident mitigation design alternative
SAR	safety analysis report
SAT	systems approach to training
SDA	standard design approval
SECY	SECY paper; the written issue paper and primary decision-making tool submitted by the NRC staff to the Commission regarding policy, security, rulemaking, and adjudicatory matters, and general information.
SER	safety evaluation report
SMR	small modular reactor
SNC	Southern Nuclear Operating Company
SNM	special nuclear material
SOC	statement of considerations
SPAR	standardized plant analysis of risk
SPDS	safety parameter display system
SRM	staff requirements memorandum
SRP	standard review plan
SSAR	site safety analysis report
SSC	structure, system, and component
SSNM	strategic special nuclear material
STS	standard technical specifications
TMI	Three Mile Island
TN	tracking number (for reference database)
TS	technical specifications
TSC	Technical Support Center
UFSAR	updated final safety analysis report
USI	unresolved safety issue
VCSNS	Virgil C. Summer Nuclear Station
VEGP	Vogtle Electric Generating Plant

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1.0 INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is considering updating and aligning regulations for nuclear power plant application reviews under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” (TN249),¹ and Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251). The NRC is also considering updating these regulations to incorporate lessons learned from new power reactor licensing reviews. These rule changes would apply to any power reactor application submitted to the NRC under Part 50 or 52. For example, the scope of impacted entities includes applications for facilities similar to large light water reactors (LWRs) operating today, large new LWR applications (e.g., similar to the KHNP APR-1400 and Westinghouse AP1000), small modular reactor designs (e.g., similar to the NuScale small modular reactor), and non-LWRs (e.g., high temperature gas reactors, fast reactors, and molten salt reactors).

1.1 Background

In a September 22, 2015, staff requirements memorandum (SRM) (Agencywide Documents Access and Management System [ADAMS] Accession No. ML15266A023; NRC 2015-TN6217) associated with SECY-15-0002, “Proposed Updates of Licensing Policies, Rules and Guidance for Future New Reactor Applications,” dated January 8, 2015 (ADAMS Accession No. ML13277A420; NRC 2015-TN6209), the Commission directed the NRC staff to proceed with a rulemaking on the alignment of licensing requirements of Parts 50 and 52. The Commission directed the NRC staff to also pursue rulemaking to incorporate lessons learned from recent new power reactor licensing reviews. The NRC plans to conduct the alignment and lessons learned rulemakings as a single, coordinated effort.

Enclosure 1 to SECY-15-0002 (ADAMS Accession No. ML13277A647; NRC 2015-TN6489) identified the regulations that the staff had recommended be modified in Part 50 to align with Part 52. In the SRM to SECY-15-0002, the Commission approved revision of the regulations in Parts 50 and 52 incorporating the policies identified by the staff in Enclosure 1.

Since the 2007 update to Part 52 (72 FR 49352, August 28, 2007; TN4796), the NRC has identified several items to evaluate in a rulemaking, including corrections, clarifications, and new requirements. These items have been identified primarily as a result of Part 52 licensing reviews conducted by the NRC since 2007. Enclosure 2 to SECY-15-0002 (ADAMS Accession No. ML19161A206; NRC 2015-TN6490) provided several examples of corrections, clarifications, and new requirements. The staff committed to informing the Commission and other stakeholders, in accordance with NRC’s standard rulemaking practices, about the specific rule changes that the staff would consider.

In the SRM to SECY-15-0002, the Commission directed the NRC staff to evaluate the priority and schedule for rulemaking in the context of Project Aim 2020 to ensure effective use of agency resources. Consequently, the NRC budgeted this rulemaking to start in fiscal year 2019.

¹ The TN number is a unique identifier for individual references in this document and aids in compilation of the references (Chapter 11). The TN number is used at first instance in each chapter and appendix and is not repeated.

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

1.2 Purpose and Scope of this Regulatory Basis

Consistent with the Commission's direction and the NRC's rulemaking process, the staff has prepared this regulatory basis in support of a Parts 50 and 52 alignment and lessons learned rulemaking. This regulatory basis does the following:

- explains why the existing regulations or policies need to be revised to address identified regulatory issues;
- explains how a change in the regulations can resolve the issues;
- explains why alternatives to rulemaking cannot resolve the problems;
- provides the scientific, policy, legal, or technical information that supports the decision to undertake rulemaking;
- discusses backfitting and issue finality considerations, as appropriate;
- discusses stakeholder interactions in developing the technical portion of the regulatory basis, and stakeholder views, to the extent known;
- explains how the recommended rulemaking will support the NRC's Strategic Plan goals; and
- explains any limitations on the scope and quality of the regulatory basis, such as known uncertainties in the data or methods of analysis.

The regulatory basis also presents the NRC's consideration to issue guidance to support or as an alternative to the rule and lists documents that have been cited or otherwise factored into the development of the document. Consistent with NRC policy and procedures, this regulatory basis does not include proposed regulatory text or a section-by-section analysis of current versus proposed regulations.

1.3 Relationship to Non-Light Water Reactor Technology

In the development of this regulatory basis, the NRC did not perform a comprehensive review of the requirements of Parts 50 and 52 for their suitability or applicability to non-LWR technology. Rather, this document focuses on the alignment issues and lessons learned outlined in SECY-19-0084 (NRC 2019-TN6210). The NRC is, however, engaged in a separate effort to develop a risk-informed, performance-based regulatory framework for advanced reactors as described in SECY-20-0032, "Rulemaking Plan on 'Risk-Informed, Technology-Inclusive Regulatory Framework For Advanced Reactors (RIN-3150-AK31; NRC-2019-0062)'" (NRC 2020-TN6805). Although these two rulemakings are proceeding as two separate activities, the NRC is coordinating its efforts so that these rulemakings result in appropriate frameworks for license applicants of all types of reactor technologies. To that end, the NRC may ultimately consider changes to Parts 50 and 52 to address non-LWRs.

1.4 Document Contents and Organization

The subsequent chapters of this document are organized as follows. Chapter 2 describes the background related to the evolution of the current regulatory framework for new reactor licensing; the associated Parts 50 and 52 processes; the Commission's policy, regulations, guidance associated with aligning Parts 50 and 52; and a summary of recent experience with new reactor licensing. Chapter 3 describes regulatory issues related to the proposed alignment and updating to reflect lessons learned. Chapter 4 describes the estimation of costs and savings of proposed alternatives for reactor licensees and the NRC. Chapter 5 addresses other impacts and issues related to using rulemaking to align Parts 50 and 52 and incorporate lessons learned from new reactor license reviews. Chapter 6 describes stakeholder involvement in the development of the scope of the regulatory basis. Chapter 7 describes the relevance of safety goal evaluation to this rulemaking effort. Chapter 8 describes how the recommended rulemaking would support the NRC's Strategic Plan for fiscal years (FYs) 2018–2022. Chapter 9 presents the conclusions. A timeline for developing the rulemaking is presented in Chapter 10. The references for sources cited in the main body and appendices are consolidated in the list provided in Chapter 11.

The appendices to this regulatory basis describe the items evaluated within each technical area in this rulemaking by topic:

- Appendix A – Applying the Severe Accident Policy Statement to New Part 50 License Applications
- Appendix B – Probabilistic Risk Assessment Requirements
- Appendix C – Three Mile Island Requirements
- Appendix D – Description of Fire Protection Design Features and Fire Protection Plans
- Appendix E – Operator Licensing
- Appendix F – Physical Security and Fitness-for-Duty Requirements
- Appendix G – Emergency Planning
- Appendix H – Part 52 Licensing Process
- Appendix I – Environmental Topics
- Appendix J – Applicability of Other Processes to the 10 CFR Part 52 Process
- Appendix K – Miscellaneous Topics

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2.0 BACKGROUND FOR THE PROPOSED RULEMAKING

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

2.1 Evolution of the Current Regulatory Framework for New Reactor Licensing

2.1.1 Licensing of Nuclear Installations

To construct or operate a nuclear power plant, an applicant must submit a safety analysis report (SAR) to the NRC for review. This document contains the design information and criteria for the proposed reactor and comprehensive data about the proposed site. It also discusses various hypothetical accident situations and the safety features of the plant that would prevent accidents or lessen their effects. In addition, the application must contain a comprehensive assessment of the environmental impact of the proposed plant.

Most operating nuclear power plants have been licensed by the NRC under a two-step process described in Part 50 (TN249). This process requires both a construction permit (CP) and an operating license (OL).

In an effort to improve regulatory efficiency and add greater predictability to the process, in 1989 the NRC established alternative licensing processes in Part 52 (TN251) that included a combined license (COL). This process combines a CP and an OL with conditions for plant operation.

Other licensing options under Part 52 include an early site permit (ESP) that allows an applicant to obtain approval for a reactor site without specifying the design of the reactor(s) that could be built there, and a certified standard plant design that can be used as a preapproved design.

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

Additional details about both licensing processes, beyond those provided in the following sections, can be found in NUREG/BR-0298, Revision 2, "Nuclear Power Plant Licensing Process," dated July 2004 (NRC 2004-TN1678).

2.1.2 Part 50 Process

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

Under the Part 50 process, a prospective nuclear power plant licensee applies first for a CP, and then for an OL. The requirements in paragraph 50.34(a) outline the information an applicant must submit in a preliminary safety analysis report to support the NRC's safety review

and issuance of a CP. Section 189a.(1)(A) of the Atomic Energy Act of 1954, as amended (AEA; 42 U.S.C. § 2239(a)(1)(A); TN663) requires that a public hearing be held before a CP is issued for a nuclear power plant. The public hearing is conducted by the Commission or a three-member Atomic Safety and Licensing Board.

An OL application includes a final safety analysis report (FSAR), whose content is specified by 10 CFR 50.34(b), which describes the licensing basis that is reviewed by the NRC to develop the agency's safety evaluation report (SER). An opportunity for a hearing is provided during an OL review. At the end of successful construction, if the NRC determines that the applicant satisfies the applicable requirements, then the NRC issues the OL, which is valid for a period of 40 years.

The NRC observed that the Part 50 licensing process had certain disadvantages. They include the greater likelihood of construction delays and rework due to changes to the design as it is finalized, and regulatory changes that occur after the CP is issued that must be addressed before approval of the OL application. In addition, the final decision by the NRC about the safety of the plant does not occur until the plant construction is nearly complete and a large capital investment has been made. Because there is little finality with regard to safety decisions made by the NRC when the CP is issued, matters that were addressed during the CP review can be revisited during the review of the OL application. Finally, the process did not incorporate a focus on standardization with its many advantages, including increased regulatory efficiency.

2.1.3 Part 52 Process

The NRC applied its experience in licensing "Part 50" reactors to the development of 10 CFR Part 52, which has been used for the most recent new reactor licensing reviews, including the COLs issued for two new facilities under construction at the Vogtle Electric Generating Plant site.

By the time the original Part 52 rule was issued in 1989 (54 FR 15372, April 18, 1989; TN6256), the Commission had long sought nuclear power plant standardization and the enhanced safety and licensing reform that standardization could make possible. For more than a decade, the Commission had been adding provisions to Part 50 and Part 2 (TN6204) to allow for limited degrees of standardization, and for as many years, the Commission had been proposing legislation to Congress on the subject. The Commission was frequently asked by members of Congress to what extent legislation on the subject was necessary, and in doing the analysis to reply to these questions, the Commission came to believe that much of what it sought could be accomplished within its current statutory authority. Thus, the Commission embarked on a standardization rulemaking.

The Commission announced its intent to pursue standardization rulemaking in its Policy Statement on Nuclear Power Plant Standardization (52 FR 34884, September 15, 1987; TN6362). The Policy Statement set forth the principles that would guide the rulemaking. In 1988, the Commission issued the proposed rule on ESPs, standard design certifications (DCs), and COLs (53 FR 32060, August 23, 1988; TN6363), which first introduced Part 52. In 1989, the Commission approved Part 52 in the final rule (54 FR 15372, April 18, 1989), providing for issuance of ESPs, standard DCs, and COLs for nuclear power reactors. The final rule was intended to achieve the early resolution of licensing issues and enhance the safety and reliability of nuclear power plants.

Based on lessons learned during the early DC reviews and discussions with nuclear industry representatives about the Part 52 licensing processes, the NRC staff submitted SECY-98-282, "Part 52 Rulemaking Plan" (NRC 1998-TN6364), on December 4, 1998, proposing to enhance Part 52. In a January 14, 1999, SRM (NRC 1999-TN6369), the Commission approved the rulemaking plan. On July 3, 2003 (68 FR 40026; TN6365), the NRC published a proposed rule. On March 13, 2006 (71 FR 12781; TN6343), the NRC issued a revised proposed rule that superseded the 2003 proposed rule and would rewrite Part 52, make changes throughout the Commission's regulations to ensure that all licensing processes in Part 52 were addressed, and clarify the applicability of various requirements to each of the processes in Part 52 (i.e., ESP, standard design approval [SDA], standard DC, COL, and manufacturing license [ML]).

The basic concept underlying Part 52 is to provide for early resolution of licensing issues by approving nuclear reactor designs through generic rulemaking. Once the designs are approved (i.e., certified), an applicant can reference them in applications for permission to build and operate nuclear power plants without needing to relitigate, in individual hearings, the issues resolved in the DC rulemaking. A DC is valid for 15 years and can be renewed for an additional 10 to 15 years.

Under the Part 52 regulatory framework, a prospective nuclear power plant operator applies for a COL that authorizes both construction and (after certain criteria are met) plant operation. The application may reference a certified design, SDA, ML, or an ESP to take advantage of reviews previously completed by the NRC.

Under the Part 52 COL process, the NRC determines and approves, before construction, the criteria that will be used to evaluate, after construction, whether the plant has been built as specified in the license. Before authorizing operation, the Commission must determine that these criteria have been met. A public hearing is required to be conducted before a COL is issued. There also is an opportunity for a hearing after a COL is issued, but before fuel loading is authorized; the hearing is limited to determining whether the acceptance criteria in the license have been met.

The NRC may approve and certify a design through a rulemaking, independent of a specific site. An application for a standard DC must contain proposed inspections, tests, analyses, and acceptance criteria (ITAAC) for the standard design. The application also must demonstrate how the applicant complies with the Commission's relevant regulations.

A DC application must contain a level of design information sufficient to enable the Commission to reach a final conclusion about all safety questions associated with the design. In general terms, a DC application should provide an essentially complete nuclear plant design, with the exception of some site-specific design features.

The application presents the design basis, the limits on operation, and a safety analysis of the structures, systems, and components (SSCs) of the facility as a whole. The scope and contents of the application are equivalent to the level of detail found in an FSAR for a currently operating plant. The NRC prepares an SER that describes its review of the plant design and how the design meets applicable regulations.

Upon determining that the application meets the relevant standards and requirements of the AEA and the NRC's regulations, the NRC typically publishes a proposed rule for public comment; the Commission may then decide to hold a hearing. The final rule associated with the standard DC is issued as an appendix to the Part 52 regulations.

The issues that are resolved in a DC rulemaking are subject to a more restrictive change process than issues that are resolved under other licensing processes. The NRC cannot modify a certified design unless it determines in a rulemaking that the change is necessary by meeting one or more of the criteria described in paragraph 52.63(a)(1).

An application for a COL under Part 52 can incorporate by reference a DC. The advantage of this approach is that the issues resolved during the DC rulemaking are precluded from reconsideration later during the COL stage.

An application for a COL under Part 52 also can incorporate by reference an ESP. An ESP resolves site safety, environmental protection, and emergency preparedness issues (if applicable) that may be either design-specific or independent of a specific nuclear plant design. The ESP application must address the safety and environmental characteristics of the site and evaluate significant impediments to developing an acceptable emergency plan. The NRC documents its findings related to site safety characteristics and emergency planning (if applicable) in an SER and those related to environmental protection issues in draft and final environmental impact statements.

After the NRC completes its safety review, the NRC conducts a mandatory public hearing. The ESP is initially valid for no less than 10 and no more than 20 years and can be renewed for 10 to 20 years.

In addition to establishing this alternative process, the requirements in Part 52 formalized expectations for new designs per the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138, August 8, 1985; TN4519) (Severe Accident Policy Statement), with explicit requirements related to the Three Mile Island (TMI) items in paragraph 50.34(f), severe accidents, probabilistic risk assessment (PRA), and other topics. However, Part 50 has not been updated to include similar requirements for these items. As a result, the two licensing processes have different technical requirements in some areas.

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

Because of the NRC's focus in recent years on the Part 52 licensing process, several Commission policies and direction related to new reactors have been translated into explicit requirements and guidance only for applicants under Part 52. This issue is discussed in SECY-15-0002 (NRC 2015-TN6209), Enclosure 1, "Improving Alignment Between New Reactor Licensing Processes," and is summarized below.

2.2.1 Application of Severe Accident Policy and Additional Commission Direction

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

The Severe Accident Policy Statement indicated that an applicant is expected to consider a range of alternatives when addressing safety issues and reducing risk from severe accidents.

The NRC conclusions about the acceptability of the design would be made through a review of the applicant's traditional engineering analysis, complemented by insights from the PRA.

In addition, the Commission's "Policy Statement on Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities" (60 FR 42622, August 16, 1995; TN6278) encouraged the use of PRA in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

Therefore, the Severe Accident Policy Statement sets an expectation that CP applications include a preliminary risk analysis. The requirements in paragraphs 52.47(a)(27) and 52.79(a)(46) implement this expectation by requiring submittal of PRA information in DC and COL applications, respectively. Similarly, paragraphs 52.47(a)(8) and 52.79(a)(17) include requirements to address TMI issues for those applications. However, these expectations have not been reflected in Part 50 requirements for new CP or OL applications.

The NRC staff completed several Commission papers in the late 1980s and early 1990s addressing issues arising from consideration of new reactor design and licensing reviews. In SECY-89-013, "Design Requirements Related to the Evolutionary Advanced Light Water Reactors," dated January 19, 1989 (NRC 1989-TN6367), the staff informed the Commission of the planned approach to ongoing reviews of evolutionary new reactor designs and identified issues that should be resolved for these designs.

A year later, in SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and Their Relationship to Current Regulatory Requirements" (NRC 1990-TN524), dated January 12, 1990, the staff recommended positions on several issues fundamental to the review of evolutionary designs. The Commission approved most of these enhancements in its June 26, 1990, SRM (NRC 1990-TN6366).

As the NRC began to review passive designs, the staff requested Commission direction on extending certain requirements to these types of designs, as well as direction on additional enhancements, in SECY-93-087, "Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light Water Reactor (ALWR) Designs" (NRC 1993-TN6212), dated April 2, 1993. In its SRM dated July 21, 1993 (NRC 1993-TN6218), the Commission extended a number of its previous positions to passive designs. The Commission also approved new positions on topics such as "leak before break" and steam generator tube ruptures.

The NRC has incorporated the expectations from the Severe Accident Policy Statement and subsequent Commission direction outlined above into requirements and guidance for new reactor applications reviewed under the provisions of Part 52. However, the NRC has not consistently updated similar regulations and guidance to support new Part 50 applications. Additionally, the NRC has not completed a detailed technical and regulatory assessment of the value proposition of applying these expectations to future non-LWR applications.

2.2.2 Three Mile Island Requirements

The criteria used to assess the resolution of severe accident issues for new reactors also include certain post-TMI requirements in 10 CFR 50.34(f).

The introductory paragraph of paragraph 50.34(f) limits its applicability to two groups of applicants: (1) applicants for a CP or ML whose application was pending as of February 16,

1982, all of whom no longer have active applications; and (2) applicants for a DC, SDA, COL, or ML under Part 52, with certain exceptions, as described in Part 52.

Requirements in Part 52 for the contents of DC and COL applications (paragraphs 52.47(a)(8) and 52.79(a)(17), respectively) state that these applications must provide information necessary to demonstrate compliance with the technically relevant portions of the TMI requirements, with certain exceptions. Therefore, new CP and OL applicants under Part 50 are not currently required to comply with the TMI items in paragraph 50.34(f).

To date, the applicant's submittals and the NRC's reviews of technically relevant portions of these requirements have been largely focused on determining the applicability of these requirements for LWR applications. The NRC has not completed, for this regulatory basis, an assessment of the value of applying these requirements to future non-LWR applications, but could clarify these requirements as part of the proposed rule.

2.2.3 PRA Requirements

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

- Paragraph 50.34(f)(1)(i), as referenced by various subparts of 10 CFR Part 52, which directs applicants to perform "a plant/site specific probabilistic risk assessment, the aim of which is to seek such improvements in the reliability of core and containment heat removal systems as are significant and practical and do not impact excessively on the plant."
- Paragraphs 52.47(a)(27) and 52.79(a)(46), which direct DC and COL applicants, respectively, to provide a description of the design-specific or plant-specific PRA and its results.
- Paragraph 50.71(h), which directs only COL holders to develop, maintain, and upgrade a PRA with a specific scope.

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

2.2.4 Fire Protection

In the SRMs for SECY-90-016 and SECY-93-087, the Commission approved positions regarding fire protection for all evolutionary and passive ALWRs. Requirements for specific information to be submitted in applications, however, are limited to the Part 52 process. Only COL applicants are required to provide a description and analysis of their fire protection design features (paragraph 52.79(a)(6)). Combined license applicants are also required to describe their fire protection plan in their applications per paragraph 52.79(a)(40). The regulations of paragraph 50.34(b) describing the content of OL applications do not include similar requirements.

2.3 Summary of Recent Experience with New Reactor Licensing

The NRC has issued a significant number of licensing actions under Part 52 since 2007. These actions include the issuance of 3 DCs, 14 COLs, 6 ESPs, and numerous license amendments and exemptions. The NRC is also reviewing the renewal of one DC. This experience has provided the NRC with some lessons learned that may warrant changes to the current regulatory structure. The NRC described this collection of lessons learned in SECY-19-0084,

“Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)” (NRC 2019-TN6210). The enclosure associated with SECY-19-0084, “List of Lessons Learned Items Included in the Scope of the Regulatory Basis for Aligning Licensing Processes and Lessons Learned from New Reactor Licensing,” contains the list of the 52 lessons learned items, grouped under several topical areas.

2.3.1 Operator Licensing

The NRC regulations governing the issuance of licenses to operators of utilization facilities do not discuss the issuance of operator licenses to individuals at utilization facilities that are under construction and not yet operating (i.e., cold plants). The NRC recently gained experience implementing the operator licensing program in these situations. For example, several groups of applicants for operator licenses have taken the requisite written examinations and operating tests at Vogtle Electric Generating Plant Units 3 and 4 (VEGP 3&4), which are utilization facilities that were under construction at the time of the written examinations and operating tests. In some cases, the NRC approved exemptions from the Commission’s regulations to facilitate the administration of these examinations and applicants’ performance of experience requirements because design and construction of the utilization facilities at VEGP 3&4 were not complete. Appendix E of this regulatory basis discusses alternatives for improving the efficiency and effectiveness of the operator licensing program at cold plants based on lessons learned from this experience. The lessons learned are related to criteria for simulation facilities used to administer the operating test and meet experience requirements, the plant walkthrough portion of the operating test, and continuing training of operator license applicants following their completion of the NRC’s initial operator licensing examination.

2.3.2 Physical Security

The NRC has identified an issue in the regulations that may result in an unnecessary burden on Parts 50 and 52 power reactor applicants and licensees. The current NRC regulations require applicants for a power reactor OL under Part 50 or holders of a COL under Part 52 to establish a protected area before unirradiated fuel is allowed onsite. Based on experience from recent new reactor licensing reviews, the NRC recognized that it may be possible to receive unirradiated fuel onsite in the protected area before implementing all of the security requirements in 10 CFR 73.55. However, these security requirements would have to be implemented at some point just prior to fuel load to address the increased risk arising from radiated fuel onsite. Appendix F of this regulatory basis discusses alternatives to amend these requirements to make clear that applicants and licensees may bring unirradiated nuclear fuel onsite and protect it in accordance with the NRC’s requirements for physical protection of special nuclear material of moderate and low safety significance.

2.3.3 Fitness for Duty

The NRC has identified lessons learned from implementation of fitness-for-duty (FFD) programs at the VEGP and Virgil C. Summer Nuclear Station construction sites. The NRC has identified requirements that could be amended to address issues concerning access to the construction site and procedures for Medical Review Officers. Other changes would clarify regulatory language, and revise Part 26, “Fitness for Duty Programs” (TN5451), based on risk insights learned from operating experience. Appendix F of this regulatory basis discusses several alternatives that evaluate these regulatory changes.

2.3.4 Emergency Planning

The NRC has identified several lessons learned from its reviews of new reactor licensing with respect to emergency planning. Appendix G of this regulatory basis discusses alternatives for addressing the following lessons learned:

- There is a disparity in the timing and level of site-specific information available to Part 50 applicants and COL and (certain) ESP applicants under Part 52 regarding when they are required to provide a complete Emergency Classification and Action Level scheme for NRC approval. (See Appendix G, Section 1.0, “Initial Classification and Action Level Scheme.”)
- There is a lack of clarity regarding which emergency plan change process applies to Part 52 licensees prior to the Commission’s paragraph 52.103(g) finding. At a January 15, 2019, Category 3 public meeting, representatives from the Nuclear Energy Institute (NEI) discussed this issue. The NRC analyzed the issue and agrees that the applicability of paragraph 50.54(q) may be unclear. (See Appendix G, Section 2.0, “Emergency Plan Change Process.”)
- The emergency planning requirements associated with Federal Emergency Management Agency (FEMA) findings and low-power operation may be unclear. The NRC also identified that requirements related to the need for a subsequent exercise at multiple unit sites may be overly burdensome. (See Appendix G, Section 3.0, “Emergency Preparedness Exercises.”)
- The requirements related to the scope of the area surrounding the site that is subject to the siting analysis may be unclear. The NRC also identified that clarification may be needed for when NRC consultation with FEMA would be required for an ESP application. (See Appendix G, Section 4.0, “Significant Impediments to Development of Emergency Plans.”)
- The requirements regarding the descriptions of contacts and arrangements with Federal, State, and local governmental agencies that are required to be included in an ESP application may warrant revision. (See Appendix G, Section 5.0, “Offsite Contacts, Arrangements, and Certifications.”)

2.3.5 Part 52 Licensing Process

The NRC has identified several lessons learned from its reviews of new reactor licensing with respect to the Part 52 licensing process. Appendix H of this regulatory basis discusses alternatives for addressing the following:

- **Design Certification Renewal and Design Certification Expiration Date**
 - The requirements for updating the contents of a DC at renewal are unclear, and the 15-year certification period of a DC may not serve the underlying purpose of the rule. (See Appendix H.1, “Design Certification Renewal.”)

- **Change Process**

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

- The change process requirements for applicants and holders of licenses that reference a certified design should be reorganized. Because the same process is described in each DC appendix, it would be more efficient to describe the change process a single time in Part 52 and include references to the process in each of the DC appendices. (See Appendix H.2, Section 1.0, “Move 10 CFR 50.59-Like Process from 10 CFR Part 52 Appendices to Subpart B.”)

- The Commission intended that Tier 1 information should include the top-level design features and performance characteristics that are most important to safety for a standard design, but did not specify what information should be included in Tier 1. A COL holder must request a license amendment and an exemption to change Tier 1 information in its plant-specific Design Control Document (DCD) (or FSAR), even where there is minimal safety significance to the change. (See Appendix H.2, Section 2.0, “Processes for Making Tier 1 Conforming Changes and Formatting Changes and Tier 2 Changes to Organization and Section Numbering.”)
- As a result of the NRC’s experience with the issuance of COLs and the review of subsequent license amendment requests (LARs), the NRC staff has identified that requiring licensees subject to the DC change process to obtain NRC approval before making certain physical changes, while allowing other (Part 50) licensees to proceed with the physical changes prior to requesting NRC approval, is inconsistent and may impose an unnecessary burden on those licensees subject to the Part 52 process. (See Appendix H.2, Section 3.0, “10 CFR Part 52 Appendix A-E Sections VIII.5.B.A and VIII.5.B.B.”)
- As a result of the NRC’s experience with the issuance of COLs and the review of LARs and other actions involving issued COLs, the NRC has identified the regulatory language differences in the Section 50.59 and the DC Section 50.59-like change processes as an issue. In particular, having distinctly different regulatory language for the applicability aspects of the two processes that are nominally similar can result in confusion and can lead to questions about why those aspects of the two processes are not the same. (See Appendix H.2, Section 4.0, “Include 10 CFR 50.59(c) Applicability Provisions in 10 CFR Part 52, 10 CFR 50.50-Like Process.”)
- Currently, there is no regulatory mechanism that would allow an ESP holder to make those changes to its site safety analysis report (SSAR) that have a limited nexus to site safety without obtaining prior NRC approval through a license amendment. Such a mechanism would be similar to the existing process for COL and OL holders, who are allowed to make certain changes to information in their FSARs without a license amendment or prior NRC approval when those changes meet preestablished criteria. (See Appendix H.2, Section 5.0, “Change Process for ESP SSARs and LWA SRS.”)

- **Design Scope and Standardization**

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

- The NRC identified that placing identical tier definitions in each appendix is repetitive; the tiers should be defined once, and this definition should be consistent across future Part 52 appendices. Currently, DC applicants are not required to include tiers in their applications. DC applicants can include no tiers, more than the three tiers defined in the Part 52 appendices, or tiers with definitions that are different than those in current Part 52 appendices. This can lead to inconsistencies and increased burden for DC and COL applicants in preparing applications and the NRC in reviewing applications. (See Appendix H.3, Section 1.0, “Modify 10 CFR 52 to Add Definitions of Tier 1, Tier 2, and Tier 2* and Require Information Consistent with Principles in SECY-19-0034 [NRC 2019-TN6257].”)
- The NRC has observed that the term “essentially complete nuclear power plant design” is mentioned in several parts of NRC’s regulations, but the term is not defined in those sections or in Section 52.1 with other definitions of terms used in Part 52. In paragraphs

52.47(c)(1) and (2), the regulations state that paragraph 52.47(c) applies to applicants who “provide an essentially complete nuclear reactor design except for site-specific elements such as service water intake structure and the ultimate heat sink.” However, the context of the term in paragraphs 52.47(c)(1) and (2) implies that a design cannot be considered “essentially complete” if it omits any element that cannot specifically be identified as being site-specific. That is, the term implies that the scope of the application includes all SSCs that are not considered to be site-specific. This term is also discussed in the 1989 final rule that established Part 52, which describes it as including “all of a plant which can affect safe operation of the plant except its site-specific elements.” (54 FR 15372, April 18, 1989). The NRC found that a definition of “essentially complete design” may be overly restrictive. (See Appendix H.3, Section 2.0, “10 CFR 52.41(c)(1) and (2), “Clarification of the Phrase ‘Essentially Complete Design.’ ”)

- The NRC’s experience with LARs involving exemptions needed during construction of VEGP 3&4 (which reference the Advanced Passive 1000 [AP1000] DC) has shown that the restrictions on changes to the AP1000 certified information based on reasons of standardization are unnecessary and do little to preserve a meaningful standardization of the design. (See Appendix H.3, Section 3.0, “10 CFR 52.63 Modifying Restrictions on Changes to a DC or COL Referencing a DC for Reasons of Standardization.”)
- The NRC has identified that Section IV.A.2 in each of the Part 52 Appendices A through D, describes the use of site parameters and site characteristics slightly differently than they are described in 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions” (TN250), paragraph 51.50(c)(2). As a result, when the NRC issued Part 52 Appendices E and F, the NRC wrote Section IV.A.2.d to be consistent with the language in paragraphs 51.50(c)(2) and 52.79(d). However, this conforming change was not made in Appendices A through D. (See Appendix H.3, Section 4.0, “Revise 10 CFR Part 52 Appendices A Through D, Sections IV.A.2.d to Clarify the Terms ‘Site Parameters’ and ‘Site Characteristics.’ ”)
- When the first DC rules were issued, it was not clear whether the requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of the DC appendices should apply to all DCs. Therefore, the NRC included them within each individual DC rule. The NRC has now issued six DC rules and each rule includes the requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f. Continuing to issue individual DC rules with these requirements would be an inefficient and unnecessarily repetitive method of regulating. (See Appendix H.3, Section 5.0, “10 CFR 52.79(d) and DC Appendices Section IV, Relocation of Requirements from DC Appendices to 10 CFR 52.79(d).”)
- In the final rule for the Economic Simplified Boiling Water Reactor (ESBWR) Design Certification (79 FR 61943, October 15, 2014; TN4146), the NRC found that Section IX of the proposed Part 52, Appendix E, would be redundant to Sections 52.99 and 52.103. In the final rule, the NRC did not include any substantive requirements in Section IX of Appendix E. In that same rulemaking, the NRC stated its intent to remove Section IX from Appendices A through D in future amendments to the regulations, separate from the ESBWR rulemaking. (See Appendix H.3, Section 6.0, “Design Certification Rule Section IX ITAAC.”)

• **Standard Design Approval**

The NRC identified the following areas concerning the SDA and its role in the Part 52 licensing process:

- Some non-LWR designers have informed the NRC that they are considering submitting applications for SDAs and major portions of the design. The NRC’s regulations do not

specify whether only one or more than one SDA may be referenced in CP, COL, and ML applications, although it is implied that more than one SDA could cover the final design of major portions of an entire facility. If more than one SDA exists for a particular design, and the scope of each of those SDAs covered only a major portion of the design as permitted under paragraph 52.135(a), then a CP, COL, or ML applicant may want to reference more than one SDA. The lack of clarity in the regulations on this matter could result in unnecessary expenditure of time and resources by both the NRC and potential applicants, and providing clarity in the regulations would be beneficial to potential applicants as well as the NRC. (See Appendix H.4, Standard Design Approval.)

- **Content of Applications**

- Recent experience with new reactor licensing highlighted the fact that applicants expend significant resources to evaluate the differences between their applications and the Standard Review Plan (SRP). Such an extensive evaluation may not be necessary. (See Appendix H.5, Section 1.0, “Modifying Requirements to Evaluate Conformance with the Standard Review Plan.”)
- The NRC has observed that Section 50.100 can be read to imply that a COL could be revoked, suspended, or modified for failure to achieve timely completion of the licensee’s proposed construction or alteration of the facility. This requirement is inconsistent with Section 50.55, which does not require conditioning of the COL to state the earliest and latest dates for completion of the construction or modification of the facility. (See Appendix H.5, Section 2.0, “Aligning Requirements for Timely Completion of Construction Requirements.”)
- The NRC has identified that currently no language in the regulations explicitly addresses the case of a COL applicant that references both an ESP and either an SDA or a DC. Clarifying the applicability of the various demonstration requirements of an applicant referencing an SDA or a DC, and an ESP would provide regulatory certainty and reduce confusion. (See Appendix H.5, Section 3.0, “Clarifying Requirements for an Applicant Referencing an Early Site Permit and a Design Certification or Approval.”)

- **Environmental Review**

- Under paragraph 2.101(a)(5), an application for a CP or COL can be submitted in two parts with the environmental report submitted first. In this situation, the regulations require an applicant to submit the information related to financial qualifications, emergency planning, and decommissioning funding assurance with the first part of the application even though it is not used in the environmental review. The NRC identified that applicants should not be required to submit this information when the environmental report is submitted first. (See Appendix I, Section 1.0, “Revising the Application Requirements in 10 CFR 2.101(a)(5).”)
- The NRC found that a COL applicant that references a DC is allowed, under paragraph 51.50(c)(2), to incorporate by reference the environmental assessment previously prepared by the NRC for the referenced DC. Section 51.50(a) does not contain a similar option for an applicant for a CP referencing a DC to incorporate by reference the EA prepared for the DC. (See Appendix I, Section 2.0, “Change to Clarify 10 CFR 51.50(a) That an Applicant for a Construction Permit Can Reference an Environmental Assessment from a Certified Design.”)

- **Applicability of Other Processes to the Part 52 Process**

The NRC has identified several lessons learned from its reviews of new reactor licensing with respect to the applicability of other regulatory processes to the Part 52 process.

Appendix J of this regulatory basis discusses alternatives for addressing the following lessons learned:

- The NRC has observed that paragraph 52.103(a) requires the NRC to issue a notice of opportunity of a hearing on compliance with the acceptance criteria in a COL not less than 180 days prior to the scheduled date of fuel load. Although an ITAAC hearing is treated as a contested proceeding under some regulations (e.g., Section 2.340 is titled, in part, “Initial decision in certain contested proceedings,” and paragraph 2.340(c) refers to initial decisions on findings in ITAAC hearings under Section 52.103), the definition of “contested proceeding” in Section 2.4 does not include ITAAC hearings within its scope. (See Appendix J, Section 1.0, “Definition of Contested Proceeding in 10 CFR 2.4.”)
- The NRC has noted that the applicability of the NRC requirement to provide annual updates to the FSAR for COL applicants that have requested the NRC to suspend its review of the application or a COL holder that is not pursuing construction may create an unnecessary burden on the COL applicant or holder. (See Appendix J, Section 2.0, “Maintenance of Records in 10 CFR 50.71(e)(3)(iii).”)
- The NRC has noted that the requirements pertaining to backfitting and issue finality in Parts 50 and 52, respectively, overlap in some areas and create inconsistencies. These inconsistencies in the regulations may lead to confusion about the applicable criteria for imposition of changes to SDAs, MLs, and ESPs. (See Appendix J, Section 3.0, “References to Issue Finality in 10 CFR 50.109.”)

• **Miscellaneous Lessons Learned**

The NRC has identified several miscellaneous lessons learned from its reviews of new reactor licensing. Appendix K of this regulatory basis discusses alternatives for addressing the following lessons learned:

- The NRC noted that paragraph 52.103(b) provides the public with an opportunity to request a hearing under paragraph 52.103(a) when one or more of the acceptance criteria of the ITAAC in the COL have not been met or will not be met. Although ITAAC hearings are supposed to be narrowly focused on the status of the acceptance criteria, a litigant wishing to challenge operation of the facility under paragraph 52.103(b) may misread paragraph 2.106(b)(2)(ii) to mean that a broad, additional opportunity to raise challenges under the AEA and the Commission’s regulations is available during the ITAAC verification process. (See Appendix K, Section 1.0, “Notice of Issuance in 10 CFR 2.103(b)(2)(ii).”)
- The NRC found that during the revision of Part 21, “Reporting of Defects and Noncompliance,”(TN5874) to address its applicability to Part 52 licensees (72 FR 49352, August 28, 2007; TN4796), the NRC unintentionally omitted “10 CFR Part 52,” from the definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication,” in Section 21.3. This omission created inconsistencies with other definitions in Section 21.3 that are applicable to Part 52 licensees. (See Appendix K, Section 2.0, “Definitions in 10 CFR 21.3.”)
- The NRC has observed that the current regulatory language in paragraph 50.34(f)(2)(iv) requiring a “console” does not clearly convey the range of safety parameter display system (SPDS) design options acceptable to the NRC. Revising the regulation to remove the term “console” would better convey that the purpose of the SPDS requirements are functional and not necessarily focused on whether there is a dedicated console. (See Appendix K, Section 3.0, “Requirement for Safety Parameter Display System Console in 10 CFR 50.34(f)(2)(iv).”)

- The NRC noted that the regulations do not adequately address changes to plant-specific technical specification (TS) bases during construction. There is no guidance on the change process applicable to plant-specific TS bases independent of any plant-specific TS changes or plant design changes, that require a license amendment, during the period between issuance of the COL and the Commission’s paragraph 52.103(g) finding. A change process for the plant-specific TS bases exists in Appendix A of the COL, but it is not effective until after the finding authorizing facility operation. (See Appendix K, Section 4.0, “Technical Specifications Bases Control Prior to the 10 CFR 52.103(g) Finding.”)
- The NRC noted that the current requirements to report emergency core cooling system (ECCS) evaluation model changes and errors as soon as they are identified may be overly burdensome to those DC applicants or holders of SDAs, COLs, or MLs whose design is not referenced by a COL holder. (See Appendix K, Section 5.0, “Requirements for Reporting Errors and Changes in ECCS Models.”)
- The NRC noted that in developing Part 52, the NRC may have underestimated the length of the time between completion of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel (BPV) Code, Section III, N-3 Data Forms (ASME 2019-TN6332) for installed systems in Part 52 nuclear power plants and the Commission finding under paragraph 52.103(g). Based on experience in the construction of VEGP 3&4, the NRC has found that a COL holder might need to conduct various repair activities that typically arise during the final stages of nuclear power plant construction. To use the ASME BPV Code, Section XI provisions, the COL holder must meet Section III through reconciliation or submit a request for an alternative to those requirements. (See Appendix K, Section 6.0, “Generic Application of ASME BPV Code, Section XI, to the Nuclear Power Plants Licensed Under 10 CFR Part 52.”)
- The current regulations identify the Regional Administrator (RA) as a recipient of a notification from certain applicants or licensees under Part 52 of information having a significant implication for public health and safety or common defense and security. However, the RA is not involved in the issuance of either SDAs or DCs, nor is the RA responsible for the receipt or review of applications for Part 52 permits, certifications, or licenses. Therefore, there may be a delay in assessing and acting upon the information because the cognizant and responsible organization for these applications and approvals has not been notified. (See Appendix K, Section 7.0, “Notification to the Director of the Office of Nuclear Reactor Regulation of Significant Implication for Public Health and Safety or Common Defense and Security.”)
- The NRC noted that the language in paragraphs 52.47(a)(21) and 52.79(a)(20) does not reflect that the NRC has discontinued the use of the priority ranking model for Generic Issues and has instead implemented a screening process using the risk criteria in RG 1.174, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” (NRC 2018-TN6335). (See Appendix K, Section 8.0, “Discontinue Use of Priority Ranking Model for Generic Issues and Allow a Risk-Informed Approach.”)
- The NRC noted that the “have been met” language in paragraph 52.97(a)(2) does not align with the “are met” language of Section 185.b of the AEA and paragraph 52.103(g). The finding made pursuant to paragraph 52.103(g) is that the acceptance criteria “are met” at the time of the finding. The words “have been met” could be understood to mean that the ITAAC were met at some earlier time but may not have been maintained, so they are no longer met at the time of the paragraph 52.97(a)(2) finding. This language could call into question whether ITAAC have been maintained when the paragraph

52.97(a)(2) finding is made. (See Appendix K, Section 9.0, “10 CFR 52.97(a)(2) ITAAC Completion at COL Issuance.”)

- The final FY 2020 annual fee rule (“Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020” [85 FR 37250; TN6389]) requires Part 52 COL holders to start being assessed annual fees upon successful completion of power ascension testing, rather than after the Commission makes a finding under the paragraph 52.103(g) finding. The rule requires new Part 50 power reactor licensees to be assessed annual fees beginning when the licensee successfully completes power ascension testing. The NRC would need to know the date on which the licensee successfully completes power ascension testing so the NRC could begin assessing annual fees under Part 171, “Annual Fees for Reactor Licensees and Fuel Cycle Licensees and Material Licensees, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals, and Government Agencies Licensed by the NRC” (TN6338). The NRC’s regulations do not currently require Part 50 reactor licensees or Part 52 COL holders to notify the NRC of completion of power ascension testing. (See Appendix K, Section 10.0, “Reporting Requirements at Completion of Power Ascension Testing – Start of Assessment of Annual Fees.”)

2.3.6 Summary of Current Licensing Approach

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

3.0 REGULATORY ISSUES

As discussed previously, in addition to establishing an alternate licensing process, the requirements in 10 CFR Part 52 (TN251) formalized expectations for new designs in accordance with the Commission's Severe Accident Policy Statement (TN4519), with explicit requirements related to the TMI items in paragraph 50.34(f), severe accidents, PRA, and other topics. However, Part 50 (TN249) has not been updated to include similar requirements. As a result, the two licensing processes have different technical requirements, and thus may not provide the same level of safety, security, or environmental protection.

Potential applicants for non-LWR designs as well as light water small modular reactors are also considering whether Part 50 is a more viable approach than Part 52 for a first-of-a-kind facility. During recent years, several potential applicants have informed the NRC of their intention to use the Part 50 process. Preapplication interactions have commenced and regulatory clarity is needed for prospective applicants' decision-making, and to support NRC planning and interactions. An additional consideration is that the vast majority of the technical requirements in Parts 50 and 52 were developed with a knowledge base rooted in LWR technologies and with the expectation that the impacted regulated facilities would be using LWR technologies. Even though some of the resultant technical requirements in Parts 50 and 52 may use technology-neutral language implying broad applicability, the rationale and perceived safety benefits were heavily influenced through development in an environment focused on LWRs.

Since the 2007 update to Part 52, the NRC has identified a number of items to address in a subsequent rulemaking, including corrections, clarifications, and new requirements. These items have been identified primarily as a result of Part 52 licensing reviews conducted by the NRC since 2007. This effort has also identified potentially beneficial changes to other parts of the regulations, including but not limited to Part 21 (TN5874), Part 73, "Physical Protection of Plants and Materials," (TN423), and Part 100, "Reactor Site Criteria." (TN282). The NRC finds that a rulemaking to implement these changes would provide further clarity and consistency to the Part 52 licensing processes and would benefit both potential future applicants in developing license applications and the NRC during review of those applications.

Rulemaking is necessary in several regulatory areas to (1) align Parts 50 and 52 and (2) incorporate lessons learned from new reactor licensing reviews in Parts 50 and 52.

Appendices A through K of this document describe the regulatory issues under consideration in the Parts 50 and 52 alignment and lessons learned rulemaking. These appendices contain the NRC's detailed technical basis related to alignment of application requirements such as the application of the Policy Statement on Severe Reactor Accidents to new Part 50 license applicants, PRA, TMI requirements, severe accident design features, fire protection design features, and descriptions of fire protection plans. The appendices also address areas related to lessons learned. Specifically, Appendices E through K contain the NRC's detailed technical basis related to operator licensing, security, emergency planning, the Part 52 process, environmental review, the applicability of the Part 52 process to other processes, and miscellaneous lessons learned.

Appendices A through K also describe the alternatives considered by the NRC and its recommended alternative in each area.

3.1 Regulatory Scope of a Parts 50 and 52 Alignment and Lessons Learned Rulemaking

3.1.1 Scope Development

The Commission provided the NRC staff with an initial scope for the rulemaking in SRM-SECY-15-0002 (NRC 2015-TN6217). The scope of this regulatory basis and the staff's recommendations are focused on regulatory issues related to the licensing of future LWRs, and was not developed to specifically include non-LWRs, fuel cycle facilities, research and test reactors, and other nonpower, noncommercial facilities. Notwithstanding this, any rule changes from this activity would apply to any power reactor application submitted to the NRC under Parts 50 or 52. For example, the scope of impacted entities includes applications for facilities similar to large LWRs operating today, large new LWR applications (e.g., similar to the KHNP APR-1400 and Westinghouse AP1000), small modular reactor designs (e.g., similar to the NuScale small modular reactor), and non-LWRs (e.g., high temperature gas reactors, fast reactors, and molten salt reactors).

On January 15, 2019, the NRC held a Category 3 public meeting (NRC 2019-TN6224) to gain feedback from external stakeholders on the scope of the development of this regulatory basis for this rulemaking (see Section 5.1 of this document, "Regulatory Efficiency"). The NRC offered stakeholders the opportunity to make a formal presentation during the meeting. Several of NEI's member organizations presented additional items and requested the NRC to include them in the rulemaking.

Also, in January 2019, the NRC's working group assigned to develop this regulatory basis asked the entire NRC staff to provide input on an initial list of rulemaking items. The working group requested the staff to comment on the items listed and to add items as needed.

Using the input received from staff and stakeholders, the working group aligned on the scope on July 11, 2019. On August 27, 2019, the NRC issued Information Paper SECY-19-0084 (NRC 2019-TN6210), which provided the Commission the detailed scope of the regulatory basis.

During the development of this regulatory basis, the NRC made the following changes, deletions, and additions to the description of the lessons learned items that were described in an enclosure in SECY-19-0084.

- Changes

The description or scope of the following items were changed from the scope described in the enclosure in SECY-19-0084:

- Amend paragraph 55.45(b) to permit a simulation facility at a cold plant to meet the criteria to be used for operator training and exams in order to allow its use for those purposes regardless of whether it meets the literal definition of a plant-referenced simulator and amend paragraph 55.31(a)(5) and Section 55.46 to permit a Commission-approved simulator to satisfy the licensing requirements for an operator to manipulate controls. The NRC changed the affected CFR section to paragraph 55.46(c)(2)(i). (See Appendix E, Section 2.1, "Criteria for Simulation Facilities.")
- Amend Section 55.46 to allow an alternative method to accomplish plant walkthrough test items that does not require applicants to enter the actual plant. The NRC identified that the correct regulation to be amended is paragraph 55.45(b), not Section 55.46. (See Appendix E, Section 2.2, "Plant Walkthrough.")

- Amend paragraphs 50.54(i-l), 55.53(e) and (f), and Section 55.46 to add a new requirement for holders of a CP or COL to maintain operator license applicants’ knowledge between the time of the NRC examination through establishment of the requalification program. During the development of the regulatory basis, the NRC decided to pursue a change to Section 55.31 rather than the original sections identified, because Section 55.31 addresses operator license applicants for whom the requirements would apply. Also, the NRC determined that it does not need to address proficiency with a rulemaking. (See Appendix E, Section 2.3, “Continuing Training for Operator License Applicants.”)
- Amend paragraph 55.45(b) to permit a simulation facility at a cold plant to meet the criteria to be used for operator training and exams in order to allow its use for those purposes regardless of whether it meets the literal definition of a plant-referenced simulator. The NRC changed the affected CFR section to Section 55.46. During the SECY writing process, the NRC identified a more effective way to address the issue. (See Appendix E, Section 2.0, “Regulatory Issues.”)
- Amend paragraph 55.31(a)(5) and Section 55.46 to permit a Commission-approved simulator to satisfy operator licensing manipulate controls requirements. The NRC changed the affected CFR section to paragraph 55.46(c)(2)(i). During the SECY writing process, the NRC identified a more effective way to address the issue. (See Appendix E, Section 2.0, “Regulatory Issues.”)
- Amend Section 52.59 to make the duration of MLs consistent with any changes to what is being recommended for DCs in this rulemaking. (See Appendix H.1, Section 1.0, “Design Certification Renewal and Design Certification Expiration Date.”)
- Amend Section 50.109 to clarify that its backfitting provisions do not apply to SDAs and MLs and issue finality for SDAs and MLs is provided by Sections 52.145 and 52.171, respectively. After SECY-19-0084 issuance, the NRC expanded the scope of this item to include ESPs. (See Appendix J, Section 3.0, “References to Issue Finality in 10 CFR 50.109.”)

- Deletions

The following items were deleted from the scope described in the enclosure in SECY-19-0084:

- Paragraph 100.20(a). This section requires the SSAR to identify physical characteristics that could pose a significant impediment to the development of emergency plans. The NRC considered removing the requirement from this section because the requirement is already included in Parts 50 and 52. After SECY-19-0084 issuance, the NRC decided that alternatives for this item should not be developed because the requirements of the paragraph are not redundant. (Related to Appendix G, Section 4.0, “Significant Impediments to Development of Emergency Plans”)
- Amend Section 52.147 to provide the option for the NRC to automatically rescind the standard design approval once the associated DC rule is issued. After the SECY issuance, and staff evaluation of this option, the NRC decided not to pursue or develop alternatives for this item because the NRC did not see a useful benefit from the recommended changes. (Related to Appendix H.4, “Standard Design Approval”)
- Amend paragraph 52.47(a) to clarify the section to state that as it applies to DC application information, the term “design control document” is equivalent to the FSAR. After SECY-19-0084 issuance, the NRC decided that alternatives for this item should not

be developed because there is no evidence of a burden to applicants or the NRC arising from the difference in terminology nor any benefit to be gained by making a change in paragraph 52.47(a) that would outweigh the cost of rulemaking. In addition, this issue has already been addressed to some degree in the recent update to RG 1.206, “Applications for Nuclear Power Plants” (NRC 2018-TN6192). (Related to Appendix H.5, “Content of Applications”)

- Amend paragraphs 51.75(c)(1), 51.92(b), and 51.92(e). These regulations specify what is required to be included in an environmental report at the COL stage with or without referencing an ESP. The NRC considered modifying this section to specify under what conditions the NRC shall prepare an environmental assessment in lieu of an environmental impact statement for a COL referencing an ESP. After issuance of SECY-19-0084, the NRC decided that this item would instead be addressed in a separate rulemaking activity. (Related to Appendix I, “Environmental Topics”)
 - Amend 10 CFR Part 140, “Financial Protection Requirements and Indemnity Agreements” (TN6372), to address challenges faced during COL licensing due to ambiguous language and applicability to greenfield sites and to revise the monetary amounts in the form of indemnity agreements that are out of date. After the SECY issuance, the NRC decided not to pursue or develop alternatives for this item because the NRC did not see a net benefit from the recommended changes. (Related to Appendix J, “Applicability of Other Processes to the 10 CFR Part 52 Process”)
 - Amend paragraphs 52.79(a)(4), 52.79(a)(5) and 52.79(a)(23). The NRC considered revising the application submission requirements of one or more of these paragraphs to account for multi-module small modular reactors to produce a mix of electricity and process steam. At least one potential applicant for a COL referencing a small modular reactor is contemplating such an arrangement at its facility. The NRC received a petition for rulemaking (ADAMS Accession No. ML20008D649; Algionis 2019-TN6373) on this matter that requested the NRC to revise its regulations for operating nuclear power plants to standardize the safe recovery and utilization of waste heat cogenerated from power operations. The NRC found that the petition did not satisfy the requirements of 10 CFR 2.802(c), “Content of petition” (ADAMS Accession No. ML20008D648; NRC 2020-TN6374). The NRC did not docket the petition because NRC regulations do not currently prohibit an applicant or licensee from designing and implementing waste heat recovery systems; additionally, optimizing use of waste heat is not within the NRC’s regulatory purview. (Related to Appendix K, “Miscellaneous Topics”)
 - Amend the language in paragraph 52.98(d) to clarify the reference to ML and Subpart F. After the SECY issuance, the NRC determined that this item is an administrative correction. The item was transferred to the semi-annual administrative rulemaking process for action. (Related to Appendix K, “Miscellaneous Topics”)
- Additions
- The following item was added to the scope described in the enclosure in SECY-19-0084:
- As previously described in Section 2.0 of this document, amend Section 50.71 to require that the COL licensee submit a notification to the NRC upon successful completion of power ascension testing. (See Appendix K, Section 10.0, “Reporting Requirements at Completion of Power Ascension Testing – Start of Assessment of Annual Fees.”)

3.1.2 Rulemaking Scope

Based on the technical evaluation provided in Appendices A through K of this document and consideration of public comments, the NRC concludes that there is a sufficient regulatory basis to proceed with rulemaking in certain areas to address regulatory requirements associated with the alignment of Parts 50 and 52 and lessons learned. However, the NRC staff has determined that some areas described in the enclosure in SECY-19-0084 can be addressed using other regulatory alternatives.

The NRC has established sufficient regulatory bases to continue with rulemaking and or guidance development for the following areas:

- Applying the Policy Statement on Severe Reactor Accidents to new Part 50 license applications (See Appendix A, “Applying the Severe Accident Policy Statement to New Part 50 License Applications.”)
- PRA requirements (See Appendix B, “Probabilistic Risk Assessment Requirements.”)
- TMI requirements (See Appendix C, “Three Mile Island Requirements.”)
- Description of fire protection design features and description of fire protection plans (See Appendix D, “Description of Fire Protection Design Features and Fire Protection Plans.”)
- Operator licensing (See Appendix E, “Operator Licensing.”)
- Physical security (See Appendix F, Section 1.0, “Physical Security.”)
- Fitness for duty (See Appendix F, Section 2.0, “Fitness for Duty.”)
- Emergency planning (See Appendix G, “Emergency Planning.”)
- Part 52 licensing process, with exceptions as described below (See Appendix H, “Part 52 Licensing Process.”)
- Environmental review, with exceptions as described below (See Appendix I, “Environmental Topics.”)
- Applicability of other processes to the Part 52 process (See Appendix J, “Applicability of Other Processes to the 10 CFR Part 52 Process.”)
- Miscellaneous topics, with exceptions described below (See Appendix K, “Miscellaneous Topics.”)

The NRC has determined that additional stakeholder input is needed prior to finalizing recommendations related to the item below:

- Amend the regulations to remove the 15-year duration for DCs established in Section 52.55 and DC renewal requirements in Sections 52.57, 52.59, and 52.61 and Part 52 DC appendices. (See Appendix H.1, Section 1.0, “Design Certification Renewal and Design Certification Expiration.”)

The NRC recommends that the NRC maintain the status quo for the following items:

- Paragraph 52.39(e). The NRC considered establishing a Section 50.59-like change process for ESPs and limited work authorizations (LWAs). This process would have allowed certain changes to be made without NRC approval. The NRC found that conducting rulemaking for this item would incur costs to both NRC and licensees, while the future benefit, if any, would likely involve only a small number of avoided licensing actions and would not be likely to

outweigh the costs. (See Appendix H.2, Section 5.0, “Change Process for ESP SSARS and LWA SARS.”)

- Paragraph 2.101(a)(5). The requirements of this paragraph provide the applicant an option to submit an application under the requirements of Part 50 or Part 52 in two parts. The staff considered modifying the requirements of this paragraph to permit the first part of a phased COL or CP application to consist solely of the environmental report plus the general administrative information specified in paragraphs 50.33(a) through (e). The NRC concluded that no changes to the regulations are needed. (See Appendix I, Section 1.0, “Revising the Application Requirements in 10 CFR 2.101(a)(5).”)
- Paragraph 51.75(c)(1) and conforming changes in paragraphs 51.92(b) and 51.92(e). These paragraphs specify the requirements for the content of an environmental report at the COL stage with or without referencing an ESP. The NRC considered modifying these requirements to clarify under what conditions the NRC shall prepare an environmental assessment in lieu of an environmental impact statement for a COL referencing an ESP. Upon evaluation of the item, the NRC decided to address the issue under another rulemaking.
- Section 50.55a. The current requirements in this section include a provision to require ASME BPV Code repairs to the facility be conducted in accordance with ASME Section III until the paragraph 52.103(g) finding is made. The NRC considered removing the condition from Section 50.55a that requires maintaining Section III for all systems until the paragraph 52.103(g) finding is made. The NRC was considering this change to permit transition to ASME Section XI for repair and replacement activities once all Section III activities had been completed for each individual system. The NRC decided not to make any changes in this regulation because the small number of potential COL holders that might implement this regulatory relaxation does not support the expense of rulemaking at this time. Combined license holders may continue to use the ASME BPV Code, Section XI, provisions as long as they do not conflict with the Section III requirements (essentially meeting Section III through reconciliation), or they may submit a request to apply the ASME BPV Code, Section XI, provisions prior to the paragraph 52.103(g) finding as an alternative to meeting the requirements in Section 50.55a. (See Appendix K, Section 6.0, “Generic Application of ASME BPV Code, Section XI, to Nuclear Power Plants Licensed Under 10 CFR Part 52.”)
- Paragraph VIII.C.6 of each DC appendix. The NRC recommends no change to these paragraphs in Part 52 to address changes to the TSs prior to the paragraph 52.103(g) finding. The regulations do not address changes to plant-specific TS bases. For a COL, the plant-specific TS administrative controls become effective after the Commission’s paragraph 52.103(g) finding. The NRC considered amending paragraph VIII.C.6 of each DC appendix to address this matter. The NRC decided not to recommend any changes to the regulations because the NRC believes COL holders already have an incentive to maintain the plant-specific technical specification bases consistent with changes in the design and licensing basis, and to the plant-specific technical specifications before the paragraph 52.103(g) finding, without the need for rulemaking or additional guidance.

3.2 Regulatory Objectives

The NRC is developing a proposed rule that would amend the current requirements for new nuclear power reactor license applications. During recent years, several potential applicants have informed the NRC of their intentions to use the Part 50 process. Preapplication

interactions have commenced and regulatory clarity is needed for prospective applicants' decision-making, and to support NRC planning and interactions.

By issuing an alignment of Parts 50 and 52 and lessons learned rulemaking, the NRC would be able to establish regulations that would ensure consistency in new reactor licensing reviews, regardless of which licensing process an applicant chooses to use. By addressing lessons learned from new reactor licensing reviews, the NRC would also be able to improve the clarity and effectiveness of these regulations for preparation and review of future new reactor license applications.

3.2.1 Applicability to NRC Licenses and Approvals

The NRC envisions that some or all of the final rule would apply to the following categories of license holders:

- current nuclear power reactors licensed under Part 50
- current nuclear power reactors licensed under Part 52.

The NRC envisions that some or all of the final rule would apply to the following categories of license applicants:

- applicants for future nuclear power reactors licensed under Part 50
- applicants for future nuclear power reactors licensed under Part 52.

The NRC envisions that some or all of the final rule would apply to the following applicants or approvals:

- applicants for future nuclear power reactor construction permits under Part 50
- applicants for future nuclear power reactor standard design approvals under Part 52.

3.3 NRC Guidance, Policy, and Implementation Issues

This section describes the NRC guidance that the agency would need to revise, and the relevant policy and implementation issues associated with a proposed rulemaking.

3.3.1 NRC Guidance

A proposed rulemaking would require the revision of existing guidance documents and the creation of new regulatory guidance documents to support the proposed rule. Appendices A through K of this document provide detailed information about the need to revise or create regulatory guidance in each technical area.

The NRC plans to issue new or revised draft guidance for comment with the proposed rule. Guidance may be affected in the following areas (as described in this document): severe accident policy (Appendix A), PRA requirements (Appendix B), TMI requirements (Appendix C), operator licensing (Appendix E), security and fitness for duty (Appendix F), emergency preparedness (Appendix G), Part 52 change processes (Appendix H.2), design scope and standardization (Appendix H.3), contents of applications (Appendix H.5), applicability of other processes (Appendix J), and miscellaneous lessons learned (Appendix K).

The NRC found that guidance would not be needed to implement the recommended rule changes in the following areas (as described in this document): fire protection design features

(Appendix D) and environmental review (Appendix I). Additional clarifying guidance in these areas may be developed outside of the rulemaking process.

3.3.2 Policy Issues

There are no policy issues that require resolution outside the rulemaking process in order for the NRC to proceed with this rulemaking on schedule. Appendices A through K in this document describe the policy issues associated with each area under consideration in this regulatory basis.

3.3.3 Implementation Issues

There are no implementation issues that require resolution outside the rulemaking process in order for the NRC to proceed with this rulemaking. Appendices A through K in this document describe the implementation issues in each regulatory area. The NRC staff will consider implementation issues in more detail during the development of the final rule.

4.0 ESTIMATES OF COSTS AND SAVINGS

The NRC must consider the potential savings and the potential costs of alternatives for reactor licensees and the NRC in the rulemaking process. This stage of the rulemaking process does not examine impacts in detail. The NRC will provide a more detailed evaluation of the benefits and costs in the regulatory analysis to be included in the proposed rule. This chapter summarizes the costs and benefits of the staff-recommended alternatives; for more detail, see each appendix to this regulatory basis.

This section presents the process for, and results of, evaluating the costs and benefits expected to result from each alternative relative to the regulatory baseline (Alternative 1). All costs and benefits are monetized, when possible. The total costs and benefits are then summed to determine whether the difference between the costs and benefits results in a positive benefit. In some cases, costs and benefits are not monetized because meaningful quantification is not possible. The values in tables throughout this regulatory basis document may appear to have summation errors, but this is due to rounding within the cost model.

The sign conventions used in this analysis are that all favorable consequences for the alternative are positive and all adverse consequences for the alternative are negative. Negative values are shown using parentheses (e.g., negative \$500 is displayed as (\$500)). The NRC used an analysis horizon extending from the rulemaking stages (beginning with the proposed rule in 2021) through 2030 for most items, determining that years beyond 2030 became too speculative for this regulatory basis. A few items (such as changes to DC regulations) necessitated calculations beyond 2030 due to the long time scale of the affected activities. Affected entities were selected using several different approaches, depending on the specifics of each alternative, and are explained in detail in the appendices.

This regulatory basis describes the incremental impacts of each alternative relative to a baseline that reflects anticipated behavior if the NRC does not undertake regulatory or nonregulatory action. The regulatory basis assumes full compliance with existing NRC requirements, including current regulations and relevant orders. This is consistent with NUREG/BR-0058, Revision 5, which states that “in evaluating a new requirement, the staff should assume that all existing NRC and Agreement State requirements have been implemented” (NRC 2020-TN6806).

In this regulatory basis, the staff used best available information regarding the number and type of future reactor applicants, considering factors such as: trends in new applications, known potential applications, under what part of the regulations each applicant would apply, and the types of reactors involved. The staff used a combination of those factors in determining the future licensees/applicants for each cost estimate. The NRC continues to engage with potential new and advanced reactor applicants regarding their licensing plans. In the interest of efficiency and timely issuance of this regulatory basis, the NRC chose not to expend additional resources updating the regulatory basis to reflect updates and revisions to these plans. The NRC will consider making appropriate changes to the regulatory analysis based on stakeholder comments on the regulatory basis and during the formulation of the proposed rule.

Industry labor rates were taken from the 2019 Bureau of Labor Statistics data. The 2019 NRC labor rate of \$131 per hour was used throughout this analysis. Because of the uncertainties in the labor market caused by the public health emergency and other factors in 2020, 2019 was selected as the base year for this cost estimate.

4.1 Cost Impact on Reactor Licensees

Sections of Appendices A through K in this document summarize the cost impacts of the rulemaking on new reactor applicants and reactor licensees for each technical area.

Among the NRC goals in amending these regulations is the goal to align the requirements of the 10 CFR Part 50 (TN249) licensing process with the Part 52 (TN251) licensing process. Over the years much has been learned about the need to review sufficiently detailed information early in the process in order to avoid costly actions during construction. As such, in certain areas, new or more detailed information (e.g., PRA results) will be required to be submitted as part of future Part 50 applications. The development of this information will likely cause an increase in cost for applicants.

However, several of the alternatives presented in this regulatory basis may result in a reduction in the burden on licensees; these reductions in burden (e.g., fewer licensing actions) are discussed more fully in each appendix. Alternatives associated with rulemaking might have slight costs to licensees for reviewing a proposed rule and submitting to the NRC comments on the proposed rule.

The NRC performed a preliminary draft regulatory analysis to determine the impacts of this rulemaking on the NRC and new reactor licensees and applicants. This section contains the NRC's initial evaluation of the costs and benefits associated with each regulatory alternative considered in the regulatory basis. The full extent of the impacts of this rulemaking, for both current and new reactor licensees and applicants, is not known at this time.

With the exception of rulemaking costs to the NRC, all but four of the staff's recommended alternatives in this regulatory basis are either effectively cost neutral, or cost beneficial. The item addressed in Appendix B, Section 1.0, "Use of Probabilistic Risk Assessment in Design"—extending Part 52 PRA requirements to Part 50 applicants and licensees—is not cost beneficial, as can be seen below. However, the NRC does not expect that a Part 50 applicant would submit a Part 50 application without a PRA. The qualitative benefits of using a PRA in reactor design are significant. It is also useful to have a PRA during construction.

Therefore, the technical determination that this item is not cost beneficial is not a reflection of the differential burden the staff would expect in reality, but is instead a function of comparing the new requirements to the status quo in a purely literal sense. This item was calculated on a per applicant basis because it is not known whether future applicants would choose to use Part 50 or Part 52, and therefore to speculate for more than one applicant using Part 50 might skew the analysis too far in the conservative direction. For more information, see Appendix B.

Similarly, the staff's recommended alternative in Appendix E is not cost beneficial, in part based on the recent experience with the length of time VEGP 3&4 have been under construction and would therefore conduct the newly required (by the suggested regulatory change) continuing training program. However, as explained in further detail in Appendix E, licensees are already choosing to conduct continuing training similar to the suggested new regulatory change. Therefore, the determination that the staff's recommendation in Appendix E is not cost beneficial is not a reflection of the differential burden in reality but results from comparing the suggested new requirements to current regulatory requirements. For this reason and because of several other uncertainties described in Appendix E, the NRC chose to perform the cost estimate for Appendix E on a per applicant/licensee basis, as in Appendix B.

The staff's recommended alternatives in Appendices A and C are also not cost beneficial, showing minor incremental costs to applicants that the staff considers to be justified based on the qualitative benefits of clarity, regulatory certainty, and efficiency. For further information, Appendices A and C contain a fuller discussion of the costs and benefits.

One of the cost beneficial appendix items in this regulatory basis is also calculated on a per licensee/applicant basis. The item, addressed in Appendix K, Section 5.0, "Requirements for Reporting Errors and Changes in ECCS Models," is cost beneficial and calculated on a per applicant/licensee basis, because of the uncertainties concerning which potential future applicants might be affected, and how much. Again, for additional details see Appendix K, Section 5.0, "Requirements for Reporting Errors and Changes in ECCS Models."

The NRC's recommended alternatives in this regulatory basis result in net averted costs (benefits) to industry of approximately \$12.2 million (7 percent net present value [NPV]) and \$18.8 million (3 percent NPV), as shown in Table 1. Therefore, this regulatory basis indicates the potential rulemaking would be cost beneficial to industry. All values are in fiscal year (FY) 2019 dollars.

Table 1 Industry Costs and Benefits, Staff's Recommended Alternatives

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App A, Policy Statement on Severe Reactor Accidents for Part 50, Industry	(\$202,000)	(\$130,000)	(\$166,000)
App B-1, Extend PRA Requirements to Part 50, Industry ^(a)	(\$2,360,000)	(\$1,640,000)	(\$2,101,000)
App B-2, Risk-Inform SSC Categorizations, Industry	\$0	\$0	\$0
App B-3, Maintain and Upgrade Plant-Specific PRA, Industry	\$57,000	\$30,000	\$43,000
App C, TMI Requirements, Industry	(\$236,000)	(\$139,000)	(\$187,000)
App D, Fire Protection Features, Industry	\$0	\$0	\$0
App E, Operator Licensing, Industry ^(a)	(\$2,580,000)	(\$1,650,000)	(\$2,120,000)
App F, Temporary Refueling Facility Physical Security, Industry	\$9,530,000	\$5,620,000	\$7,540,000
App F, FFD Requirements for Construction Licensees, Industry	(\$36,000)	(\$16,000)	(\$25,000)
App G, Initial Emergency Classification and Action Level Scheme, Industry	\$0	\$0	\$0
App G, Emergency Plan Change Process, Industry	\$0	\$0	\$0
App G, Emergency Preparedness Exercises, Industry	\$133,000	\$75,000	\$103,000
App G, Significant Impediments to Development of Emergency Plans, Industry	\$20,000	\$11,000	\$16,000
App G, Offsite Contacts, Arrangements, and Certifications, Industry	\$20,000	\$11,000	\$16,000
App H, DC Renewals, Industry ^(b)	\$19,200,000	\$8,580,000	\$13,600,000
App H, 50.59-Like Process, Industry	\$0	\$0	\$0
App H, Tier 1 and Tier 2 Changes, Industry	\$0	\$0	\$0
App H, FSAR Change Process, Industry	\$0	\$0	\$0

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App H, 50.59 Applicability Provisions, Industry	\$0	\$0	\$0
App H, SSAR Change Process, Industry	\$34,000	\$27,000	\$31,000
App H, Tier 1, 2, and 2 ^(a) Definitions, Industry	\$845,000	\$469,000	\$651,000
App H, Essentially Complete Design, Industry	\$86,000	\$51,000	\$68,000
App H, Standardization Restrictions on Design Changes, Industry	\$75,000	\$41,000	\$58,000
App H, Define Site Parameters and Characteristics, Industry	\$0	\$0	\$0
App H, Relocation of Requirements from DC Appendices Section IV to 52.79(d), Industry	\$0	\$0	\$0
App H, ITAAC Requirements, Industry	\$0	\$0	\$0
App H, Referencing Multiple Standard Design Approvals, Industry	\$0	\$0	\$0
App H, Modifying Requirements to Evaluate Conformance with SRPs, Industry	\$772,000	\$456,000	\$611,000
App H, Timely Completion of Construction Requirements, Industry	\$0	\$0	\$0
App H, Requirements for Referencing an ESP and a DC or DCA, Industry	\$0	\$0	\$0
App I, Removing Requirement for Environmental Information in 10 CFR 2.101(a)(5), Industry	\$0	\$0	\$0
App I, Referencing an EA from a Certified Design, Industry	\$487,000	\$287,000	\$385,000
App J, Definition of Contested Proceeding, Industry	\$0	\$0	\$0
App J, Maintenance of Records in 10 CFR 50.71(e)(3)(iii), Industry	\$169,000	\$93,000	\$130,000
App J, References to Issue Finality in 10 CFR 50.109, Industry	\$0	\$0	\$0
App K, Notice of Issuance in 10 CFR 2.106(b)(2)(ii), Industry	\$0	\$0	\$0
App K, Definitions in 10 CFR 21.3, Industry	\$0	\$0	\$0
App K, Safety Parameter Display System Console, Industry	\$58,000	\$32,000	\$45,000
App K, Technical Specifications Bases Control prior to the 10 CFR 52.103(g) Finding, Industry	\$0	\$0	\$0
App K, Requirements for Reporting Errors and Changes in ECCS Models, Industry ^(a)	\$67,000	\$41,000	\$54,000
App K, Generic Applicability of ASME BPV Code, Industry	\$0	\$0	\$0
App K, Notification of Significant Implication for Public Health and Safety or Common Defense and Security, Industry	\$0	\$0	\$0
App K, Discontinue Use of Priority Ranking Model for Generic Issues and Allow a Risk-Informed Approach, Industry	\$0	\$0	\$0
App K, ITAAC Completion at COL Issuance, Industry	\$0	\$0	\$0

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App K, Reporting Requirements at Completion of Power Ascension Testing, Industry	\$0	\$0	\$0
Total^(c)	\$26,200,000	\$12,200,000	\$18,800,000

(a) These rows represent cost estimates on a per applicant/licensee basis as described above.

(b) This row represents a cost estimate on a per DC basis as described above.

(c) Totals may not add up exactly due to rounding, all values rounded to three significant figures.

ASME = American Society of Mechanical Engineers; BPV = Boiler and Pressure Vessel; DC = design certification; DCA = design certification application; CFR = Code of Federal Regulations; EA = environmental assessment; ECCS = emergency core cooling system; ESP = early site permit; FFD = fitness for duty; FSAR = final safety analysis report; ITAAC = inspections, tests, analyses, and acceptance criteria; NPV = net present value; PRA = probabilistic risk assessment; SRP = Standard Review Plan; SSAR = site safety analysis report; SSC = structure, system, and component; TMI = Three Mile Island.

The cost estimates for several appendices showed high costs or benefits to industry, shown in the table above. Specifically:

- The cost estimate for Appendix F, “Physical Security and Fitness for Duty Requirements,” shows very high averted costs to applicants and licensees. The recommendation would enable applicants to store unirradiated nuclear fuel anywhere onsite in accordance with Section 73.67.
- The cost estimate for Appendix H.1, “Design Certification Renewal,” results in very high averted costs to applicants/licensees. The recommendation would eliminate the expiration date for future DCs, obviating the need to submit future DC renewal applications.
- The cost estimate for Appendix H.3, Section 3.0, “10 CFR 52.63 Modifying Restrictions on Changes to a DC or COL Referencing a DC for Reasons of Standardization,” related to Tier 1, 2, and 2* definitions, shows high averted costs to applicants and licensees. The alternative would clarify the scope of information required to be classified as Tier 1.
- The cost estimate for Appendix H.5, Section 1.0, “Modifying Requirements to Evaluate Conformance with the Standard Review Plan,” results in significant averted costs to applicants and licensees. The recommendation would eliminate the requirement for an applicant to develop and submit a detailed analysis of how the application meets each SRP review criterion.
- The cost estimate for Appendix I, Section 2.0, “Change to Clarify 10 CFR 51.50(a) that an Applicant for a Construction Permit Can Reference an Environmental Assessment from a Certified Design,” shows considerable averted costs to applicants due to not having to perform an additional severe accident mitigation design alternatives (SAMDA) analysis, as described in Appendix I.
- The cost estimate for Appendix A, “Applying the Severe Accident Policy Statement to New Part 50 License Applications,” results in incremental costs for a future Part 50 applicant to address design issues prior to the application process, as described in Appendix A.
- The cost estimate for Appendix B, Section 1.0, “Use of Probabilistic Risk Assessment in Design,” related to extending Part 52 PRA requirements to Part 50 applicants/licensees, shows a high cost for a future Part 50 applicant to develop and submit the results of a PRA, as described above and in Appendix B, “Probabilistic Risk Assessment Requirements.”
- The cost estimate for Appendix C, “Three Mile Island Requirements,” results in incremental costs for a future Part 50 applicant to address the additional requirements in

paragraph 50.34(f) that are not already required in other parts of NRC regulations, as described in Appendix C.

- The cost estimate for Appendix E, “Operator Licensing,” results in high costs to applicants/licensees to meet a new requirement for facility licensees at cold plants to maintain the knowledge, skills, and abilities of operator license applicants who have successfully completed the NRC initial licensing examination as described above and in Appendix E.

4.2 Cost Impact on the NRC

Overall, this rulemaking would result in a significant one-time cost to the NRC followed by ongoing savings, as described below:

- Initially, the NRC would incur incremental costs to undertake the rulemaking process. These costs include the preparation of the regulatory basis, the proposed and final rules, and accompanying guidance. The costs would include staff and contractor time to prepare proposed rule language, draft guidance, supporting analyses (e.g., a regulatory analysis and Office of Management and Budget [OMB] Paperwork Reduction Act of 1995 [44 U.S.C. 3501 *et seq.*; TN6376] burden analysis), and a *Federal Register* notice (FRN) and to conduct public outreach efforts during rule and guidance development. After publishing the proposed rule, the NRC would incur costs associated with resolving public comments and preparing the final rule, guidance, and supporting documentation for the rulemaking.
- By changing the current regulatory framework (e.g., the submission of the results of a PRA in a Part 50 application) to align the relevant regulations with the commensurate safety benefits, the NRC would save resources over time. That new regulatory framework would provide important design insights to the NRC staff earlier in the licensing process, thereby reducing the number of requests for additional information during the review. The revised framework would obviate the need for some exemptions and LARs, thereby reducing both the number and complexity of new reactor licensing action requests. These changes would result in a more efficient process and save the staff time and resources.

Taking rulemaking costs into account, the staff’s recommended alternatives in this regulatory basis would result in averted costs to the NRC of approximately \$5.8 million (7 percent NPV) and \$10.8 million (3 percent NPV), as shown in Table 2. Therefore, taken as a whole, the staff’s recommended alternatives would be cost beneficial to the NRC. All values are in FY 2019 dollars.

Table 2 NRC Costs and Benefits, Staff’s Recommended Alternatives

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App A, Policy Statement on Severe Reactor Accidents for Part 50, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App B-1, Extend PRA Requirements to Part 50, NRC ^(a)	(\$135,000)	(\$106,000)	(\$121,000)
App B-2, Risk-Inform SSC Categorizations, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App B-3, Maintain and Upgrade Plant-Specific PRA, NRC	(\$109,000)	(\$92,000)	(\$101,000)
App C, TMI Requirements, NRC	(\$227,000)	(\$160,000)	(\$194,000)
App D, Fire Protection Features, NRC	(\$82,000)	(\$65,000)	(\$74,000)

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App E, Operator Licensing, NRC ^(a)	(\$271,000)	(\$211,000)	(\$243,000)
App F, Temporary Refueling Facility Physical Security, NRC	(\$315,000)	(\$256,000)	(\$289,000)
App F, FFD Requirements for Construction Licensees, NRC	(\$71,000)	(\$68,000)	(\$71,000)
App G, Initial Emergency Classification and Action Level Scheme, NRC	(\$53,000)	(\$45,000)	(\$50,000)
App G, Emergency Plan Change Process, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App G, Emergency Preparedness Exercises, NRC	(\$209,000)	(\$176,000)	(\$194,000)
App G, Significant Impediments to Development of Emergency Plans, NRC	(\$126,000)	(\$100,000)	(\$114,000)
App G, Offsite Contacts, Arrangements, and Certifications, NRC	(\$126,000)	(\$100,000)	(\$114,000)
App H, DC Renewals, NRC ^(b)	\$20,600,000	\$9,020,000	\$14,400,000
App H, 50.59-Like Process, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App H, Tier 1 and Tier 2 Changes, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App H, FSAR Change Process, NRC	(\$271,000)	(\$211,000)	(\$243,000)
App H, 50.59 Applicability Provisions, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App H, SSAR Change Process, NRC	(\$234,000)	(\$187,000)	(\$212,000)
App H, Tier 1, 2, and 2* Definitions, NRC	\$277,000	\$123,000	\$196,000
App H, Essentially Complete Design, NRC	(\$32,000)	(\$35,000)	(\$35,000)
App H, Standardization Restrictions on Design Changes, NRC	(\$45,000)	(\$45,000)	(\$46,000)
App H, Define Site Parameters and Characteristics, NRC	(\$82,000)	(\$65,000)	(\$74,000)
App H, Relocation of Requirements from DC Appendices Section IV to 52.79(d), NRC	(\$189,000)	(\$147,000)	(\$169,000)
App H, ITAAC Requirements, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App H, Referencing Multiple Standard Design Approvals, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App H, Modifying Requirements to Evaluate Conformance with SRPs, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App H, Timely Completion of Construction Requirements, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App H, Requirements for Referencing and ESP and a DC or DCA, NRC	(\$5,000)	(\$4,000)	(\$5,000)
App I, Removing Requirement for Environmental Information in 10 CFR 2.101(a)(5), NRC	\$0	\$0	\$0
App I, Referencing an EA from a Certified Design, NRC	\$1,000	(\$18,000)	(\$10,000)
App J, Definition of Contested Proceeding, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App J, Maintenance of Records in 10 CFR 50.71(e)(3)(iii), NRC	(\$41,000)	(\$32,000)	(\$37,000)
App J, References to Issue Finality in 10 CFR 50.109, NRC	(\$135,000)	(\$106,000)	(\$121,000)
App K, Notice of Issuance in 10 CFR 2.106(b)(2)(ii), NRC	(\$41,000)	(\$32,000)	(\$37,000)
App K, Definitions in 10 CFR 21.3, NRC	(\$82,000)	(\$65,000)	(\$74,000)

Activity	Quantitative Benefit (Cost)		
	Undiscounted	7% NPV	3% NPV
App K, Safety Parameter Display System Console, NRC	(\$13,000)	(\$17,000)	(\$15,000)
App K, Technical Specifications Bases Control prior to the 10 CFR 52.103(g) Finding, NRC	\$0	\$0	\$0
App K, Requirements for Reporting Errors and Changes in ECCS Models, NRC ^(a)	(\$49,000)	(\$45,000)	(\$47,000)
App K, Generic Applicability of ASME BPV Code, NRC	\$0	\$0	\$0
App K, Notification of Significant Implication for Public Health and Safety or Common Defense and Security, NRC	(\$82,000)	(\$65,000)	(\$74,000)
App K, Discontinue Use of Priority Ranking Model for Generic Issues and Allow a Risk-Informed Approach, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App K, ITAAC Completion at COL Issuance, NRC	(\$41,000)	(\$32,000)	(\$37,000)
App K, Reporting Requirements at Completion of Power Ascension Testing, NRC	(\$41,000)	(\$32,000)	(\$37,000)
Total^(c)	\$16,700,000	\$5,800,000	\$10,800,000

(a) These rows represent cost estimates on a per applicant/licensee basis as described above.

(b) This row represents a cost estimate on a per DC basis as described above.

(c) Totals may not add up exactly due to rounding, all values rounded to three significant figures.

ASME = American Society of Mechanical Engineers; BPV = Boiler and Pressure Vessel; DC = design certification; DCA = design certification application; CFR = Code of Federal Regulations; EA = environmental assessment; ECCS = emergency core cooling system; ESP = early site permit; FFD = fitness for duty; FSAR = final safety analysis report; ITAAC = inspections, tests, analyses, and acceptance criteria; NPV = net present value; NRC = U.S. Nuclear Regulatory Commission; PRA = probabilistic risk assessment; SRP = Standard Review Plan; SSAR = site safety analysis report; SSC = structure, system, and component; TMI = Three Mile Island.

- The cost estimate for Appendix H.1, related to DC renewals, results in very high averted costs to the NRC. The recommendation would eliminate the need for the NRC to review future DC renewal applications. The total averted cost to the NRC would increase with each affected DC where renewal would have been required.
- The cost estimate for Appendix H, Section 1.0, related to Tier 1, 2, and 2* definitions, shows significant averted costs to the NRC. The recommendation would clarify the scope of Tier 1 information, reducing the need for NRC staff to interact with applicants to communicate expectations.
- The cost estimate for Appendix I, Section 1.0, related to removing requirement for environmental information, results in notable averted costs to the NRC. The recommendation would eliminate the need for the NRC to evaluate information that is not required if an environmental report is submitted.
- The cost estimate for Appendix E, related to operator licensing, shows notable costs as described above and in Appendix E. The recommendation would require the NRC to review new information provided on the license applications addressing continuing training requirements for operator license applicants.

4.3 Cost Justification

As shown above, the staff's recommended alternatives would result in net averted costs to industry and the NRC of approximately \$18.0 million (7 percent NPV) and \$29.7 million (3 percent NPV), making the overall potential rulemaking cost beneficial.

4.4 Uncertainty Analysis

Because this regulatory analysis is based on estimates of values that are sensitive to plant-specific cost drivers and plant dissimilarities, the NRC provides the following analysis of the variables that have the greatest amount of uncertainty. To perform this analysis, the NRC used a Monte Carlo simulation analysis using the @Risk software program.²

Monte Carlo simulations involve introducing uncertainty into the analysis by replacing the point estimates of the variables used to estimate base case costs and benefits with probability distributions. By defining input variables as probability distributions instead of point estimates, the influence of uncertainty on the results of the analysis (i.e., the net benefits) can be effectively modeled.

The probability distributions chosen to represent the different variables in the analysis were bounded by the range-referenced input and the NRC's professional judgment. When defining the probability distributions for use in a Monte Carlo simulation, summary statistics are needed to characterize the distributions. These summary statistics include (1) the minimum, most likely, and maximum values of a program evaluation and review technique (PERT) distribution;³ (2) the minimum and maximum values of a uniform distribution; and (3) the specified integer values of a discrete population. The NRC used the PERT distribution to reflect the relative spread and skewness of the distribution defined by the three estimates.

The NRC performed the Monte Carlo simulation by repeatedly recalculating the results 10,000 times. For each iteration, the cost model chose the values in the cost model randomly from the probability distributions that define the input variables. The model recorded the values of the output variables for each iteration and used these resulting output variable values to define the resultant probability distribution, in terms of costs and benefits.

Figure 1, Figure 2, and Figure 3 display the histograms of the net incremental costs and benefits from the regulatory baseline (Alternative 1 of each appendix item) of the staff's recommended alternatives.

² Information about the @Risk software is available at <http://www.palisade.com>.

³ A PERT distribution is a special form of the beta distribution with specified minimum and maximum values. The shape parameter is calculated from the defined "most likely" value. The PERT distribution is similar to a triangular distribution in that it has the same set of three parameters. Technically, it is a special case of a scaled beta (or beta general) distribution. The PERT distribution is generally considered superior to the triangular distribution when the parameters result in a skewed distribution because the smooth shape of the curve places less emphasis in the direction of skew. Similar to the triangular distribution, the PERT distribution is bounded on both sides and, therefore, may not be adequate for some modeling purposes if the capture of tail or extreme events is desired.

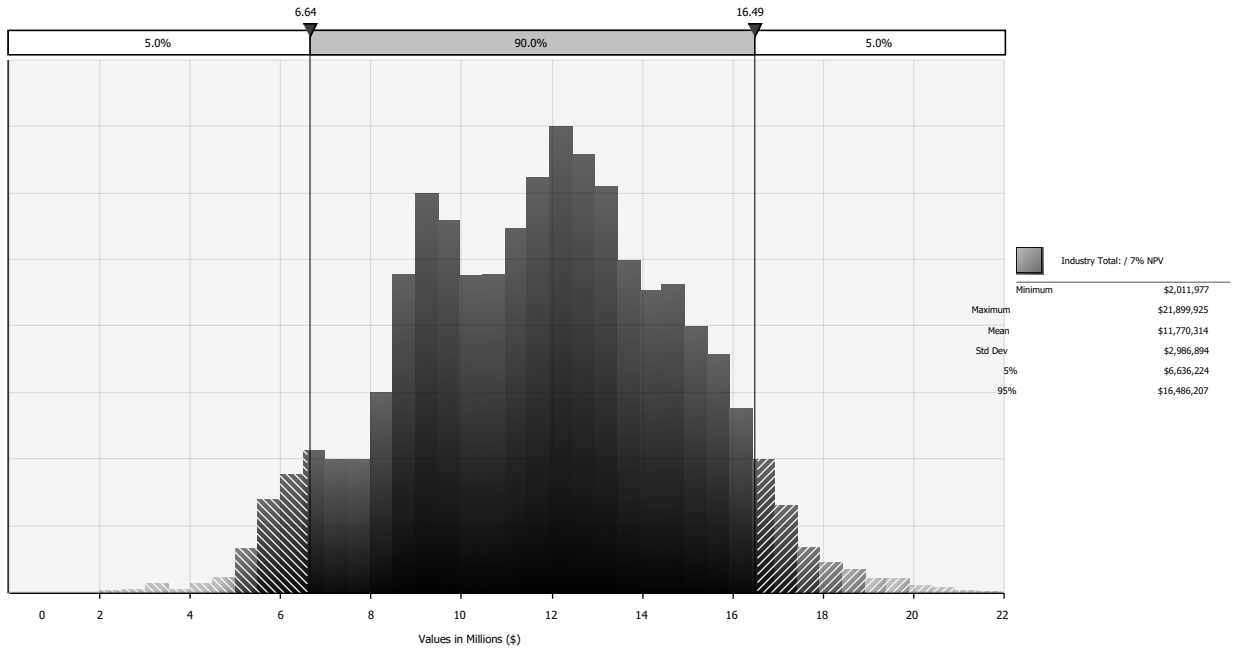


Figure 1 Industry Totals, 7% NPV

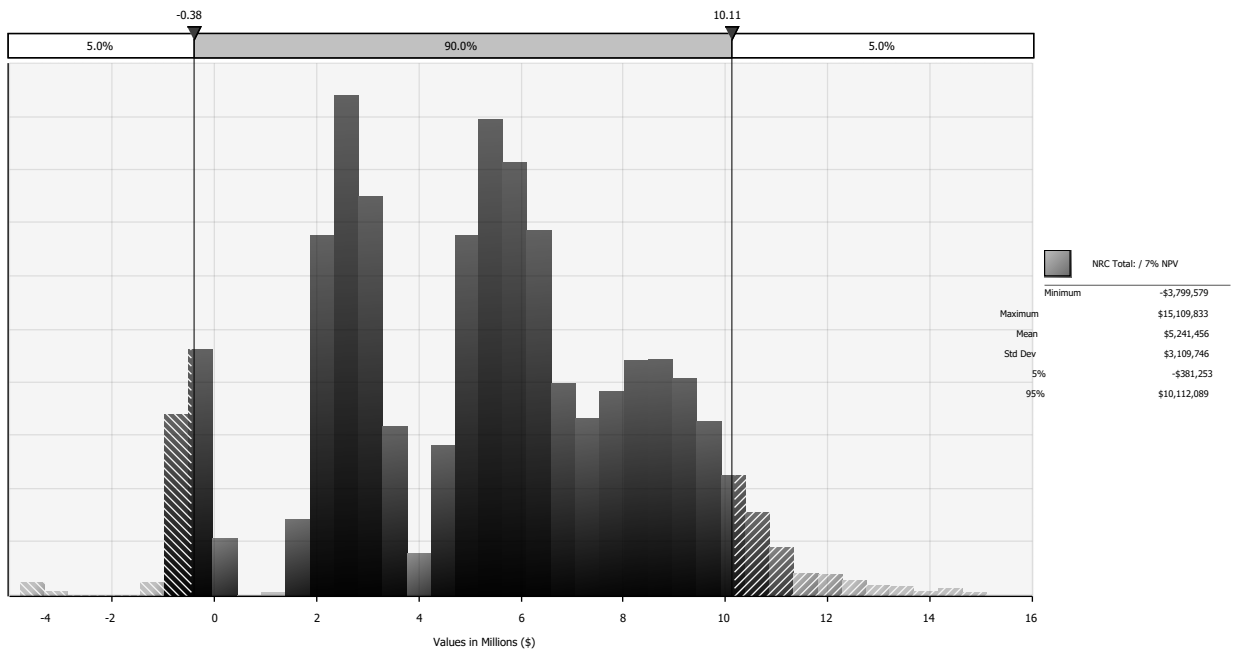


Figure 2 NRC Totals, 7% NPV

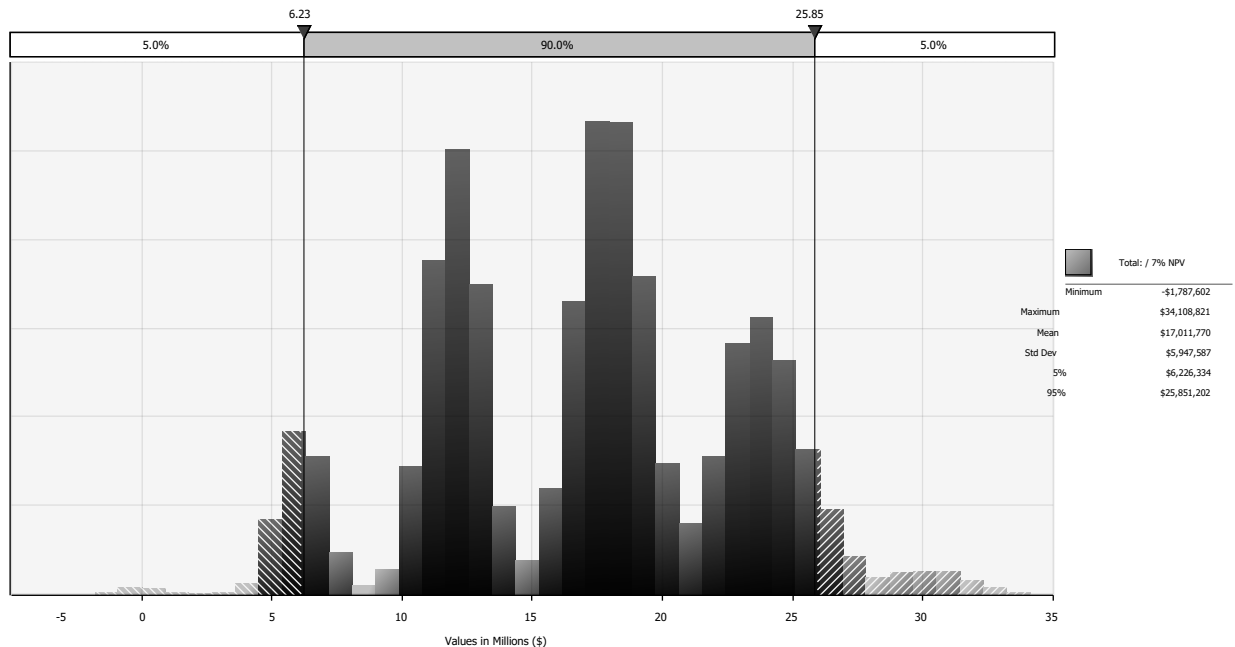


Figure 3 Combined Totals, 7% NPV

As shown in Figure 1, the staff's recommended alternatives would result in averted costs to industry of approximately \$12.2 million, using a 7 percent NPV. The uncertainty analysis indicates that there is a greater than 99 percent chance that these alternatives would result in averted costs to industry. As shown in Figure 2, the staff's recommended alternatives would result in averted costs to the NRC of approximately \$5.75 million, including rulemaking costs. There is approximately a 92 percent chance the alternatives would be cost beneficial to the NRC. As shown in Figure 3, the staff's recommended alternatives would result in net averted costs of approximately \$18.0 million, and greater than a 99 percent chance the alternatives would result in net averted costs.

4.5 Nonquantified Benefits

In addition to the quantified costs discussed in the regulatory analysis, the attributes of regulatory efficiency and public confidence would produce nonquantified benefits for the industry and the NRC as summarized in the next chapter.

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5.0 OTHER IMPACTS AND REGULATORY CONSIDERATIONS

Other impacts and issues related to using rulemaking to align 10 CFR Parts 50 (TN249) and 52 (TN251) and address lessons learned from new reactor license reviews include improvement of regulatory efficiency, achieving increased public confidence, complying with the National Environmental Policy Act (42 U.S.C. § 4321 *et seq.*; TN661) and the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*; TN6377), addressing backfitting and issue finality provisions, conducting peer review of the regulatory basis, and determining the impacts on public health and safety as well as on State, local, and Federally recognized Indian Tribal governments, as described in the following sections.

5.1 Regulatory Efficiency

The NRC is pursuing rulemaking to update new reactor regulations. The regulations would accomplish the following:

1. Improve alignment between the reactor licensing processes in Parts 50 and 52, including implementation of the policy decisions described in Appendices A through D of this document. These recommended changes would help ensure consistent safety standards are applied, regardless of the process used to license a new reactor. This alignment would result in a licensing process that has enhanced regulatory stability, predictability, and clarity.
2. Update Part 52 and supporting regulations, including Part 50, to address lessons learned from recent new reactor license reviews. These recommended enhancements are described in Appendices E through K of this document.

Addressing these recommended changes as part of a single rulemaking effort would be more efficient than addressing them in separate and independent rulemakings and would help ensure continuity and consistency between new reactor licensing regulations as the changes are made. A single rulemaking effort also would make it easier for stakeholders to understand all the changes and provide meaningful input.

The revised regulations would result in a licensing process that has enhanced regulatory stability, predictability, and clarity. The revised regulations would result in a reduction in the need for the development and review of case-by-case exemption requests and requests for additional information (RAIs) for new reactor license applicants.

Reliance on the exemption and RAI processes to address shortcomings in licensing actions is not ideal because these processes require more resources to address license application issues on a case-by-case basis. These processes do not provide the same degree of certainty or finality of agency decisions as would rulemaking. In addition, the NRC attempts to avoid regulation by exemption when it can address an issue through generic actions such as rulemaking. The estimated benefits of the recommended rulemaking action include (1) fewer exemption requests than under current regulations; (2) fewer RAIs to address shortcomings, inconsistencies, and gaps in the current regulations; (3) consistent regulatory applicability across the Parts 50 and 52 processes; (4) efficiencies gained from lessons learned during license application reviews; and (5) the use of a more risk-informed performance-based licensing framework for the Part 50 process.

5.2 Increased Public Confidence

In addition to enhancing regulatory efficiency, using rulemaking to align Parts 50 and 52 and addressing lessons learned from new reactor license reviews would increase public confidence in the NRC's ability to improve its regulations, adapt to regulatory needs identified by stakeholders, provide opportunities for stakeholder to provide input to the changes to the new reactor licensing process, and maintain the NRC's role as an effective industry regulator. In addition, the rulemaking process includes the greatest opportunity for Commission and public engagement on the issues related to the new reactor licensing process. Public notice and comment during rulemaking would provide the widest range of viewpoints for Commission consideration during the rule's development.

5.3 Compliance with the National Environmental Policy Act

When Part 52 was issued in 1989, the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(3). As stated in the FRN for the Part 52 final rule (54 FR 15372, April 18, 1989; TN6256), the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in paragraph 51.22(c)(3). Similarly, when Part 52 was updated in 2007, as stated in the FRN for that final rule (72 FR 49352, August 28, 2007; TN4796), the NRC determined that the regulation met the eligibility criteria for the categorical exclusion set forth in paragraphs 51.22(c)(1), (c)(2), and (c)(3). Similarly, this regulatory basis contemplates changes to the NRC's new reactor licensing regulatory framework. The NRC has determined that these amendments also fall within the types of actions described as categorical exclusions in paragraphs 51.22(c)(1), (c)(2), and (c)(3). Therefore, neither an environmental impact statement nor an environmental assessment would be required. If the NRC decides to pursue rulemaking that would authorize activities not considered in the 2007 final rule, the NRC will evaluate the environmental impacts of any newly authorized activities. The agency will make any document prepared to comply with the National Environmental Policy Act available for public comment with the proposed rule.

5.4 Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), enacted in September 1980, requires agencies to consider the impact of their regulatory proposals on small entities, analyze alternatives that minimize small entity impacts, and make their analyses available for public comment.

None of the licensees or CP holders fall within the definition of "small entities" set forth by the NRC in 10 CFR 2.810, "NRC size standards." Therefore, a proposed rulemaking would not have a significant economic impact on a substantial number of small entities.

5.5 Backfitting and Issue Finality

For the most part, the new provisions in the recommended rule would be requirements for future new reactor license applicants, voluntary alternatives for current new reactor applicants and licensees, clarifications, or non-mandatory relaxations to current requirements. Although some changes could affect licensees currently constructing a nuclear power plant, the NRC does not expect these licensees to be constructing nuclear power plants at the time this rulemaking's final rule goes into effect. Therefore, the recommended rule would not constitute backfitting under Part 50 for current licensees, or affect the issue finality of any approval issued under Part 52. If an entity is constructing a nuclear power plant when the proposed rule is issued or

final rule goes into effect, then the NRC will address the backfitting implications of the applicable regulatory change in the proposed or final rule, as applicable.

5.6 Peer Review of Regulatory Basis

The Office of Management and Budget's *Final Information Quality Bulletin for Peer Review* (TN6378) requires each Federal agency to subject "influential scientific information" to peer review prior to dissemination. The Office defines "influential scientific information" as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." The regulatory basis does not contain "influential scientific information." Therefore, a peer review of the regulatory basis is not needed.

5.7 Impact on Public Health and Safety

The need for a Parts 50 and 52 alignment and lessons learned rulemaking is not based on safety or security concerns. Regulatory changes in these areas are aimed at making the new reactor licensing process more efficient, predictable, or clear. Thus, a Parts 50 and 52 alignment and lessons learned rulemaking would have no impacts on public health and safety or the common defense and security.

5.8 Impact on State, Local, and Federally Recognized Indian Tribal Governments

Portions of the recommended rulemaking would be applicable to current licensees and applicants. This rulemaking may affect State, local, or Tribal nations; however, alternatives associated with this rulemaking do not include impacts that would affect these stakeholders more than the general public. Alternatives associated with rulemaking might involve slight costs to these stakeholders for reviewing a proposed rule and submitting to the NRC comments on the proposed rule. The NRC plans to continue to employ a broad and diverse outreach strategy on this rulemaking. This strategy includes opportunities for the public, States, and the Tribal nations to participate and have their voice(s) heard by the NRC, including conducting a public meeting during the public comment period for the regulatory basis and again for the proposed rulemaking.

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6.0 STAKEHOLDER INVOLVEMENT

To obtain feedback from external stakeholders about the scope of the development of the regulatory basis for this rulemaking, the NRC held a Category 3 public meeting on January 15, 2019. In addition to the use of the agency's public meeting notification system and use of social media, 3 nongovernmental organizations, 5 industry organizations, and 18 representatives from industry were contacted to notify them of the meeting. The NRC also reached out to all Agreement States, all non-Agreement States, all State Liaison Officers and all Federally recognized Tribal nations. The NRC offered the opportunity for stakeholders to make formal presentations during the meeting. The NRC detailed the results of this public meeting in a meeting summary (NRC 2019-TN6224). The meeting summary can be found in ADAMS under Accession No. ML19023A046.

Several public meetings were held after the NRC issued SECY-19-0084 (NRC 2019-TN6210) and commenced development of this regulatory basis.

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). The NRC staff briefed the ACRS members on the NRC scoping activities and the items chosen for inclusion in the scope of the regulatory basis. The staff received the member's observations on the implementation of 10 CFR Part 52 (TN251) process, based on their individual perspectives from their participation in past reviews of ESP, DC, and COL applications. The staff received views and comments from the ACRS staff as individual members. No ACRS letter was issued on the topic. The slides and transcript for that meeting are available in ADAMS under Accession No. ML19294A009 (NRC 2019-TN6225).

On November 21, 2019, the NRC held a Category 3 public meeting to discuss the status of the rulemaking. The NRC briefed the public on its scoping activities and the items chosen for inclusion in the scope of the regulatory basis. The NRC desired feedback from the public on the scope of the rulemaking as described in SECY-19-0084. In that meeting, NEI and other industry representatives asked questions and provided comments about the scope of the rule. The NRC detailed the results of this public meeting in a meeting summary (NRC 2019-TN6223). The summary can be found in ADAMS under Accession No. ML19344C768.

On April 29, 2020, the NRC held a public meeting via teleconference to provide an update on the staff's efforts since the November public meeting. The NRC received comments and questions from the public about the rulemaking scope and schedule. The NRC detailed the results of this public meeting in a meeting summary (NRC 2020-TN6342). The summary can be found in ADAMS under Accession No. ML20141L609.

6.1 NRC Observations on Stakeholder Feedback

At the January 15, 2019, Category 3 public meeting, NEI led an industry panel discussion of 18 suggested changes for consideration (NRC 2019-TN6228). In addition, NEI submitted a list of 20 additional suggested changes for consideration (NEI 2019-TN6265) that were not discussed during the meeting but were included in the meeting summary. The NRC reviewed the stakeholder feedback to inform the development of this regulatory basis and the preliminary draft regulatory analysis. The NRC received stakeholder feedback in several of the technical areas included in the scope of the regulatory basis.

Appendices A through K in this document include observations on stakeholder feedback specific to each regulatory area.

6.1.1 General Observations on Stakeholder Feedback

The NRC received feedback from stakeholders, as described in the following section. There was no feedback from private citizens, nongovernmental organizations, or State and local governments.

6.1.2 Licensees and Industry Representatives

Licensees and industry representatives gave the following feedback on the rulemaking process and schedule:

- The rulemaking should be accelerated as much as possible to enable future applicants to incorporate the regulatory changes in their applications. There is little time between the planned issuance of the final rule and the creation of the technology-inclusive regulatory framework.
- The NRC should hold more frequent meetings with industry during the development of the regulatory basis, on specific topics of interest, in order to ensure the public's views are properly considered in the rule.
- The NRC should ensure that all LARs related to new reactor construction are reviewed for potential regulatory changes that would preclude the need for the request.
- The NRC should conduct a line-by-line comparison of the two regulations to ensure that all gaps are identified and addressed.
- The rulemaking scope should be divided into two or more rulemakings as a means of expediting development of the rule. There were various conflicting opinions from the public on this item.

Licensees and industry gave the following feedback on specific items. These comments are addressed in this document in the appendices indicated.

- The rulemaking should establish a more reasonable timeframe for meeting the requirement to update the site-specific PRA prior to fuel loading. The rulemaking should also establish more reasonable timeframes and frequencies for the periodic upgrade of the PRA to reflect endorsed consensus standards. (See Appendix B, "Probabilistic Risk Assessment Requirements.")
- The rulemaking should clarify the paragraph 55.46(c)(1) definitions and use of Commission-approved simulators and plant-referenced simulators. (See Appendix E, "Operator Licensing.")
- The rulemaking should include regulatory or guidance changes that modify Section 26.4 to allow escorted access during construction similar to operational plant requirements in paragraph 73.55(g)(7), to permit visitors to perform safety- or security-related work. (See Appendix F, "Physical Security and Fitness for Duty Requirements.")
- The rulemaking should improve various aspects of the DC renewal process, including allowing DC renewals to be submitted following a facility's construction and initial operation, removing the 15-year DC duration and the 2-year DC application window, and clarifying the language of Section 52.57 regarding what it means to "bring up to date" the information and data contained in the previous application. (See Appendix H.1, "Design Certification Renewal.")

- The rulemaking should modify requirements to make it easier for Part 52 licensees to make changes during construction. (See Appendix H.2, “Change Process.”)
- The rulemaking should provide a more flexible change process for Tier 1 changes that do not decrease the level of safety. (See Appendix H.2, “Change Process.”)
- The rulemaking should enable the use of the Section 50.59 process for Part 52 regulatory changes. (See Appendix H.2, “Change Process.”)
- The rulemaking should include regulatory or guidance changes that eliminate the need to maintain both Tier 1 information and the duplicate Tier 1 information contained in Appendix C of each COL. (See Appendix H.2, “Change Process.”)
- The rulemaking should establish a Section 50.59-like change process for ESP and LWAs. (See Appendix I, “Environmental Topics.”)
- The rulemaking should include regulatory or guidance changes that revise paragraph 2.101(a)(5) to permit a phased COL application consisting of the environmental report plus general administrative information. The rulemaking should also consider the option to eliminate the detailed radiological evaluation from the environmental report. (See Appendix I, “Environmental Topics.”)
- The rulemaking should clarify the process for licensees to make changes to the TS Bases document prior to the paragraph 52.103(g) finding. (See Appendix K, “Miscellaneous Topics.”)
- The rulemaking should change the annual fee provision to begin at the completion of power ascension testing rather than at the time that the paragraph 52.103(g) finding is made. (See Appendix K, “Miscellaneous Topics.”)

Licensees and industry gave the following feedback on several specific items that were not included in the scope of the regulatory basis:

- The rulemaking should propose regulatory or guidance changes that create a process that avoids delays in the issuance of COLs due to errors noted in the referenced DC or referenced COL.

This item was proposed several different times by NEI during the development of the regulatory basis. At the April 29, 2020, Category 3 public meeting, the NRC indicated that because the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2011 *et seq.*; TN663) requires that the NRC resolve all open safety issues prior to issuance of a license, the NRC did not see any regulatory changes that would solve this concern. The NRC staff also summarized its position on this issue in a September 8, 2020 letter to NEI (NRC 2020-TN6387).

- The rulemaking should eliminate the NRC’s requirement for a DC applicant to submit a complete application prior to docketing.
- The rulemaking should include regulatory or guidance changes that allow the use of preliminary design information as the basis of an SDA.
- The rulemaking should include regulatory or guidance changes that change the Section 20.1406 requirement that applicants identify the methods to be used to limit radioactivity contamination of the environment at the time of the application. Industry representatives proposed that the regulations be changed to allow for the development of such methods before the paragraph 52.103(g) determination. The NRC considered this

issue during the scoping process and determined that this item does not belong within the scope of the rule. The reason the item was screened out is because the NRC found that the item would be best addressed through the development of guidance outside of rulemaking.

The next opportunity for the public to provide feedback on this rulemaking would be when this regulatory basis is published.

6.2 Planned Interactions with the Advisory Committee on Reactor Safeguards

As discussed previously, on September 20, 2019, the staff met with members of the Subcommittee on Regulatory Policies and Practices of the ACRS, who provided input as individual members.

The NRC staff will provide the regulatory basis to the ACRS at the time of publication. The staff will brief the ACRS on the regulatory basis if requested and will follow normal rulemaking processes for ACRS engagement during the Parts 50 and 52 alignment and lessons learned rulemaking process.

6.3 Cumulative Effects of Regulation

The NRC has implemented a program to address the possible cumulative effects of regulation in the development of regulatory bases for rulemakings. The concept of cumulative effects of regulation is an organizational effectiveness challenge that results from a licensee or other affected entity implementing several complex positions, programs, or requirements within a prescribed implementation period and with limited available resources, including the ability to access technical expertise to address a specific issue. The NRC requests feedback from the public at this regulatory basis stage on the cumulative effects that may result from the recommended rulemaking. The NRC will consider the comments received as it develops the proposed rule. The NRC will continue to engage with and request feedback from the public at the proposed rule stage on the cumulative effects that may result from the alignment of licensing requirements of Parts 50 and 52 and the incorporation of lessons learned from new reactor licensing reviews.

6.4 Questions for Public Comment

The NRC welcomes comments on any aspect of this regulatory basis but is particularly interested in obtaining additional information related to the five questions provided in the related FRN.

7.0 SAFETY GOAL EVALUATION

Safety goal evaluations are applicable to regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard in paragraph 50.109(a)(3).

This regulatory basis does not contain any new regulatory impositions of this type. Rather, it supports a rulemaking that would establish regulations that would ensure consistency in new reactor licensing reviews, regardless of the licensing process an applicant chooses to use. By addressing lessons learned from new reactor licensing reviews, the NRC would also be able to improve the clarity and effectiveness of these regulations for review of future new reactor license applications.

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8.0 NRC STRATEGIC PLAN

The recommended rulemaking would support the NRC's Strategic Plan for FYs 2018–2022 in relation to the safety strategic goal of assuring the safe use of radioactive materials and the security strategic goal of assuring the secure use of radioactive materials. It would contribute to attaining the NRC Strategic Plan's strategies to maintain and further risk-inform the regulatory framework for safety and security. It would support an NRC licensing initiative with a future regulatory benefit, considering Commission and Congressional interest in reactor licensing. Finally, the public has substantial interest in this topic.

The NRC's strategic goals are as follows:

- Safety: Ensure the safe use of radioactive materials.
- Security: Ensure the secure use of radioactive materials.

The actions recommended in this regulatory basis primarily support the NRC's Strategic Plan in the following areas:

- Safety Strategy 1, which is to maintain and enhance the NRC's regulatory programs, using information gained from domestic and international operating experience, lessons learned, and advances in science and technology
- Safety Strategy 2, which is to further risk-inform the current regulatory framework in response to advances in science and technology, policy decisions, and other factors, including prioritizing efforts to focus on the most safety-significant issues
- Security Strategy 1, which is to maintain and further risk-inform the current regulatory framework for security using information gained from operating experience, lessons learned, external and internal assessments, technology advances, and changes in the threat environment.

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9.0 CONCLUSION

The NRC finds that there is sufficient regulatory basis to proceed with rulemaking. Specifically, the NRC has extensive experience with new reactor licensing, and recent experience has shown that changes to existing requirements are necessary for efficiency, clarity, and openness during the new reactor licensing process. The 10 CFR Parts 50 (TN249) and 52 (TN251) alignment and lessons learned rulemaking may codify certain exemptions from regulatory requirements associated with operator licensing, security, emergency preparedness, environmental reviews, and other aspects of the Part 50 and 52 licensing process. Alignment of Parts 50 and 52, in the areas of severe accident policy, PRA, TMI requirements, and fire protection design features, would ensure consistency in new reactor licensing reviews, regardless of the licensing process an applicant chooses to use. By addressing lessons learned, from new reactor licensing reviews, the NRC would also be able to improve the clarity and effectiveness of these regulations for review of future new reactor license applications.

In summary, this rulemaking would ensure consistency in new reactor licensing reviews; provide for an efficient new reactor licensing process; reduce the need for exemptions from existing regulations and LARs; address lessons learned from new reactor licensing reviews deemed relevant by the NRC staff; and support the principles of good regulation, including openness, clarity, and reliability.

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10.0 RULEMAKING DEVELOPMENT TIMELINE

The NRC is making this regulatory basis available for public comment by stakeholders, including the commercial nuclear power industry (e.g., vendors and utilities), governmental and nongovernmental organizations, and individuals.

This activity is considered a medium priority rulemaking. Key milestones and target completion dates for the rulemaking deliverables can be found on the NRC's Rules and Petitions Web page under Planned Rulemaking Activities, <https://www.nrc.gov/about-nrc/regulatory/rulemaking/rules-petitions.html>

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APPENDIX A – APPLYING THE SEVERE ACCIDENT POLICY STATEMENT TO NEW PART 50 LICENSE APPLICATIONS

The U.S. Nuclear Regulatory Commission (NRC) expects that new nuclear power plant designs will achieve a higher standard of severe accident safety performance than earlier designs. Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251), light water reactor (LWR) design certification (DC), combined license (COL), standard design approval (SDA), and manufacturing license (ML) applicants are required to provide a description and analysis of design features for the prevention and mitigation of severe accidents. However, for new power reactor applicants under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities” (TN249), the regulations do not include analogous criteria for an LWR construction permit (CP) or an LWR operating license (OL). Additionally, the existing severe accident regulations do not apply to non-LWR applicants. Although the NRC has not completed, for this regulatory basis, an assessment of whether new requirements are needed for future non-light water reactor (non-LWR) applications in Part 50 or 52, it could clarify these requirements as part of the proposed rule.

1.0 EXISTING REGULATORY FRAMEWORK

The American Society of Mechanical Engineers (ASME) and the American Nuclear Society (ANS) jointly prepared a consensus standard for probabilistic risk assessment (PRA). The NRC has endorsed ASME/ANS RA-Sa-2009, “Addenda to ASME/ANS RA-S-2008, Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications” (ASME/ANS 2009-TN6220). The NRC documented this endorsement in Regulatory Guide 1.200, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-informed Activities” (NRC 2009-TN6211). The regulatory guide defines a severe accident as “an accident that involves extensive core damage and fission product release into the reactor vessel and containment, with potential release to the environment.”

On August 8, 1985, the Commission published the “Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants” (50 FR 32138, August 8, 1985; TN4519) (the Severe Accident Policy Statement). In this statement, the Commission said it “fully expects that vendors engaged in designing new standard (or custom) plants will achieve a higher standard of severe accident safety performance than their prior designs.” Criteria given in the policy statement that the NRC uses to assess the resolution of severe accident issues for new power reactors include the completion of a PRA, the consideration of severe accident vulnerabilities the PRA exposes, and the insights that the PRA may add to the assurance of no undue risk to public health and safety.

In its staff requirements memoranda (SRMs), dated June 26, 1990 (NRC 1990-TN6366), and July 21, 1993 (SRM-SECY-93-087; NRC 1993-TN6218), about SECY-90-016 (NRC 1990-TN524), “Evolutionary Light-Water Reactor Certification Issues and their Relationship to Current Regulatory Requirements,” and SECY-93-087, “Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor Designs,” (NRC 1993-TN6212), respectively, the Commission approved the NRC staff’s recommended positions pertaining to severe accident and containment performance for future LWR designs. On August 28, 2007 (72 FR 49352; TN4796), the Commission revised Part 52, establishing requirements for DC,

SDA, and ML LWR applicants to address prevention and mitigation of severe accidents consistent with SECY-90-016 and SECY-93-087. Combined license applicants must also provide this information, which is normally incorporated by reference to the design.

For prevention of severe accidents, an applicant evaluates the issues identified in SECY-90-016 and SECY-93-087 (e.g., anticipated transients without scram, midloop operation, station blackout, fire protection, and intersystem loss-of-coolant accident) or those that are applicable to their design. For mitigation of severe accidents, an applicant evaluates the severe accident phenomena to assess their design relative to the containment performance goals as approved by SRM-SECY-93-087. The severe accident phenomena identified as examples in paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) are design-dependent and specific to LWRs. They include core concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass.

With regard to currently operating plants, the Commission concluded in the 1985 Severe Accident Policy Statement that “existing plants pose no undue risk to public health and safety and [the Commission] sees no present basis for immediate action on generic rulemaking or other regulatory changes for these plants because of severe accident risk.”

Nonetheless, the Commission has continued to take reasonable steps to further reduce the risk associated with severe accidents at existing plants through its regulatory programs. For example, the Commission amended its regulations in Part 50 to address several key issues related to severe accidents: station blackout (53 FR 23203, June 21, 1988; TN6215), anticipated transients without scram (ATWS) (49 FR 26036, June 26, 1984; TN6214), hydrogen generation and control (50 FR 3498, January 25, 1985; TN6216), and beyond-design-basis external events (84 FR 39684, August 9, 2019; TN6213).

The NRC has also implemented a containment performance improvement program based on insights described in the resolution of Generic Safety Issue 157. This is documented in NUREG-0933, “Resolution of Generic Safety Issues” (NRC 2019-TN6337) regarding containment performance under severe accident conditions and a program for individual plant examination for severe accident vulnerabilities.

Because of these regulations and programs, there continues to be reasonable assurance of adequate protection of public health and safety regarding severe accidents at existing operating nuclear power plants. Future LWR Part 50 applicants would be subject to these Part 50 requirements. Applications would be assessed for containment performance and severe accident vulnerabilities. Although these Part 50 applicants would not be required by regulation to comply with the additional requirements imposed on applicants under Part 52, these applicants would need to address the severe accident issues analogous to the requirements of Part 52 for the NRC to make its adequate protection determination under the Atomic Energy Act of 1954, as amended (AEA; 42 U.S.C. § 2011 *et seq.*; TN663).

2.0 REGULATORY ISSUES

The Part 50 framework does not address the Commission’s Severe Accident Policy Statement, which described the Commission’s expectation that new power reactor applicants would submit a PRA with consideration of severe accident vulnerabilities, and the Part 52 requirements that applicants for LWR DCs, COLs, SDAs, or MLs address the prevention and mitigation of severe accidents. New power reactor applicants under Part 50 would not be required by regulation to comply with these requirements, although the Part 50 regulations require the applicant to

address some severe accident phenomena (i.e., station blackout, ATWS, combustible gas control, and beyond-design-basis external events). Further, the NRC would require these applicants to address the severe accident issues required of Part 52 applicants to enable the NRC to make its adequate protection determination under the AEA.

3.0 DISCUSSION OF ALTERNATIVES

3.1 Alternative 1: No-Action

3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework and not require a new Part 50 LWR CP or OL applicant to provide a description and analysis of design features for the prevention and mitigation of severe accidents.

3.1.2 Assessment of Alternative 1

Under Alternative 1, LWR applicants using the Part 50 licensing process would not be required by regulations to address all severe accident issues, unlike certain Part 52 applicants.

3.2 Alternative 2: Rulemaking

3.2.1 Description of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to add to Part 50 requirements analogous to paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to provide descriptions and analyses of severe accident design features in LWR CP and OL applications.

3.2.2 Assessment of Alternative 2

In this alternative, the NRC would pursue rulemaking to apply current severe accident requirements under paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to those applications for LWR CPs and OLs that are submitted under Part 50 after the effective date of this rulemaking's final rule. These Part 50 applicants would be required to provide a description and analysis of design features for the prevention and mitigation of severe accidents, just as the Part 52 applicants (e.g., DC and COL) must do. This would promote consistent implementation of the Commission's Severe Accident Policy Statement for Parts 50 and 52 applicants. The rulemaking would improve the clarity of regulatory requirements, which is expected to promote regulatory certainty and review efficiencies.

3.3 Alternative 3: Develop New Guidance or Revise Existing Guidance

3.3.1 Description of Alternative 3

Under Alternative 3, the existing regulations would remain unchanged and the NRC would pursue development of new guidance or revision of existing guidance to clarify the applicability of current severe accident requirements under paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to applications for LWR CPs and OLs submitted under Part 50.

3.3.2 *Assessment of Alternative 3*

Under Alternative 3, the NRC would develop new guidance or revise existing guidance (i.e., NUREG-0800, “Standard Review Plan”; NRC 2007/2019-TN6221) to address the applicability of current severe accident requirements under paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to applications for LWR CPs and OLs submitted under Part 50. Because guidance cannot change the meaning of regulations and the regulations at issue here would remain unchanged, this alternative would not resolve the current inconsistency between the Part 50 framework and the Commission’s Severe Accident Policy Statement and therefore would not resolve the underlying concerns.

4.0 REGULATORY SCOPE

Section 50.34, “Contents of applications; technical information,” would be amended to require LWR CP and OL applicants, whose applications are submitted after the effective date of this rulemaking’s final rule, to provide a description and analysis of design features for the prevention and mitigation of severe accidents. Applicants would need to consider challenges to containment integrity caused by phenomena such as core concrete interaction, steam explosion, high-pressure core melt ejection, hydrogen combustion, and containment bypass.

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

5.1 NRC Guidance

Standard Review Plan Section 19.0, “Probabilistic Risk Assessment and Severe Accident Evaluation for New Reactors” would be revised to clarify that the guidance contained therein is applicable to Part 50 LWR CP and OL applicants.

5.2 Policy Issues

No change in Commission policy is required, and SRM-SECY-15-0002 is the policy supporting this recommended change in the regulations. If pursued, the rulemaking would promote consistent implementation of the Commission’s Severe Accident Policy Statement for Parts 50 and 52 applicants.

6.0 IMPACTS

6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing power reactor licensing process as described in the current regulations and guidance. The NRC would not pursue amending Part 50 to add new requirements for a LWR CP or OL applicant to provide a description and analysis of design features for the prevention and mitigation of severe accidents.

6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, or security.

6.1.2 *Impacts on Applicants and Licensees*

This alternative would have no incremental impact on licensees. Each applicant for an OL would submit a final safety analysis report that would include information demonstrating how it would comply with the severe accident regulations in Part 50 consistent with current regulations.

6.1.3 *Impacts on the NRC*

This alternative would have no incremental impact on the NRC.

6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.1.5 *Summary of Costs and Benefits*

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would pursue rulemaking to revise Part 50 with requirements analogous to paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to add requirements for applications for LWR CPs and OLs that are submitted to the NRC after the effective date of this rulemaking's final rule. Those applicants would be required to provide a description and analysis of severe accident design features.

6.2.1 *Impacts on Public Health, Safety, and Security*

This alternative would continue to provide reasonable assurance of adequate protection of public health, safety, and security. It would update the regulations in Part 50 to promote regulatory consistency and provide technically equivalent outcomes for license reviews conducted under both Parts 50 and 52.

6.2.2 *Impacts on Applicants and Licensees*

This alternative would result in setting clear requirements via the NRC's regulations, which would help prospective new power reactor license applicants make informed decisions regarding which licensing process is best suited to their business needs.

The NRC expects that the additional requirements for the contents of applications related to severe accident design and analysis (i.e., requirements analogous to Sections 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23)) will lead to incremental costs for future LWR applicants under Part 50. Severe accident issues that Part 50 applicants would be required to address (i.e., station blackout, ATWS, combustible gas control, and beyond-design-basis external events) would need to be analyzed approximately three years earlier than under current regulations. This results in costs to applicants due to the time value of money, so the cost estimate uses the net present value (NPV) of assessing these design issues an average of 3 years earlier at an average cost of \$500,000, resulting in an NPV of approximately (\$101,000) for performing the actions earlier. Additionally, during the design phase Part 50 applicants would need to address the severe accident issues analogous to the requirements of Part 52.

The staff did not estimate an increase in burden for this regulatory change because a Part 50 applicant today would need to address the severe accident issues analogous to the requirements of Part 52 for the NRC to make its adequate protection determination under the AEA, even though the applicant would not be required by regulation to do so. This regulatory change in Alternative 2 is beneficial because it clarifies the licensing application process and increases the consistency between Parts 50 and 52. As with other estimates of future applicants in this regulatory basis, the staff assumes one applicant in 2024 (unaffected by this final rule), another in 2027 (with the incremental costs occurring in 2024), and a third in 2030 (with the incremental costs in 2027). As shown in Table A-1 below, this results in incremental costs to applicants of (\$130,000) using a 7 percent NPV and (\$166,000) using a 3 percent NPV.

Table A-1 Industry Costs for Alternative 2

Year	Activity	Number of Actions	NPV of Earlier Design Changes	Cost		
				Undiscounted	7% NPV	3% NPV
2024	Design Changes prior to application	1	(\$100,752)	(\$100,752)	(\$71,834)	(\$86,909)
2027	Design Changes prior to application	1	(\$100,752)	(\$100,752)	(\$58,638)	(\$79,534)
Total:				(\$201,503)	(\$130,473)	(\$166,443)

The improved clarity of regulatory requirements afforded by this rulemaking would provide more regulatory certainty and improve review efficiencies.

6.2.3 Impacts on the NRC

By revising Part 50 to be consistent with the current review of severe accidents under the Part 52 process, the NRC expects to reduce the number of requests for additional information and potentially extraneous interactions with the applicant regarding the contents of an application. This would result in a more efficient process and save NRC staff time and resources. The regulation would achieve adequate protection of public health and safety in the same way for all LWR applications. The NRC would incur rulemaking costs to develop the proposed and final rule and make changes to regulatory guides and NUREG-0800. These costs are estimated to be approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table A-2.

Table A-2 Rulemaking Costs for Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 *Summary of Costs and Benefits*

This alternative would provide clarity, efficiency, and regulatory certainty to licensees and applicants, and result in costs to the NRC and applicants of approximately (\$236,000) using a 7 percent NPV.

6.3 **Alternative 3: Develop New Guidance or Revise Existing Guidance**

Under Alternative 3, the existing regulations would remain unchanged and the NRC would pursue development of new guidance or revision of existing guidance to clarify the applicability of current severe accident requirements under paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) to applications for LWR CPs and OLs submitted under Part 50.

6.3.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change regulatory requirements, there would be no increase or reduction in public health, safety, and security.

6.3.2 *Impacts on Licensees and Applicants*

This alternative would have no incremental impacts on licensees or applicants.

6.3.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC, aside from the modifications to associated guidance, estimated at approximately (\$45,000) using a 7 percent NPV and (\$50,000) using a 3 percent NPV, as shown in Table A-3.

Table A-3 Regulatory Guide Costs for Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
Total:					(\$53,481)	(\$45,184)	(\$49,677)

6.3.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.3.5 *Summary of Costs and Benefits*

This alternative would provide some clarity to licensees and applicants, and result in regulatory guide modification costs of approximately (\$45,000) using a 7 percent NPV.

7.0 **BACKFITTING AND ISSUE FINALITY**

None of the alternatives presented by the NRC in this appendix, if implemented, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52.

Alternative 1 would maintain the status quo of not having Part 50 requirements for severe accidents analogous to paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23) for new Part 50 power reactor applicants. There would be no change in Part 50 requirements. Alternative 2 would revise the current regulations in Part 50, but these changes would apply to only applicants for an LWR CP or OL under Part 50 after the effective date of this rulemaking's final rule. A CP applicant would not be within the scope of the backfitting provision in Section 50.109. Alternative 2 would not require an OL applicant to change its CP, so Alternative 2 would not constitute backfitting for an OL applicant.

Under Alternative 3, the NRC's changes to guidance documents would not impose any requirement applicable to a licensee or applicant.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, "Rulemaking," to revise Part 50 to include requirements analogous to paragraphs 52.47(a)(23), 52.79(a)(38), 52.137(a)(23), and 52.157(f)(23), which require applicants under Part 52 to provide descriptions and analyses of severe accident design features. This alternative promotes consistent implementation of the Commission's Severe Accident Policy Statement for Parts 50 and 52 applicants. The rulemaking would improve the clarity of regulatory requirements, which is expected to promote regulatory certainty and review efficiencies but result in incremental costs to applicants and the NRC to achieve these benefits.

APPENDIX B – PROBABILISTIC RISK ASSESSMENT REQUIREMENTS

The recommended alignment and updating of the language describing the U.S. Nuclear Regulatory Commission's (NRC's) policies related to the use of probabilistic risk assessment in design; risk-informed categorization of structures, systems, and components; and maintenance and upgrading of plant-specific probabilistic risk assessments are addressed in the following sections of this appendix.

1.0 USE OF PROBABILISTIC RISK ASSESSMENT IN DESIGN

The NRC's Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities (60 FR 42622, August 16, 1995; TN6278) (PRA Policy Statement) encourages the use of probabilistic risk assessment (PRA) in the design of all new power reactors. Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), an application for a design certification (DC), standard design approval (SDA), or manufacturing license (ML) must include a description of the design-specific PRA and its results. Applications for a combined license (COL) must include a description of the plant-specific PRA and its results, which would address plant- and site-specific aspects of the design. The NRC is considering whether requirements to use PRA in design should also apply to applications for a construction permit (CP) and an operating license (OL) under Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249).

1.1 Existing Regulatory Framework

Section 50.34, "Contents of applications; technical information," of the NRC's regulations establishes the requirements for technical information needed for new reactor applications. Each applicant for a CP, under paragraph 50.34(a), "Preliminary safety analysis report," or an OL, under paragraph 50.34(b), "Final safety analysis report," must submit a safety analysis report describing the facility and containing specific information. Aside from Part 52 nuclear power plants, only those plants with a CP or ML pending as of February 16, 1982, were required under paragraph 50.34(f), "Additional TMI [Three Mile Island]-related requirements," to perform a PRA. (All of these Part 50 applications have been withdrawn.) Consequently, there is no longer any requirement to perform a PRA prior to submittal of an application for a CP or OL under Part 50.

Section 50.71, "Maintenance of records, making of reports," establishes certain recordkeeping and reporting requirements for nuclear reactor licensees. Paragraph 50.71(e) requires OL holders to periodically update the final safety analysis report (FSAR). This would apply to the description and results of the plant-specific PRA if they are included in a licensee's FSAR. Paragraph 50.71(e)(3)(iii) also requires COL holders to update the FSAR annually until the paragraph 52.103(g) finding. The CP holders that have a pending OL have no analogous requirement unless they apply for a risk-informed licensing action (e.g., Section 50.69, "Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors"). In that case, they would have to maintain a PRA that is technically adequate to support that application, upgrade it prior to the initial loading of fuel, and then maintain and

upgrade the PRA until the permanent cessation of operations.¹ Paragraph 50.71(h) requires each COL holder to develop, maintain, and upgrade a PRA that includes the initiating events and modes of operation covered by NRC-endorsed consensus standards for PRA.

Under paragraph 52.47(a)(27), applications for a DC must include an FSAR with a description of the design-specific PRA and its results.

Under paragraph 52.79(a)(46), applicants for a COL must include an FSAR with a description of the plant-specific PRA and its results.

Under paragraph 52.137(a)(25), applicants for an SDA must include an FSAR with a description of the design-specific PRA and its results if the portion of the SDA for which approval is sought can be modeled in a manner that is consistent with NRC-endorsed consensus standards for PRA.

Under paragraph 52.157(f)(31), applicants for an ML must include an FSAR containing the information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in 10 CFR Chapter I (TN6351), including a description of the design-specific PRA and its results.

The Commission's PRA Policy Statement calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA. The Commission explained that it believed "that PRA methods can be used to derive valuable insights, perspective, and general conclusions as a result of an integrated and comprehensive examination of the design of nuclear facilities, facility response to initiating events, the expected interactions among facility structures, systems, and components, and between the facility and its operating staff."

In its Policy Statement on Safety Goals for the Operations of Nuclear Power Plants (51 FR 30028, August 21, 1986; TN594) (Safety Goals Policy Statement), the Commission published qualitative goals and quantitative objectives for the safety of nuclear power plants. The goals were that nuclear power plant operation should impose no significant additional risk on individuals and its risk should not be a significant addition to other societal risks. The objectives would be used to determine that the goals had been met. The first objective was that risk from a reactor accident of prompt fatality to an average individual near a nuclear power plant should not exceed 0.1 percent of risks from other accidents to which the U.S. population is generally exposed. The second objective was that cancer fatality risk to the population from nuclear reactor operations should not exceed 0.1 percent of all other cancer fatality risks. The Commission expressed confidence in the use of PRA to make such assessments and to bring uncertainties into better focus.

1.2 Regulatory Issues

Part 52 requires the use of PRA in the design of reactors, and the results of the PRA are factored into the NRC's review of the proposed design. Part 50 does not contain an equivalent

¹ The NRC has endorsed consensus standards that cannot be met until the as-built configuration of the plant is known (e.g., in lieu of a seismic PRA, applicants for a DC, CP, and OL may perform seismic margins analysis). When the PRA is revised to cover an initiating event or mode that it did not cover before, or to adopt a new method, that is considered an "upgrade." Consequently, the plant-specific PRA required by 10 CFR 50.71(h)(1) will always be an upgrade. Current standards specify a peer review after an upgrade, but regulations do not require that the peer review be completed prior to the initial loading of fuel.

requirement (except for certain licensing actions that have been withdrawn), so the NRC's reviews of CP and OL applications do not benefit from the results of and insights gained from a PRA for a proposed design. In addition, unless this information is reported, the NRC may not be able to risk-inform its review of Part 50 applications. This inconsistency in the NRC's regulatory framework also poses a conflict with the Commission's PRA Policy Statement, in which the Commission affirmed that PRA should be used in the design of new reactors.

In the Commission's Safety Goals Policy Statement, the quantitative objectives are to keep reactor accident fatality risk to local individuals below 0.1 percent of general U.S. accident risk and cancer fatality risk to the population below 0.1 percent of all cancers. For light water reactors (LWRs), the NRC has used surrogates for these objectives (i.e., core damage frequency and release frequencies²). Without a PRA, these surrogates cannot be quantified for new LWRs licensed under Part 50.

In addition, as seen with other first-of-a-kind applications (e.g., the Economic Simplified Boiling-Water Reactor DC [79 FR 61943, October 15, 2014; TN4146]), the NRC's access to PRA results allows it to risk-inform its licensing reviews. This substantially increases the safety focus of the review. Part 52 also requires the use of a plant-specific PRA in licensing a new reactor; Part 50 does not. The Part 50 license application may include risk-significant structures, systems, and components (SSCs) (e.g., the ultimate heat sink) that are outside the scope of the design-specific PRA (if there is one). Also, site-specific parameters (e.g., external hazards) should be addressed in a plant-specific PRA and the results and insights should be reported in the CP application so the suitability of the design for the proposed site can be confirmed. Departures from the design in the CP might not be assessed appropriately without having access to the PRA.

Furthermore, to be useful in the operating phase, the plant-specific PRA required of a Part 52 COL holder must accurately reflect the as-built plant. Even if they have a PRA, holders of a Part 50 OL have no requirement to maintain it to accurately reflect the as-built, as-operated plant. Before loading fuel, OL holders should perform walkdowns to confirm that the plant-specific PRA models the as-built plant. The PRA should be upgraded to cover all initiating events and modes for which consensus standards have been endorsed by the NRC. Subsequently, it should be maintained and upgraded as necessary until the permanent cessation of operations.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework.

1.3.1.2 Assessment of Alternative 1

Alternative 1 would allow applicants for new reactors under Part 50 to apply for a CP without developing a PRA for the proposed design. It would allow the holder of a new OL to enter the operational phase without a plant-specific PRA.

² Prior to the operational phase, applicants and licensees use large release frequency (LRF). After loading fuel, licensees use large early release frequency (LERF).

This alternative is not consistent with the Commission policy that calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA. In the PRA Policy Statement, the Commission affirmed that PRA “can be used to derive valuable insights, perspective, and general conclusions as a result of an integrated and comprehensive examination of the design of nuclear facilities.” This alternative does not incorporate the lessons learned during the licensing of plants under Part 52, for which PRA was used to improve a proposed design on more than one occasion. Results and insights from the PRA also focused the NRC’s safety review. The results and insights from PRA could be used to improve the design of plants licensed under Part 50. For example, a PRA may show that it is advantageous to reconfigure a flow path to use diverse components rather than merely increasing redundancy. Also, reporting the results and insights from PRA in applications for a CP would allow the staff to focus its review on the most safety-significant aspects of the plant.

1.3.2 Alternative 2: Extend Current PRA Requirements in Part 52 to Part 50 Applicants

1.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to apply current PRA requirements under Part 52 to applications made pursuant to Part 50. Specifically, this alternative would amend paragraph 50.34(a) to add a new requirement that future applicants for CPs under Part 50 must develop a plant-specific PRA. They would include a description of the plant-specific PRA and its results in the preliminary safety analysis report (PSAR). This alternative would also amend paragraph 50.34(b) to add a new requirement that future applicants for OLs under Part 50 must include a description of the plant-specific PRA and its results in the FSAR.

Under this alternative, the NRC would also revise Section 50.71 to require an OL holder to periodically update the description and results of the plant-specific PRA in its FSAR. This alternative would also modify the requirements in paragraph 50.71(h)(1) to make them broadly applicable to all reactor designs. The rule would delete language that is specific to LWRs (e.g., Level 1 and Level 2) and retain the broader requirement to develop, maintain, and upgrade a PRA. The scope of the PRA for the particular reactor type would be defined in regulatory guidance.

1.3.2.2 Assessment of Alternative 2

Alternative 2 would align PRA requirements imposed on applicants for new plants licensed under Part 50 with those already addressed under Part 52.

All licensees would have a plant-specific PRA that covers all initiating events and modes of operation for which consensus standards have been endorsed by the NRC. The expected result would be that licensees would have a tool for risk-informed applications that are expected to reduce costs and improve safety. The NRC would be able to risk-inform its licensing reviews, substantially increasing the safety focus of these reviews.

1.4 Regulatory Scope

Under Alternative 2, regulations in Section 50.34 concerning the content of applications for a CP would be changed to include a requirement to describe and report the results of a plant-specific PRA. Regulations in Section 50.71 governing the development, maintenance, and upgrading of a plant-specific PRA for the operational phase would be revised to extend their application to new OLs issued under Part 50.

1.5 NRC Guidance, Policy, and Implementation Issues

No new regulatory guidance on PRA for LWRs would be needed. Existing guidance on PRA is sufficient.³ The scope of some regulatory guides (RGs) may need to be extended to applications for a CP or an OL:

- **RG 1.174**, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” (NRC 2018-TN6335)
- **RG 1.200**, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities” (NRC 2009-TN6211)
- **RG 1.201**, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance” (NRC 2006-TN6279)
- **RG 1.205**, “Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants” (NRC 2009-TN6280)
- **RG 1.206**, “Applications for Nuclear Power Plants” (NRC 2018-TN6192).

Alternative 2 would align Part 50 with existing Commission policy for new reactor applications. No change in Commission policy would be required. No conflict between policies has been identified.

1.6 Impacts

1.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would continue with the existing licensing process, as described in the current regulation and guidance. The NRC would not pursue any changes.

1.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 *Impacts on Applicants and Licensees*

This alternative would have no incremental impacts on applicants and licensees.

1.6.1.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC.

1.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

³ DC/COL-ISG-028, “Interim Staff Guidance on Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application” (NRC 2016-TN6281), identifies high-level and supporting requirements of the PRA Standard (ASME/ANS 2009-TN6220) that apply to applications for DCs and COLs. It would apply to applications for CPs, as well.

1.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Extend Part 52 PRA Requirements to Part 50 Applicants

Under this alternative, the NRC would pursue rulemaking to apply current PRA requirements under Part 52 to applications made pursuant to Part 50.

1.6.2.1 Impacts on Public Health, Safety, and Security

Alternative 2 would require CP applicants to prepare a plant-specific PRA in accordance with the Commission’s PRA Policy Statement, which affirmed that PRA should be used in the design of new reactors. They would be required to describe this PRA and report its results in the PSAR. In the design phase, CP applicants would have the opportunity to develop their designs to avoid or mitigate severe accident vulnerabilities found using the PRA.

Operating license applicants would have to amend the description of the plant-specific PRA and its results in the FSAR. The revised description would include any differences from the PRA described in the PSAR. The OL applicant would have the opportunity to avoid or mitigate vulnerabilities identified using PRA during construction.

Based on the factors above, the impacts on public health, safety, and security would be positive.

1.6.2.2 Impacts on Applicants and Licensees

Construction permit applicants would incur the cost of having the reactor vendor develop a PRA, to use in the design phase, and to include its description and results in the PSAR. The estimated required resources for this activity is approximately 15,000 hours. However, the PRA would allow the applicant to make use of risk insights earlier in the design of the plant, which would contribute to cost savings in both construction and operation of the plant. In addition, the applicants would be able to take advantage of risk-informed licensing actions significantly earlier in the process, allowing for reduced regulatory burden. All Part 50 OL holders, to date, have voluntarily developed and maintained PRAs without the requirement in the regulations, and the regulatory changes in Alternative 2 are consistent with the Commission’s PRA Policy. The NRC quantified the costs of developing the PRA for each construction applicant (assuming an application in 2024 after the issuance of the final rule) at approximately (\$1.64 million) using a 7 percent net present value (NPV) and (\$2.01 million) using a 3 percent NPV, shown in Table B-1.

Table B-1 Industry Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	PRA development costs to applicant	1	15333	\$134	(\$2,059,106)	(\$1,468,114)	(\$1,776,203)
2025-2027	Maintain PRA during construction	3	750	\$134	(\$302,151)	(\$176,123)	(\$238,591)
Total:					(\$2,361,258)	(\$1,644,238)	(\$2,014,794)

Operating license applicants would incur the cost of upgrading the PRA prior to loading fuel. The estimated burden for this is 1,000 hours. This would give them the opportunity to use the PRA in the operational phase for risk-informed programs that they may find beneficial (e.g., risk-

informed surveillance frequencies and completion times for technical specifications or risk-informed categorization of SSCs). If used, this may allow applicants to reduce their regulatory burden and maintenance costs. All Part 50 licensees have upgraded their PRAs without a regulatory requirement, and no potential applicant has informed the NRC that they do not intend to perform a PRA. Therefore, this burden was not quantified.

After licensing, new reactor licensees under Part 50 would have an ongoing obligation to maintain and upgrade the PRA pursuant to paragraph 50.71(h). The estimated cost for this is 750 hours per year for the life of the plant. Again, this would allow licensees to be able to take advantage of risk-informed licensing actions, which would allow licensees to reduce regulatory burden and manage plant risk more effectively. In addition, the licensee would be able to use the PRA to meet existing regulatory requirements, such as the Reliability Assurance Program and the Maintenance Rule in Section 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants." Because the risk results are used in the environmental analysis, specifically the severe accident mitigation alternatives, the review burden would be decreased by the NRC knowing and understanding the PRA results. Furthermore, departures from the design in the CP would have a lower review burden with a PRA available.

Regardless of the lack of regulatory requirements for PRAs for Part 50 licensees, all OL holders have voluntarily maintained and upgraded their PRAs. Licensees would not likely choose to maintain and upgrade their PRAs if it were not cost-effective. For these reasons, as above, the NRC considers that the benefits of the PRA would outweigh the costs to new reactor licensees. However, the NRC did quantify the costs of maintaining and upgrading the PRA for each new reactor licensee at approximately (\$176,000) using a 7 percent NPV and (\$239,000) using a 3 percent NPV, as shown in Table B-1. This assumes a new reactor applicant would apply in 2024 and begin maintaining and upgrading the PRA annually in 2025 through 2027, at which point the process of loading fuel would begin and the existing PRA requirements would take effect.

The net impact on industry per new reactor applicant (CP) and licensee would be approximately (\$1.64 million) using a 7 percent NPV and (\$2.01 million) using a 3 percent NPV, as shown in Table B-1. The NRC chose to estimate costs on a per applicant basis because the qualitative benefits described above are expected to balance out the costs, and this would only affect a future applicant who planned to use Part 50. The staff expects that some future applicants may use Part 50 instead of Part 52; therefore, the number of affected applicants is highly speculative. Due to these issues, calculating costs for multiple future licensees would overrepresent the quantitative costs in a potentially misleading manner.

1.6.2.3 Impacts on the NRC

Although there would be a minor additional burden on the NRC to review the PRA results, it would be offset by having access to PRA information, which would allow the NRC to risk-inform its review of the CP application and the OL application, both the safety and environmental assessments, for improved effectiveness and efficiency. Models that are developed for the NRC for the standardized plant analysis of risk (SPAR models) could be developed with higher confidence in their validity. Quantifying these benefits was impractical, but the NRC expects the benefits would exceed the costs. The NRC would also incur rulemaking costs in this alternative of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table B-2.

Table B-2 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

In addition, the costs for the NRC to develop a SPAR model would be less, based on the availability of the PRA information submitted in the COL or CP application.

1.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 Summary of Benefits and Costs

Construction permit applicants and OL applicants would have the opportunity to avoid design vulnerabilities that can be identified using PRA. They would be prepared to use the PRA for risk-informed applications during the operational phase.

Alternative 2 would require CP applicants to develop and describe a plant-specific PRA and report its results in the PSAR. Operating license applicants would have to amend this description and report in the FSAR to reflect the as-built condition. Operating license holders would have to modify the PRA description and results in periodic updates to the FSAR to account for plant-specific changes.

For each new reactor applicant under Part 50 the NRC estimates a burden of approximately (\$1.64 million) using a 7 percent NPV. Alternative 2 also would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent NPV.

1.7 Backfitting and Issue Finality

Neither of the alternatives would constitute backfitting as defined in Section 50.109, “Backfitting,” or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no change to existing regulations, other requirements, or NRC staff positions. Alternative 2 would only apply to CP applicants and those OL applicants with a FSAR that includes a description of the plant-specific PRA after the effective date of this rulemaking’s final rule. A CP applicant would not be within the scope of the backfitting provision in Section 50.109. Alternative 2 would not require an OL applicant to change its CP, so Alternative 2 would not constitute backfitting for an OL applicant.

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the

rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The staff recommends adoption of Alternative 2, “Extend Current PRA Requirements in Part 52 to Part 50 Applicants.” It is the only option that is consistent with Commission policy on the use of PRA in design. While Alternative 2 could result in considerable costs to a new reactor applicant that planned to use Part 50 without a PRA, the staff considers this possibility exceedingly unlikely because of the benefits from using a PRA discussed in this appendix. As a result, the staff does not expect that a CP applicant would apply under Part 50 without a PRA. Furthermore, those costs may be offset by the considerable benefits of being able to use the PRA throughout the design and construction process.

2.0 RISK-INFORMED CATEGORIZATION OF STRUCTURES, SYSTEMS, AND COMPONENTS

Normally, the NRC imposes special requirements on each safety-related SSC. (The definition of safety-related SSCs is in Section 50.2, “Definitions.”)

Light water reactor licensees under Part 50 and applicants for an SDA, a COL, or ML under Part 52 may opt to implement an alternative regulatory framework under Section 50.69 based on categorizing the safety significance of the function performed by an SSC. Certain special requirements need not be imposed on safety-related SSCs that are of low safety significance. This option is not available to holders of CPs or COLs or applicants for DCs. The NRC is considering whether CP holders, COL holders, and DC applicants should be able to use this alternative framework.

2.1 Existing Regulatory Framework

In Section 50.69, the NRC provides a set of requirements that certain applicants and licensees can voluntarily select as an alternative to applicable special treatment requirements. The special treatment that would otherwise be imposed is relaxed for safety-related and non-safety-related SSCs that perform only low safety-significant functions. The requirements for which the alternative risk-informed process under Section 50.69 may instead be applied are listed in paragraph 50.69(b)(1).

Currently, this rule applies to a holder of an OL under Part 50 or a renewed license under Part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants” (TN4878), an applicant for a CP or OL under Part 50, and applicants for an SDA, COL, or ML under Part 52. It is not available to an applicant for a DC or a CP or COL holder.

Under Section 52.63, “Finality of standard design certifications,” the Commission may not modify, rescind, or impose new requirements on the certification information while it is in effect (i.e., issued or renewed) unless at least one criterion listed in this section is met.

Under Section 52.98, “Finality of combined licenses; information requests,” the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, or the inspections, tests, analyses, and acceptance criteria (ITAAC) unless certain criteria are satisfied.

Each appendix to Part 52 is a DC rule. Section VIII of each DC rule describes a process for modifying the plant that is similar to Section 50.59, “Changes, tests and experiments.”

The Commission’s PRA Policy Statement calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA.

In response to a petition for rulemaking (PRM-50-110; NEI 2015-TN6491), the Commission directed the staff to consider in the rulemaking process the issue of whether to allow holders of a COL to adopt risk-informed classification of SSCs under Section 50.69. See SRM-SECY-18-0106 (NRC 2020-TN6496).

2.2 Regulatory Issues

When certifying a design, risk-informed review offers a safety benefit by allowing the licensee and the NRC to focus their efforts on the most risk-significant SSCs during design and design review. Risk-informed classification of SSCs in the design phase would also allow the use of alternative special treatment requirements for establishing the suitability of SSCs for the proposed design. This can result in cost savings for licensees that reference the design (e.g., in procurement and maintenance). The savings are most significant if alternative special treatment requirements can be applied at the time of initial procurement of SSCs for new construction.

Changes to the special treatment requirements applied to SSCs constitute a design change. For Part 52 licensees under construction, even changes similar to those authorized under 10 CFR 50.59, “Changes, tests and experiments,” are likely to entail a license amendment. This is because they are likely to involve a departure from the design referenced in the COL application or alteration of the ITAAC that are part of the COL. Changes to the design undertaken by CP holders will be evaluated along with the rest of the OL application, so they do not incur a similar regulatory burden. However, experience with current COL holders suggests that this difference may be manageable.

Once the operating phase begins, there is no longer any technical difference between an OL and a COL. Allowing OL holders but not COL holders to apply Section 50.69 lacks a technical basis. Because the use of Section 50.69 is voluntary, the COL holder can determine whether using Section 50.69 is cost beneficial, a determination that may vary from one plant to another.

Neither the cost savings afforded by the alternative special treatment requirements of Section 50.69 nor the safety benefit of focusing on the most risk-significant SSCs should be withheld from DC applicants or COL holders.

2.3 Discussion of Alternatives

2.3.1 Alternative 1: No-Action

2.3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework.

2.3.1.2 Assessment of Alternative 1

Combined license holders and DC applicants would still not be able to implement an alternative regulatory framework for treatment of SSCs under Section 50.69, even if they have a PRA that is technically adequate to support this framework.

This would not be consistent with the Commission policy that calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA.

2.3.2 Alternative 2: Allow Combined License Holders to Risk-Inform the Categorization of SSCs After the Commission Finds That All Acceptance Criteria of the License Have Been Met

2.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to allow COL holders to implement risk-informed classification of SSCs under Section 50.69 at the earliest point when the agency would have assurance that the plant has been built in a manner that is consistent with the license; that is, once the Commission finds that all of the license's ITAAC have been met (pursuant to paragraph 52.103(g)).

2.3.2.2 Assessment of Alternative 2

COL holders would have the same option to use Section 50.69 as OL holders currently have. Combined license holders would be able to implement an alternative regulatory framework for treatment of SSCs under Section 50.69 once the Commission makes the paragraph 52.103(g) finding. These licensees could benefit from using Section 50.69 to achieve costs savings and focus on the most significant SSCs once the ITAAC are satisfied. This approach would ensure that risk-informed categorization would not conflict with ITAAC. Alternative 2 also would be consistent with Commission policy that calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA.

2.3.3 Alternative 3: Allow Construction Permit Holders, Combined License Holders, and Design Certification Applicants to Risk-Inform the Categorization of SSCs

2.3.3.1 Description of Alternative 3

Under this alternative, the NRC would pursue rulemaking to allow CP holders, COL holders, and DC applicants to implement risk-informed classification of SSCs under Section 50.69 as soon as they have a PRA that is technically adequate for that purpose.⁴ For COL holders, this could

⁴ Regulatory Guide 1.200 provides one acceptable approach for defining the technical adequacy of a PRA.

occur before or after the Commission finds that all of the license's ITAAC have been met (pursuant to paragraph 52.103(g)).

2.3.3.2 Assessment of Alternative 3

Alternative 3 would enable combined license holders and DC applicants to propose risk-informed categorization and treatment of SSCs under Section 50.69. CP holders would have the same option to use Section 50.69 as COL holders would, thereby aligning Parts 50 and 52 regarding the option to use Section 50.69. All of these entities could benefit from using Section 50.69 to achieve cost savings and focus on the most significant SSCs. COL holders could experience these benefits at an earlier point in time in the licensing process than under Alternative 2. In addition, the NRC now has sufficient experience to support case-by-case consideration of future DC applications that propose to use Section 50.69. Also, the NRC's experience with license amendments during construction of a nuclear power plant licensed under Part 52 has shown that changes to ITAAC before the paragraph 52.103(g) finding can be successful. Alternative 3 also would be consistent with Commission policy that calls for increased use of PRA in all regulatory matters to the extent supported by the state of the art in PRA.

2.4 Regulatory Scope

Under Alternatives 2 and 3 the NRC would conduct rulemaking to amend Section 50.69. Under Alternative 2, holders of a COL could use Section 50.69 once the Commission finds that the ITAAC acceptance criteria of the COL are met. Under Alternative 3, a COL holders' use of Section 50.69 would not be limited by the timing of the paragraph 52.103(g) finding. A CP holder would also be allowed to use 50.69. In addition, under Alternative 3, DC applicants would be extended the same opportunity as SDA and ML applicants under the current rule.

2.5 NRC Guidance, Policy, and Implementation Issues

No new regulatory guidance on PRA would be needed. Existing guidance on PRA is sufficient.⁵ The scope of regulatory guidance may need to be extended to CP and COL holders. Affected RGs include the following:

- **RG 1.200**, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities"
- **RG 1.201**, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance."

No change in Commission policy would be required. No conflict between policies has been identified.

⁵ DC/COL-ISG-028," Interim Staff Guidance on Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application," identifies high-level and supporting requirements of the standard that apply to applications for DCs and COLs. It would apply to applications for CPs, as well.

2.6 Impacts on Public Health, Safety, and Security

2.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing licensing process, as described in the current regulation and guidance. The NRC would not pursue any changes.

2.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants and licensees.

2.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Allow COL Holders to Risk-Inform the Categorization of SSCs After the Commission Finds That All Acceptance Criteria of the License Have Been Met

2.6.2.1 Impacts on Public Health, Safety, and Security

Combined license holders might choose to upgrade the plant-specific PRA earlier than required.⁶ By improving the focus on safety-significant SSCs, a small but beneficial impact on public health, safety, and security is expected.

2.6.2.2 Impacts on Applicants and Licensees

Combined license holders might choose to incur the cost of maintaining the PRA and upgrading it even earlier than required by paragraph 50.71(h)(1). This would be offset by the fact that COL holders would be allowed to use Section 50.69 earlier. This has the potential to reduce the cost of special treatment for safety-related SSCs that only perform functions of low safety significance. It would improve the focus on safety-significant SSCs. Because these options are

⁶ The NRC has endorsed consensus standards that cannot be met until the as-built configuration of the plant is known (e.g., seismic margins analysis is performed in lieu of a seismic PRA). When the PRA is revised to cover an initiating event or mode that it did not cover before, or to adopt a new method, that is considered an "upgrade." Consequently, the plant-specific PRA required by 10 CFR 50.71(h)(1) will always be an upgrade. Current standards specify a peer review after an upgrade, but regulations do not require that this peer review be completed prior to the initial loading of fuel.

voluntary, it is the licensee’s prerogative to decide whether this would be cost-effective. Therefore, the NRC did not estimate these burdens quantitatively.

2.6.3 Impacts on the NRC

Alternative 2 would allow COL holders to apply for the opportunity to use Section 50.69. The NRC would incur the obligation to review such applications, but the incremental impact would be small if any other risk-informed application is requested, which is very likely. Over the life of the plant, the NRC would incur lower costs to inspect and regulate low risk-significant SSCs. The NRC chose to consider these costs and averted costs as cancelling out and did not estimate them quantitatively. The NRC would incur rulemaking costs with this alternative of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table B-3 .

Table B-3 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

2.6.3.1 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.3.2 Summary of Benefits and Costs

Combined license holders after the Commission makes the paragraph 52.103(g) finding would be allowed to use Section 50.69, which has the potential to reduce the cost of special treatment for safety-related SSCs that only perform functions of low safety significance. Because COL holders are already required to upgrade and maintain a plant-specific PRA prior to loading fuel, the only incremental cost would be that of performing the categorization and the licensing action itself. These are voluntary actions that licensees would only take after deciding they are cost beneficial, and therefore the NRC estimates the net costs of Alternative 2 are due to rulemaking, approximately (\$106,000) using a 7 percent NPV.

2.6.4 Alternative 3: Allow Construction Permit Holders, Combined License Holders, and Design Certification Applicants to Risk-Inform the Categorization of SSCs

2.6.4.1 Impacts on Public Health, Safety, and Security

With Alternative 3, a COL holder might choose to upgrade the plant-specific PRA earlier than required. A CP holder also could use Section 50.69. These actions are voluntary, but if undertaken, would improve public health and safety by allowing these licensees to focus early on SSCs that have greater safety significance. In addition, under Alternative 3, a DC applicant may choose to perform a more detailed and costly PRA than is needed to support deterministic

design. Such action is voluntary. However, if undertaken, it would improve public health, safety, and security by allowing applicants to focus early on SSCs that are most important to safety.

2.6.4.2 Impacts on Applicants and Licensees

Combined license holders might incur the cost of maintaining the PRA and upgrading it even earlier than required by paragraph 50.71(h)(1). This would be offset by the fact that COL holders would be allowed to use Section 50.69 earlier. CP holders would also be able to risk-inform the categorization of SSCs under Section 50.69 by maintaining and upgrading the PRA, and the staff considers these costs and benefits to offset one another as with COL holders. This has the potential to reduce the cost of special treatment for safety-related SSCs that only perform functions of low safety significance. It would improve the focus on safety-significant SSCs. Because implementation of risk-informed categorization and treatment of SSCs is voluntary, it is the prerogative of the licensee to determine whether this would be cost-effective; therefore, the NRC did not estimate these burdens quantitatively.

Reactor vendors might choose to upgrade their PRA to allow for risk-informed categorization and treatment of SSCs under Section 50.69. This could occur earlier than required by paragraph 52.47(a)(27) for a DC. This has the potential to reduce the burden on applicants and licensees, who would no longer need to conduct procurement and testing activities for safety-related SSCs that only perform functions of low safety significance. This would improve the focus on safety-significant SSCs. Because implementation of risk-informed categorization and treatment of SSCs is voluntary, it is the prerogative of the applicant to determine whether this would be cost-effective, and therefore the NRC did not estimate these burdens quantitatively.

2.6.5 Impacts on the NRC

This alternative would allow COL holders to apply for the opportunity to use Section 50.69 before or after the paragraph 52.103(g) finding. CP holders also could use Section 50.69. The NRC would incur the obligation to review such applications, but the incremental impact would be very small. Over the life of the plant, the staff would incur lower costs than under Alternative 1 to inspect and regulate SSCs of low risk significance. In addition, under this alternative, DC applicants would have the opportunity to propose risk-informed categorization and treatment of SSCs under Section 50.69. The NRC would incur the obligation to review such applications, but the incremental impact would be very small. The initial review of safety-related SSCs of low risk significance would be reduced. Over the life of the plant, the staff would incur a lower cost than under Alternative 1 to inspect and regulate SSCs of low risk significance. In addition, during any reviews of COL applications related to the DC, the effort to review these SSCs would be reduced. The NRC chose to consider these costs and averted costs as cancelling one another out and did not estimate them quantitatively. The NRC would incur rulemaking costs with this alternative of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table B-4.

Table B-4 NRC Rulemaking Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

2.6.5.1 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.5.2 Summary of Benefits and Costs

Construction permit holders, combined license holders, and DC applicants would be allowed to use Section 50.69, which has the potential to reduce the cost of special treatment for safety-related SSCs that only perform functions of low safety significance. The earlier this happens, the more substantial the cost savings that will accrue to the licensee. These are voluntary actions that licensees would only take after deciding they are cost beneficial, and therefore the NRC estimates the net costs of Alternative 2 are due to rulemaking, approximately (\$106,000) using a 7 percent NPV.

2.7 Backfitting and Issue Finality

None of the alternatives presented by the NRC in this appendix, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo of not permitting CP holders, COL holders, and DC applicants to implement an alternative regulatory framework for the treatment of SSCs under Section 50.69. Alternative 2 would result in allowing COL holders the option to adopt Section 50.69 after the Commission finds that all acceptance criteria of the license have been met. No new requirements or staff positions would be placed on COL holders under Alternative 2. Alternative 3 would result in allowing COL holders the option to adopt Section 50.69 if the holder has a technically adequate PRA before or after the Commission finds that all ITAAC acceptance criteria of the license have been met. In addition, Alternative 3 would allow CP holders and DC applicants the option to adopt Section 50.69. No new requirements or staff positions would be placed on COL holders or DC applicants under Alternative 3.

2.8 Stakeholder Feedback

2.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

2.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The staff recommends adoption of Alternative 3, “Allow Construction Permit Holders, Combined License Holders, and Design Certification Applicants to Risk-Inform the Categorization of SSCs.” This alternative would allow DC applicants, CP holders, and COL holders to exercise an option that is available to all other applicants under Part 52 and other nuclear power reactor licensees. The staff has sufficient experience to evaluate such requests, if they are submitted.

3.0 MAINTAINING AND UPGRADING THE PLANT-SPECIFIC PROBABILISTIC RISK ASSESSMENT

All COL holders must have a plant-specific PRA for the operational phase under paragraph 50.71(h). Further, to be useful, the PRA must be maintained to be consistent with the as-built, as-operated plant. The PRA must be upgraded to cover initiating events and modes for which consensus standards on PRA are endorsed by the NRC.⁷ Currently, paragraph 50.71(h) requires the COL holder’s PRA to cover the initiating events and modes for which NRC-endorsed consensus standards on PRA exist one year prior to the scheduled date for initial loading of fuel.

When paragraph 50.71(h) was issued in 2007, several consensus standards to address new initiating events and modes were under development. The rule was intended to promote prompt adoption of these standards once they were endorsed. One year was perceived as ample time to do so. Because of changes in the consensus standards on PRA, this may no longer be the case. Moreover, the NRC has already endorsed standards for all initiating events relevant to LWRs, so future applications under Part 52 will have to address them. If the requirement is extended to applications under Part 50, it will apply to all future LWR applications.

In addition, linking the timing of a PRA upgrade to loading fuel makes it possible that identical plants, licensed at the same time, will be required to develop one model for the first plant to be completed, and a different PRA model for a subsequent plant. Requiring licensees to develop, maintain, and upgrade two different PRA models for plants that are essentially identical is unnecessarily burdensome. (One licensee has already requested a license amendment to address this problem.) Regulatory stability would be enhanced if the applicable PRA standards were identified when a CP or COL is issued.

⁷ The NRC has endorsed consensus standards that cannot be met until the as-built configuration of the plant is known (e.g., seismic margins analysis is performed in lieu of a seismic PRA). When the PRA is revised to cover an initiating event or mode that it did not cover before, or to adopt a new method, that is considered an “upgrade.” Consequently, the plant-specific PRA required by 10 CFR 50.71(h)(1) will always be an upgrade. Current standards specify a peer review after an upgrade, but regulations do not require that this peer review be completed prior to the initial loading of fuel.

3.1 Existing Regulatory Framework

Paragraph 50.71(h)(1) requires that each holder of a COL develop a Level 1 and a Level 2 PRA, which is an approach specific to LWRs.⁸ The PRA must be completed before the scheduled date for initial loading of fuel. It must cover the initiating events and modes for which NRC-endorsed consensus standards on PRA exist 1 year prior to that date.

Paragraph 50.71(h)(2) requires that each holder of a COL maintain and upgrade the PRA required by paragraph 50.71(h)(1). The upgraded PRA must cover initiating events and modes of operation contained in NRC-endorsed consensus standards on PRA in effect 1 year prior to each required upgrade. The PRA must be upgraded every 4 years until the permanent cessation of operations under paragraph 52.110(a).

Paragraph 50.71(h)(3) requires that each holder of a COL upgrade the PRA to cover all modes and all initiating events before applying to renew the plant's license.

Paragraph 52.47(a)(27) requires applicants for DCs to include an FSAR with a description of the design-specific PRA and its results.

Paragraph 52.79(a)(46) requires applicants for a COL to include an FSAR with a description of the plant-specific PRA and its results.

Paragraph 52.137(a)(25) requires applicants for an SDA to include an FSAR with a description of the design-specific PRA and its results if the portion of the standard design for which approval is sought can be modeled consistent with endorsed PRA consensus standards.

Paragraph 52.157(f)(31) requires applicants for an ML to include an FSAR containing the information necessary to establish that the design of the reactor to be manufactured complies with the technical requirements in 10 CFR Chapter I, including a description of the design-specific PRA and its results.

3.2 Regulatory Issues

Paragraph 50.71(h) requires COL holders to develop a plant-specific PRA before loading fuel, to upgrade it as necessary, and to maintain it until the permanent cessation of operations. Under Part 50, OL holders are not required to maintain a PRA, even if they have one.⁹ For plants licensed in the future, the lack of a requirement in Part 50 conflicts with the Commission position stated in the PRA Policy Statement that it expects a plant-specific PRA that accurately represents the as-built, as-operated plant to be available to manage risk effectively during the operational phase.

⁸ For LWRs, PRAs are categorized by levels. A Level 1 PRA is a core damage frequency analysis. A Level 2 PRA is a radionuclide release frequency analysis. A Level 3 PRA is a consequence analysis with risk integration. For more information, see "Types of Risk Assessments" in the [NRC fact sheet on probabilistic risk assessment](#).

⁹ An operating license holder may adopt a risk-informed program that the staff approves on the basis of a technically acceptable PRA. When the NRC issues such an amendment, it will normally impose a license condition requiring the licensee to maintain the PRA model to reflect the as-built, as-operated plant in conformance with NRC-endorsed consensus standards for PRA at the time of the amendment request. This condition may be relocated to the administrative controls section of the technical specifications.

Part 52 specifies the scope of the PRA that COL holders must maintain; Part 50 does not. A PRA remains useful only when it reflects the as-built, as-operated plant. Requirements to maintain and upgrade a plant-specific PRA until permanent cessation of operations should apply to every licensee that is required to develop a PRA. Otherwise, during the operational phase the as-built, as-operated plant will likely diverge from the plant reflected in the PRA model.

In addition, paragraph 50.71(h)(2) specifies that upgrades must be performed every 4 years. However, an upgrade is necessary only if the licensee determines that the PRA must cover NRC-endorsed consensus standards on PRA that were not in effect five years earlier. If the licensee determines that no upgrade is needed and does not want to perform one voluntarily, then there is no need to upgrade the PRA. At the end of the next 4-year interval, the evaluation will be repeated.

An upgrade may be needed for any of several reasons, for example:

- NRC endorsement of a new, changed, or enhanced consensus standard
- a particular risk-informed application entails enhanced capability to meet one or more guidelines of a consensus standard.

Finally, an upgrade may also be appropriate because a licensee decides to adopt a new methodology (e.g., for analyzing human error, updating data, quantification, or treatment of common-cause failure).

Deferring an upgrade for a fixed interval is a problem because the plant-specific PRA may not conform to NRC-endorsed PRA standards or use state of the art methods until necessary upgrades are completed. An upgrade should not be deferred once the benefit of performing it is identified.

The scope of the PRA required prior to loading fuel is established one year prior to the scheduled date of loading fuel. Such a short interval made sense when PRA standards were evolving quickly, and PRA models were simpler. Now that standards are more stable and comprehensive (for LWRs), there are fewer and less risk-significant gaps in the risk model and, therefore, less urgency to close the minor gaps that remain.

Linking the scope of the first PRA upgrade to the scheduled date of loading fuel is a problem for another reason. Two identical units licensed at the same time and under construction schedules that overlap may be required to develop two different PRA models. This has the potential to place an undue burden on the licensee based on the timing of the NRC's endorsement of a new or revised standard. There is no commensurate safety benefit.

The problem is exacerbated because upgrading the PRA to meet a recently endorsed standard would be added to the workload of licensee's PRA staff in the final months before loading fuel. The last few months prior to loading fuel already entail a great deal of PRA-related work, including several walkdowns to confirm that the PRA models are adjusted as necessary to reflect the as-built plant.

The length of time required to upgrade a PRA to a new consensus standard is now significantly longer than it was when paragraph 50.71(h) was issued. Consensus standards in PRA now include processes for peer review as well as resolution of facts and observations documented

during that process. Consequently, licensees could be challenged to meet current regulations because licensees may have only one year to complete work that is now expected to take longer.

Current requirements dictate upgrading the PRA according to a calendar cycle. This is a problem because the safety benefit of an upgrade is delayed for some licensees, while others may not have enough time to complete the upgrade without licensing action (e.g., an exemption request). There is no safety basis for this method of scheduling upgrades. Moreover, schedule constraints fall on licensees unequally, based on when they happened to schedule the initial loading of fuel and when the NRC happens to endorse a standard. Licensees with more than one unit must upgrade them on independent schedules even if the units are identical. This is a regulatory burden that has no safety benefit.

3.3 Discussion of Alternatives

3.3.1 Alternative 1: No-Action

3.3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework.

3.3.1.2 Assessment of Alternative 1

Combined license holders would continue to be required to upgrade the plant-specific PRA to cover initiating events and modes for which new or revised consensus standards for PRA had been endorsed by the NRC one year prior to the scheduled date for the initial loading of fuel. Subsequent upgrades would still be required every four years.

Upgrades would continue to be based on the calendar, tied to the initial loading of fuel for each unit. This would perpetuate the regulatory burden without commensurate safety benefit.

3.3.2 Alternative 2: Apply Consensus Standards Endorsed Prior to Issuance of a Construction Permit or Combined License

3.3.3 Description of Alternative 2

Under this alternative, the NRC would amend its regulations to require future CP and COL holders to upgrade the plant-specific PRA to cover all initiating events and modes endorsed by the NRC when the CP or COL is issued. This allows licensees to defer upgrades that might be needed to address consensus standards that have been endorsed by the NRC during construction. The plant-specific PRA would need to be upgraded to address new or revised consensus standards endorsed during the period of construction within five years after the initial loading of fuel.

3.3.4 Assessment of Alternative 2

This rulemaking alternative would allow CP and COL holders to defer upgrading the plant-specific PRA to cover initiating events and modes for which new or revised consensus standards in PRA are endorsed by the NRC during the construction phase. Because the NRC has already endorsed consensus standards to address all initiating events at full power, and because other regulations address the management of risk in other modes, there is adequate

assurance that risk will be managed until the plant-specific PRA is upgraded to address all endorsed standards.

3.3.5 *Alternative 3: Apply Consensus Standards Endorsed Prior to Issuance of a Construction Permit or Combined License and Revise the Schedule for Upgrading the PRA*

3.3.5.1 *Description of Alternative 3*

Under this alternative, the NRC would amend its regulations to require future CP and COL holders to upgrade the plant-specific PRA to cover all initiating events and modes endorsed by the NRC when the CP and COL was issued. The plant-specific PRA would need to be upgraded to address new or revised consensus standards endorsed during the period of construction within five years after the initial loading of fuel. Subsequent upgrades would be required within five years of NRC endorsement of a new or revised consensus standard in PRA. Upgrades would also be required with a change in methodology.

3.3.5.2 *Assessment of Alternative 3*

This rulemaking alternative would allow CP and COL holders to defer upgrading the plant-specific PRA to cover initiating events and modes for which new or revised consensus standards in PRA are endorsed by the NRC during the construction phase. Because the NRC has already endorsed consensus standards to address all initiating events at full power, and because other regulations address the management of risk in other modes, there is adequate assurance that risk will be managed.

In addition, this alternative would make requirements for subsequent upgrades apply more uniformly to all licensees who rely on PRA for plant design changes, operation, and maintenance. It would simplify the upgrading of PRA models for multiple units licensed at the same time; over the life of the plant, most upgrade schedules would no longer be tied to the scheduled date for initial loading of fuel.

3.4 **Regulatory Scope**

Under Alternative 2, prior to the scheduled date for the initial loading of fuel, holders of licenses issued after the effective date of this rulemaking's final rule would be required to develop a plant-specific PRA that covers initiating events and modes for which consensus standards are endorsed by the NRC as of the date when a CP or COL is issued. The endorsement of consensus standards during the construction phase would not affect the PRA required by paragraph 50.71(h)(1). Licensees would have a fixed interval after loading fuel to upgrade the plant-specific PRA to address initiating events and modes for which new or revised standards have been endorsed since the plant's CP or COL was issued.

Under Alternative 3, paragraph 50.71(h)(2) would require licensees in the operational phase that are required to have a plant-specific PRA to upgrade it within a fixed interval after the NRC endorses a new or revised PRA standard. Licensees that decide to adopt a new PRA method would also have a fixed interval during which to complete an upgrade to the PRA model.

3.5 NRC Guidance, Policy, and Implementation Issues

No new regulatory guidance on PRA would be needed. Existing guidance on PRA is sufficient.¹⁰ The scope of regulatory guidance may need to be extended to COL holders. Affected RGs include the following:

- **RG 1.200**, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities”
- **RG 1.201**, “Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance.”

No change in Commission policy is required. No conflict between policies has been identified.

3.6 Impacts

3.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing licensing process, as described in the current regulation and guidance. The NRC would not pursue any changes in regulation or guidance.

3.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

3.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants and licensees.

3.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

3.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

¹⁰ DC/COL-ISG-028, “Interim Staff Guidance on Assessing the Technical Adequacy of the Advanced Light-Water Reactor Probabilistic Risk Assessment for the Design Certification Application and Combined License Application,” identifies high-level and supporting requirements of the standard that apply to applications for DCs and COLs. It would apply to applications for CPs, as well.

3.6.2 *Alternative 2: Apply Consensus Standards Endorsed Prior to Issuance of a Construction Permit or Combined License*

The NRC has already endorsed consensus standards for PRA that cover all initiating events for LWRs. If a standard that addresses a new mode of operation is issued during construction or if a revised standard is endorsed, then an upgrade would be required once the initial fuel load is completed. This would be a negligible delay to the upgrade, comparable to what is allowed for some licensees under current regulations.

Other regulations provide reasonable assurance that public health, safety, and security are maintained in modes for which consensus standards have not yet been endorsed, for example, Section 50.65, “Requirements for monitoring the effectiveness of maintenance at nuclear power plants.”

3.6.2.1 *Impacts on Public Health, Safety, and Security*

This alternative would defer the requirement to upgrade the PRA to meet consensus standards endorsed after a COL or CP is issued. Because endorsed consensus standards already cover all initiating events for LWRs, this would have only a small effect, and other regulations address risk when plants are in modes for which standards have not yet been endorsed. There would be no reduction in public health, safety, and security.

3.6.2.2 *Impacts on Applicants and Licensees*

This alternative would reduce the burden on applicants and licensees, deferring the requirement to address PRA standards endorsed during construction. This alternative would allow for deferral without the need for an exemption request, which the NRC estimates take licensees approximately 200 labor hours to prepare and submit. The NRC assumed Alternative 2 could result in one averted exemption request in 2027 and another in 2030; therefore, the averted costs to licensees of alternative 2 are approximately \$30,000 (7 percent NPV) and \$43,000 (3 percent NPV), as shown in Table B-5.

Table B-5 Industry Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2027	Averted exemption request from licensee	1	212	\$134	\$28,457	\$16,562	\$22,464
2030	Averted exemption request from licensee	1	212	\$134	\$28,457	\$13,520	\$20,558
Total:					\$56,913	\$30,082	\$43,022

3.6.2.3 *Impacts on the NRC*

The NRC would incur rulemaking costs under this alternative but would not need to expend resources on reviewing exemption requests as discussed above. Alternative 2 would result in costs to the NRC of approximately (\$92,000) using a 7 percent NPV and (\$101,000) using a 3 percent NPV, as shown in Table B-6.

Table B-6 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2027	Averted NRC review of exemption request	1	102	\$131	\$13,350	\$7,770	\$10,538
2030	Averted NRC review of exemption request	1	102	\$131	\$13,350	\$6,342	\$9,644
Total:					(\$108,719)	(\$91,627)	(\$101,280)

3.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 Summary of Benefits and Costs

For licensees, regulatory uncertainty would be eliminated. There would be no reason to seek exemption from regulations to address requirements that are affected by NRC actions that are beyond the control of licensees. Alternative 2 would result in incremental costs to licensees and the NRC of approximately (\$62,000) using a 7 percent NPV and (\$58,000) using a 3 percent NPV.

3.6.3 Alternative 3: Apply Consensus Standards Endorsed Prior to Issuance of a Construction Permit or Combined License and Revise the Schedule for Upgrading the PRA

This alternative would have little impact on public health, safety, or security. It makes upgrade schedule requirements uniform for all licensees in the operational phase, rather than the current system which imposes schedules ranging from little more than one year to nearly five years, based solely on the date on which the NRC endorses a consensus standard and the date on which a licensee scheduled initial loading of fuel.

3.6.3.1 Impacts on Public Health, Safety, and Security

This alternative would have the same impact as Alternative 2.

3.6.3.2 Impacts on Applicants and Licensees

This alternative would eliminate the variation in the amount of time licensees have to cover initiating events and modes of operation addressed in new or revised consensus standards for PRA. It would have no incremental impacts on applicants and licensees, other than eliminating the potential for the need to request an exemption request, which the NRC estimates takes licensees approximately 200 labor hours to prepare and submit. The NRC assumed Alternative 3 could result in one averted exemption request in 2027 and another in 2030; therefore, the averted costs to licensees of Alternative 3 would be approximately \$30,000 (7 percent NPV) and \$43,000 (3 percent NPV), as shown in Table B-7.

Table B-7 Licensee Averted Costs, Alternative 3

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2027	Averted exemption request from licensee	1	212	\$134	\$28,457	\$16,562	\$22,464
2030	Averted exemption request from licensee	1	212	\$134	\$28,457	\$13,520	\$20,558
Total:					\$56,913	\$30,082	\$43,022

3.6.3.3 Impacts on the NRC

The NRC would incur rulemaking costs in this alternative but would not need to expend resources on reviewing exemption requests as discussed above. Alternative 2 would result in costs to the NRC of approximately (\$92,000) using a 7 percent NPV and (\$101,000) using a 3 percent NPV, as shown in Table B-8.

Table B-8 NRC Costs and Averted Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2027	Averted NRC review of exemption request	1	102	\$131	\$13,350	\$7,770	\$10,538
2030	Averted NRC review of exemption request	1	102	\$131	\$13,350	\$6,342	\$9,644
Total:					(\$108,719)	(\$91,627)	(\$101,280)

3.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.3.5 Summary of Benefits and Costs

For licensees, regulatory uncertainty would be eliminated. There would be no reason to seek exemption from regulations to address requirements that are affected by NRC actions that are beyond the control of licensees. Alternative 3 would result in incremental costs to licensees and the NRC of approximately (\$62,000) using a 7 percent NPV and (\$58,000) using a 3 percent NPV.

3.7 Backfitting and Issue Finality

None of the alternatives presented by the NRC in this appendix, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo of requiring upgrades to the PRA based on the date of NRC endorsement of a consensus standard and the scheduled date of the initial loading of fuel. Alternatives 2 and 3 would only apply to applications for a CP or COL submitted after the effective date of this rulemaking’s final rule and would not affect a DC or early site permit referenced in a COL application.

3.8 Stakeholder Feedback

3.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, the Nuclear Energy Institute (NEI) made a presentation about its suggestions for this rulemaking. Comments related to paragraph 50.71(h) were consistent with Alternatives 2 and 3.

3.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The staff recommends adoption of Alternative 3, “Apply Consensus Standards Endorsed Prior to Issuance of a Construction Permit or Combined License and Revise the Schedule for Upgrading the PRA.” First, licensees that are required to have a PRA should cover the initiating events and modes for which consensus standards have been endorsed prior to issuance of a CP or COL. Consensus standards endorsed by the NRC during plant construction need not be addressed until after the initial loading of fuel. Second, when upgrading of the PRA is required, instead of varying between one year and five years without a specific basis, the schedule will be the same for all licensees.

APPENDIX C – THREE MILE ISLAND REQUIREMENTS

The introductory paragraph to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities” (TN249), paragraph 50.34(f), “Additional TMI-related requirements” limits its applicability to two groups of applicants:

- applicants for a construction permit (CP) or manufacturing license (ML) whose application was pending as of February 16, 1982, all of whom no longer have active applications; and
- applicants for a standard design certification (DC), standard design approval (SDA), combined license (COL), or ML under 10 CFR Part 52, “Licenses, Certifications, and Approvals of Nuclear Power Plants,” (TN251) with certain exceptions described in Part 52.

Therefore, new CP and operating license (OL) applicants under Part 50, “Domestic Licensing of Production and Utilization Facilities,” are not currently required to comply with the additional Three Mile Island (TMI) items in paragraph 50.34(f).

The U.S. Nuclear Regulatory Commission (NRC) is considering revising paragraph 50.34(f) via rulemaking so that the TMI requirements in paragraph 50.34(f) apply to new power reactor applications submitted under Part 50, with the same exceptions given for Part 52 applicants. The NRC has not completed, for this regulatory basis, an assessment of the value of applying these requirements to future non-light water reactor (non-LWR) applications, but could clarify these requirements as part of the proposed rule.

In addition, the NRC is considering deleting a requirement in paragraph 50.34(f)(2)(i) that is addressed in 10 CFR Part 55, “Operators’ Licenses” (TN6229), Section 55.46, “Simulation facilities.”

1.0 EXISTING REGULATORY FRAMEWORK

Paragraph 50.34(f) requires applicants for a DC, SDA, COL, or ML to provide information necessary to demonstrate compliance with any technically relevant positions of the requirements in paragraphs 50.34(f)(1) through (3), with the exception of paragraphs 50.34(f)(1)(xii), (f)(2)(ix), and (f)(3)(v). Paragraph 50.34(f)(1)(xii) requires an applicant to perform an evaluation of alternative hydrogen control systems, paragraph 50.34(f)(2)(ix) requires an applicant to provide a system for hydrogen control that can safely accommodate hydrogen generated by the equivalent of a 100 percent fuel-clad metal-water reaction, and paragraph 50.34(f)(3)(v) requires that containment integrity will be maintained during an accident that releases hydrogen generated from 100 percent fuel-clad metal-water reaction accompanied by either hydrogen burning or the added pressure from post-accident inerting.

In the “Combustible Gas Control in Containment” final rule (68 FR 54123, September 16, 2003; TN6230), the Commission consolidated in Section 50.44 the combustible gas control requirements for all future applicants for or holders of a CP or an OL under Part 50, and all future applicants for DCs, SDA, COLs, and MLs under Part 52. In the 2007 Part 52 final rule, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (72 FR 49352, August 28, 2007; TN4796), the Commission included in several new sections of Part 52 specific exceptions from the combustible gas control requirements in paragraph 50.34(f) for DC, SDA, COL, and ML applicants because they were required by Section 50.44 to comply with the combustible gas control requirements. Paragraphs 52.47(a)(8) (for DC applicants), 52.137(a)(8) (for SDA

applicants), 52.79(a)(17) (for COL applicants), and 52.157(f)(12) (for ML applicants) contain the paragraph 50.34(f) requirements and exceptions.

Under paragraph 52.79(a)(17), applicants for a COL are excepted from paragraph 50.34(f)(2)(xxv). Instead, the requirements in Appendix E, Section IV.E.8.a(i) apply as required under paragraph 52.79(a)(21). Paragraph 50.34(f)(2)(xxv) requires a CP or ML applicant whose application was pending on February 16, 1982, or a DC, SDA, COL, or ML applicant under Part 52, to describe how it will provide an onsite Technical Support Center and an onsite Operational Support Center. It also requires that a CP applicant whose application was pending on February 16, 1982, to describe how it will provide a near site Emergency Operations Facility.

Also, paragraph 50.34(f)(2)(i) requires applicants for a DC, SDA, COL, or ML to provide simulator capability that correctly models the control room and includes the capability to simulate small-break loss-of-coolant accidents (LOCAs). Similar requirements are found in Section 55.46 for CP, OL, and COL applicants and licensees. Section 55.46 contains requirements for the use of a simulation facility for the administration of the Part 55 operating test and plant-referenced simulators to meet experience requirements for applicants for operator and senior operator licenses. Specifically, paragraph 55.46(c)(1) provides requirements to simulate small-break LOCAs:

A plant-referenced simulator used for the administration of the operating test or to meet experience requirements in § 55.31(a)(5) must demonstrate expected plant response to operator input and to normal, transient, and accident conditions to which the simulator has been designed to respond. The plant-referenced simulator must be designed and implemented so that it: ... (i) Is sufficient in scope and fidelity to allow conduct of the evolutions listed in §§ 55.45(a)(1) through (13), and 55.59(c)(3)(i)(A) through (AA), as applicable to the design of the reference plant....

Included in paragraph 55.59(c)(3)(i)(G) is “Loss of coolant, including — (3) Large and small, including leak-rate determination.” In addition, “plant-referenced simulator” is defined in Section 55.4, “Definitions,” as “a simulator modeling the systems of the reference plant with which the operator interfaces in the control room, including operating consoles, and which permits use of the reference plant's procedures.”

Section 55.2, “Scope,” states in part that the regulations in Part 55 are applicable to “any facility license,” where “facility” is defined in Section 55.4 as “any utilization facility as defined in Part 50 of this chapter.” A “Utilization facility” is defined in Section 50.2 to mean “(1) Any nuclear reactor other than one designed or used primarily for the formation of plutonium or U-233; or (2) An accelerator-driven subcritical operating assembly used for the irradiation of materials containing special nuclear material and described in the application assigned docket number 50-608.”

2.0 REGULATORY ISSUES

An inconsistency exists between Parts 50 and 52 regarding the submittal of information under paragraph 50.34(f). Additionally, a regulatory and safety assessment of the need for applying the TMI requirements to non-LWRs has not been completed for this regulatory basis. As described above, applicants for a DC, SDA, COL, or ML under Part 52 are required to submit information in paragraph 50.34(f) with certain exceptions described in Part 52, while applicants under Part 50 are not required to submit the information in paragraph 50.34(f). In recognition of

this inconsistency in paragraph 50.34(f) requirements, in SRM-SECY-15-0002 (NRC 2015-TN6217), the Commission endorsed rulemaking to align Parts 50 and 52.

One of the requirements for CP applicants with pending applications when paragraph 50.34(f) was issued was the requirement in paragraph 50.34(f)(2)(i). This requirement was later added to Section 55.46 in the "Operators' Licenses and Conforming Amendments" final rule (52 FR 9453, March 25, 1987; TN6231). Therefore, because paragraph 50.34(f) applies to DC, SDA, COL, and ML applicants and Section 55.46 applies to CP, OL, and COL applicants, paragraph 50.34(f)(2)(i) is redundant for COL applicants. If the NRC undertakes a rulemaking to make the requirements in paragraph 50.34(f) applicable to all new Part 50 applicants, then paragraph 50.34(f)(2)(i) would become redundant to Section 55.46 for CP and OL applicants, too.

Furthermore, an inconsistency exists between Parts 50 and 55 for DC, SDA, and ML applicants. These applicants must comply with the simulator capability requirement in paragraph 50.34(f)(2)(i); however, requirements for simulation facilities in Part 55 are not applicable to DC, SDA, or ML applicants. These applicants are not facility licensees, which are authorized to operate a nuclear power reactor, so these applicants would not need or require training and qualification of licensed operators under Part 55. Therefore, DC, SDA, and ML applicants are not required to comply with the requirements in Part 55 for operators' licenses.

3.0 DISCUSSION OF ALTERNATIVES

3.1 Alternative 1: No-Action

3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework.

3.1.2 Assessment of Alternative 1

This alternative would maintain the status quo. The inconsistencies between Parts 50 and 52 described above would remain and the intent of SECY-15-0002 to align Parts 50 and 52 regarding the requirements of paragraph 50.34(f) would not be fulfilled. Also, the requirement in paragraph 50.34(f)(2)(i) would continue to be redundant to Section 55.46 for COL applicants, and an inconsistency between Parts 50 and 55 would remain for DC, SDA, and ML applicants.

3.2 Alternative 2: Rulemaking to Align the Regulations

3.2.1 Description of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to revise paragraph 50.34(f) such that it would apply to new power reactor applications submitted under Part 50 with the same exceptions given for Part 52 applicants. Specifically, CP and OL applicants would be excepted from paragraphs 50.34(f)(1)(xii), (f)(2)(ix), (f)(2)(xxv), and (f)(3)(v). Also, the requirement in paragraph 50.34(f)(2)(i) would be deleted from paragraph 50.34(f). The NRC would also conduct a regulatory and safety assessment to determine which TMI requirements may be applicable to non-LWRs and apply those needed to address safety and risk issues not covered by other existing regulations and guidance.

3.2.2 *Assessment of Alternative 2*

Alternative 2 would revise the current regulations in Part 50 to align them with Part 52. A Part 50 applicant would provide the same information as a Part 52 applicant. Also, the Part 50 applicant would be excepted from paragraphs 50.34(f)(1)(xii), (f)(2)(ix), (f)(2)(xxv), and (f)(3)(v), the same as a Part 52 applicant.

Also, CP, OL and COL applicants would address the simulator requirements in Section 55.46 only, instead of Section 55.46 and paragraph 50.34(f)(2)(i). There would no longer be an inconsistency between Parts 50 and 55, so DC, SDA, and ML applicants would not need to address requirements for simulator capability currently in paragraph 50.34(f)(2)(i).

4.0 REGULATORY SCOPE

Under Alternative 2, paragraph 50.34(f) would be amended to apply to new power reactor applications submitted under Part 50 with the same exceptions given for Part 52 applicants. The simulator requirements in paragraph 50.34(f)(2)(i) that also appear in Section 55.46 would be deleted from paragraph 50.34(f).

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

Under Alternative 2, the same guidance used for a Part 52 submittal would be used for a Part 50 submittal, and this would need to be updated and reflected in the current guidance. No new regulatory guidance would need to be developed.

No change in Commission policy is required. No conflict between policies has been identified.

6.0 IMPACTS

6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing licensing process as described in the current regulations and guidance. The NRC would not pursue any changes.

6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees.

6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.1.5 *Summary of Costs and Benefits*

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would undertake a rulemaking to revise paragraph 50.34(f) as described in Section 3.2.2, “Assessment of Alternative 2” of this appendix.

6.2.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would require an applicant submitting under Part 50 to follow paragraph 50.34(f), with the same exceptions as an applicant submitting under Part 52, the impacts on public health, safety, and security would be positive.

In addition, although this alternative would result in deletion of simulator capability requirements from paragraph 50.34(f)(2)(i), this requirement and others related to nuclear power plant simulation facilities would remain in Part 55.

6.2.2 *Impacts on Licensees*

The rulemaking alternative would require Part 50 applicants to follow paragraph 50.34(f), as Part 52 applicants already have to do, resulting in some additional requirements for Part 50 applicants. However, some of the provisions in paragraph 50.34(f) exist elsewhere in 10 CFR Chapter I (TN6351), and are already required of Part 50 applicants. In a review of these requirements, the NRC staff estimates that approximately 10 would need to be addressed in the application process as a result of Alternative 2, with applicants needing approximately 57 hours to address each item. The staff is using an assumption of one applicant in 2024, another in 2027, and a third in 2030, throughout this regulatory basis where applicable. This results in estimated incremental costs of (\$140,000) using a 7 percent NPV and (\$187,000) using a 3 percent NPV, shown in Table C-1, below. The staff considers these costs to be justified by the benefit of aligning the Parts 50 and 52 processes by requiring the use of paragraph 50.34(f) for both, providing regulatory certainty and clarity.

Table C-1 Industry Part 50 Applicant Costs to Address New Provisions

Year	Activity	Number of Actions	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Industry address TMI requirements	10	57	\$134	(\$78,634)	(\$56,065)	(\$67,830)
2027	Industry address TMI requirements	10	57	\$134	(\$78,634)	(\$45,766)	(\$62,074)
2030	Industry address TMI requirements	10	57	\$134	(\$78,634)	(\$37,358)	(\$56,807)
Total:					(\$235,902)	(\$139,189)	(\$186,712)

This alternative would also reduce the regulatory burden for COL, CP, and OL applicants because the requirement in paragraph 50.34(f)(2)(i) that is now redundant to requirements under this alternative, would be deleted and therefore would not need to be addressed more than once in applications. This alternative would also reduce the regulatory burden for DC, SDA, and ML applicants by deleting the requirement in paragraph 50.34(f)(2)(i), which these applicants do not need to address.

6.2.3 Impacts on the NRC

There would be an impact on the NRC because the NRC would review an application submitted under Part 50 using the same requirements as they do now for an application submitted under Part 52. For each additional requirement that applicants address, described in the previous section, the NRC would have a corresponding review taking approximately 23 hours. The NRC considers that these costs will be justified by the benefit of aligning the Parts 50 and 52 application processes as discussed previously in this appendix.

The NRC would incur costs for this alternative, estimated to be approximately (\$160,000) using a 7 percent net present value (NPV) and (\$194,000) using a 3 percent NPV, as shown in Table C-2.

Table C-2 NRC Rulemaking Costs

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2024	NRC review TMI requirement responses	10	23	\$131	(\$30,458)	(\$21,716)	(\$26,273)
2027	NRC review TMI requirement responses	10	23	\$131	(\$30,458)	(\$17,727)	(\$24,043)
2030	NRC review TMI requirement responses	10	23	\$131	(\$30,458)	(\$14,470)	(\$22,003)
Total:					(\$226,791)	(\$159,652)	(\$193,782)

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 Summary of Costs and Benefits

This rulemaking alternative would result in an increase in costs for licensees, applicants, and the NRC. The NRC asserts these potential cost increases would be small and balanced by the benefits of regulatory certainty, clarity, and reduced burden on applicants from deleting paragraph 50.34(f)(2)(i). This rulemaking alternative would result in costs to the NRC and industry estimated to be approximately (\$299,000) using a 7 percent NPV.

7.0 BACKFITTING AND ISSUE FINALITY

Neither of the alternatives presented by the NRC in this appendix would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to paragraph 50.34(f), thereby imposing no change in requirements or NRC staff positions. Alternative 2 would require applications for CPs and OLs submitted after the effective date of this rulemaking's final rule to include information regarding paragraph 50.34(f) with the same exceptions given to a Part 52 applicant. These CP and OL applicants would not be within the scope of Section 50.109. Alternative 2 also would remove redundancies and an inconsistency in the regulations, thereby imposing no change in requirements or NRC staff positions.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, "Rulemaking to Align the Regulations," to revise paragraph 50.34(f) to (1) require future Part 50 applicants to provide information regarding paragraph 50.34(f) with the same exceptions given to an applicant that submits under Part 52; and (2) remove redundancies and an inconsistency between paragraph 50.34(f)(2)(i) and Section 55.46. Additionally, the NRC would conduct a regulatory and safety assessment to determine which TMI requirements may be applicable to non-LWRs and apply those needed to address safety and risk issues not covered by other existing regulations and guidance. While this alternative is not cost beneficial, the staff considers that the qualitative benefits of requiring applicants to submit the equivalent technical information independent of which licensing process is used in addition to improved regulation clarity and regulatory certainty may offset the quantified costs.

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APPENDIX D – DESCRIPTION OF FIRE PROTECTION DESIGN FEATURES AND FIRE PROTECTION PLANS

Under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251), applicants for a standard design certification (DC), combined license (COL), standard design approval (SDA), or a manufacturing license (ML) are required to provide information describing the fire protection design features necessary to comply with 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” (TN249), Appendix A, “General Design Criteria for Nuclear Power Plants,” Criterion (GDC) 3, “Fire protection,” and Section 50.48, “Fire protection”. In addition, under Part 52, an applicant for a COL is required to describe how its fire protection program will be implemented.

Under Section 50.34, “Contents of applications; technical information,” there is no explicit similar requirement for an applicant for a construction permit (CP) or an operating license (OL).

In SRM-SECY-15-0002 (NRC 2015-TN6217), the Commission directed the staff to revise the regulations in Part 50 for new power reactor applications to more closely align with requirements in Part 52 by incorporating the requirements identified by the staff in SECY-15-0002 (NRC 2015-TN6209).

1.0 EXISTING REGULATORY FRAMEWORK

The primary objectives of fire protection programs at U.S. nuclear power plants are to minimize the probability of occurrence and the consequences of fire. To meet these objectives, the fire protection programs for nuclear power plants are designed to provide reasonable assurance, through defense-in-depth, that a fire will not prevent the necessary safe-shutdown functions from being performed and that if a fire occurs, then radioactive releases to the environment will be minimized.

The regulatory framework that the NRC has established for nuclear power plant fire protection programs consists of GDC 3, as described in Section 50.48.

1.1 Fire Protection Requirements Under Part 50

Paragraph 50.48(a)(1) requires that each holder of an OL issued under Part 50 or a COL issued under Part 52 must have a fire protection plan that satisfies GDC 3. This fire protection plan must describe the overall fire protection program for the facility; identify the various positions within the licensee's organization that are responsible for the program; state the authorities that are delegated to each of these positions to implement those responsibilities; and outline the plans for fire protection, fire detection and suppression capability, and limitation of fire damage.

Paragraph 50.48(a)(2) requires that the fire protection plan must describe specific features necessary to implement the program such as 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 structures, systems, and components (SSCs) important to safety so that the capability to shut down the plant safely is ensured.

Paragraph 50.48(a)(4) states that each applicant for a SDA, DC, or ML under Part 52 must have a description and analysis of the necessary fire protection design features for the standard plant to demonstrate compliance with GDC 3.

The introductory paragraph to Appendix A of Part 50 states that an application for a CP, DC, COL, SDA, or ML, must include the principal design criteria for a proposed facility. The principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety, which are SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. The GDC in Appendix A of Part 50 establish minimum requirements for the principal design criteria for water-cooled nuclear power plants similar in design and location to plants for which CPs have been issued by the Commission.

GDC 3 states that SSCs important to safety shall be designed and located to minimize, consistent with other safety requirements, the probability and effect of fires and explosions. Noncombustible and heat-resistant materials shall be used wherever practical throughout the unit, particularly in locations such as the containment and control room. Fire detection and firefighting systems of appropriate capacity and capability shall be provided and designed to minimize the adverse effects of fires on SSCs important to safety. Firefighting systems shall be designed to ensure that their rupture or inadvertent operation does not significantly impair the safety capability of these SSCs.

Part 50 is based upon the two-step licensing process whereby certain important information is submitted at the CP stage and then supplemented with more detailed information at the OL stage. Section 50.34 describes the information that should be in the application when the applicant is applying for a CP and an OL.

For the CP phase, paragraph 50.34(a)(3)(i) states that the preliminary design of the facility must be submitted including the principal design criteria of the facility, which, at minimum, include the GDC in Appendix A of Part 50. Therefore, a CP applicant must address GDC 3, which relates to fire protection.

For the OL phase, paragraph 50.34(b) does not require an OL applicant to provide the information required by paragraphs 50.48(a)((1)-(2). Although an OL applicant would not be required by regulation to provide this information, these applicants would need to provide this information to enable the NRC to make its adequate protection determination under the Atomic Energy Act (42 U.S.C. § 2011 *et seq.*; TN663).

1.2 Fire Protection Requirements Under Part 52

For a DC application, paragraph 52.47(a)(18) requires the applicant to provide a description and analysis of the fire protection design features for the standard plant necessary to comply with GDC 3 and Section 50.48.

For a COL application, paragraph 52.79(a)(6) requires the applicant to provide a description and analysis of the fire protection design features for the nuclear power reactor necessary to comply with GDC 3 and Section 50.48. In addition, paragraph 52.79(a)(40) requires the applicant to provide a description of the fire protection program required by Section 50.48 and its implementation.

For an SDA application, paragraph 52.137(a)(18) requires the applicant to provide a description and analysis of the fire protection design features for the standard plant necessary to comply with GDC 3 and Section 50.48.

For an ML application, paragraph 52.157(f)(2), requires the applicant to provide a description and analysis of the fire protection design features for the nuclear power reactor necessary to comply with GDC 3 and Section 50.48.

2.0 REGULATORY ISSUES

An inconsistency exists between Parts 50 and 52 regarding how the NRC requests information about fire protection from an applicant. Part 52 contains regulations that require COL, DC, SDA, and ML applicants to provide a description and analysis of the fire protection design features necessary to comply with GDC 3 and Section 50.48. Under Part 50, for the CP phase, paragraph 50.34(a)(3)(i) only requires that the preliminary safety analysis report include the preliminary design of the facility including the principal design criteria of the facility. Although the principal design criteria include the GDC, and therefore GDC 3, the requirement in paragraph 50.34(a)(3)(i) lacks the specificity of the Part 52 requirements to provide a description and analysis of the fire protection design features necessary to comply with GDC 3.

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

3.0 DISCUSSION OF ALTERNATIVES

3.1 Alternative 1: No-Action

3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework.

3.1.2 Assessment of Alternative 1

Although Part 50 applicants provide fire protection information to enable the NRC to make its adequate protection determination, inconsistencies between Parts 50 and 52 would preclude fulfillment of the intent of SECY-15-0002 in aligning Parts 50 and 52 regarding fire protection. These inconsistencies could lead to inefficiencies and unpredictability for the Part 50 applicant and the possibility of the NRC issuing requests for additional information after an application is submitted. It may also require the NRC to have more interactions with a future applicant in pre-submittal meetings to discuss the information the NRC needs to make its safety finding.

3.2 Alternative 2: Perform Rulemaking to Clarify the Current Requirement in Part 52 to Part 50 Applicants

3.2.1 *Description of Alternative 2*

Under Alternative 2, the NRC would pursue rulemaking to revise paragraphs 50.34(a) and (b). This revision would clarify the information regarding fire protection that an applicant under Part 50 would submit for a CP or OL.

3.2.2 *Assessment of Alternative 2*

Alternative 2 would revise the current regulations in paragraphs 50.34(a) and (b). The changes would improve the clarity, consistency, and alignment of new nuclear power reactor licensing requirements between Parts 50 and 52. It would ensure the greatest degree of public participation in amending the requirements and provide greater clarity regarding the standards and processes to be applied to a new Part 50 license application. Setting clear requirements in the NRC's regulations also would help stakeholders considering new nuclear power reactor license applications to make well-informed decisions regarding which licensing process is best suited to their specific needs. This alternative would also fulfill the intent of SECY-15-0002 by aligning Parts 50 and 52 regarding fire protection.

4.0 REGULATORY SCOPE

Under Alternative 2, paragraph 50.34(a) would be amended to add a section requiring the applicants for a CP to provide information about how the fire protection design features comply with GDC 3, and paragraph 50.34(b) would be amended to add a section requiring the applicants for an OL to provide information about how the fire protection design features comply with GDC 3 and Section 50.48.

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

5.1 NRC Guidance

If Alternative 1 is adopted, then no regulatory guidance would need to be developed.

If Alternative 2 is adopted, then no regulatory guidance would need to be developed. This alternative would only align the wording in Part 50 to more clearly match the wording in Part 52.

5.2 Policy Issues

There are no policy issues because there would be no changes to the fire protection requirements.

6.0 IMPACTS

This section analyzes the two alternatives for the revision of Part 50 to more clearly match the wording in Part 52 to minimize applicant confusion.

6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing new nuclear power reactor licensing process as described in the current regulations and guidance.

6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

6.1.2 Impacts on Applicants and Licensees

If no action is taken to clarify the regulations, a future applicant submitting under Part 50 would need to interpret what information is required in both stages of the application. This ambiguity could lead to inefficiencies and unpredictability for the applicant. The applicant may also need to participate in additional pre-submittal meetings with the NRC in order to understand the information submittal requirements related to fire protection information.

6.1.3 Impacts on the NRC

If the applicant does not provide the correct or sufficient information regarding fire protection because of the lack of clarity in the rule, the NRC may be required to participate in additional pre-submittal meetings with the applicant or issue requests for additional information after an application is submitted, or both.

6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 Alternative 2: Perform Rulemaking to Apply the Current Requirement in Part 52 to Part 50 Applicants

Under this alternative, the NRC would undertake a rulemaking to make changes to Section 50.34 to align it with Part 52.

6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would involve only the alignment of Part 50 with that of Part 52 and would not impose any new requirements on Part 50 applicants, there would be no change in public health, safety, and security.

6.2.2 Impacts on Licensees

For a new submittal under Part 50, this alternative may result in a cost savings to licensees by adding clarity to information requirements regarding fire protection that has not been already quantified. There would be no changes in regulatory requirements.

6.2.3 Impacts on the NRC

The NRC may incur reduced administrative burden associated with new nuclear power reactor license reviews by increasing the clarity of NRC's regulations by more clearly matching the wording in Part 50 to that of Part 52. The NRC would incur rulemaking costs estimated to be approximately (\$65,000) using a 7 percent net present value (NPV) and (\$74,000) using a 3 percent NPV, as shown in Table D-1.

Table D-1 NRC Rulemaking Costs

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
Total:					(\$81,937)	(\$64,846)	(\$73,925)

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 Summary of Costs and Benefits

The industry would benefit from increased clarity of requirements and the NRC may benefit from reduced administrative burden under this alternative. The NRC would incur rulemaking costs of approximately (\$65,000) using a 7 percent NPV.

7.0 BACKFITTING AND ISSUE FINALITY

Neither of the alternatives presented by the NRC in this appendix, if implemented, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to Section 50.34, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would require Part 50 applicants to meet the same application information requirements concerning fire protection that Part 52 applicants must satisfy. A CP applicant would not be within the scope of the backfitting provision in Section 50.109. Alternative 2 would not require an OL applicant to change its CP, so Alternative 2 would not constitute backfitting for an OL applicant.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, "Perform Rulemaking to Clarify the Current Requirement in Part 52 to Part 50 Applicants," to amend paragraphs 50.34(a) and 50.34(b). This would increase the clarity of NRC regulations, align Parts 50 and 52, and meet the intent of SECY-15-0002, which offsets the cost of rulemaking estimated at (\$65,000) using a 7 percent NPV.

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APPENDIX E – OPERATOR LICENSING

The U.S. Nuclear Regulatory Commission (NRC) regulations governing the issuance of licenses to operators of utilization facilities do not discuss the issuance of operator licenses to individuals at utilization facilities that are under construction and not yet operating (i.e., “cold” plants). The NRC recently gained experience implementing the operator licensing program at cold plants. For example, several groups of applicants for operator licenses have taken the requisite written examinations and operating tests at Vogtle Electric Generating Plant Units 3 and 4 (VEGP 3&4), which are utilization facilities that were under construction at the time of the written examinations and operating tests. In some cases, the NRC approved exemptions from the Commission’s regulations to facilitate the administration of these examinations and applicants’ performance of experience requirements because design and construction of the utilization facilities at VEGP 3&4 were not complete. This appendix discusses options for improving the efficiency and effectiveness of the operator licensing program at cold plants based on lessons learned from this experience. The lessons learned are related to criteria for simulation facilities used to administer the operating test and meet experience requirements, the plant walkthrough portion of the operating test, and continuing training for operator license applicants after their completion of the NRC’s initial operator licensing examination.

1.0 EXISTING REGULATORY FRAMEWORK

1.1 Requirements

The regulations at Title 10 of the *Code of Federal Regulations* (10 CFR) Part 55, “Operators’ Licenses” (TN6229), establish procedures and criteria for the issuance of licenses to operators and senior operators of utilization facilities licensed under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities” (TN249), 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251), or 10 CFR Part 54, “Requirements for Renewal of Operating Licenses for Nuclear Power Plants (TN4878). The regulations in Part 55 distinguish between “operator” and “senior operator” licenses; throughout this document, the phrase “operator” refers to both operators and senior operators and the phrase “operator’s license” refers to the licenses for both.

In Section 55.31, “How to apply,” the NRC requires, among other things, applicants for an operator license to complete and file NRC Form 398, “Personal Qualification Statement—Licensee.” On NRC Form 398, the applicant must provide evidence of having successfully completed the facility licensee’s requirements to be licensed as an operator, and an authorized representative of the facility licensee must certify this evidence. This certification must include details of the applicant’s qualifications and courses of instruction administered by the facility licensee and describe the nature of the training received at the facility.

In Section 55.46, “Simulation facilities,” the NRC addresses requirements for the use of a simulation facility for the administration of the operating test and plant-referenced simulators to meet experience requirements for applicants for an operator license. Definitions of the terms “plant-referenced simulator” (PRS), “reference plant,” and “simulation facility” are included in Section 55.4, “Definitions.” Notably, a PRS is defined as “a simulator modeling the systems of the reference plant with which the operator interfaces in the control room, including operating consoles, and which permits use of the reference plant’s procedures.” “Reference plant” is

defined as “the specific nuclear power plant from which a simulation facility’s control room configuration, system control arrangement, and design data are derived.”

To meet the experience requirements of paragraph 55.31(a)(5), an operator license applicant must provide evidence that he or she, as a trainee, has successfully manipulated the controls of either the facility for which a license is sought or a PRS that meets the requirements of paragraph 55.46(c), including the requirement to use “models relating to nuclear and thermal-hydraulic characteristics that replicate the most recent core load in the nuclear power reference plant for which a license is being sought.”

In paragraph 55.45(b), the NRC requires that the operating test be administered in a plant walkthrough and in either a simulation facility that the Commission has approved for use after application has been made by the facility licensee under paragraph 55.46(b), a PRS, or the plant, if approved for use in the administration of the operating test by the Commission. In paragraph 55.40(a), the NRC requires, in part, that the NRC use the criteria in NUREG-1021, “Operator Licensing Examination Standards for Power Reactors” (NRC 2017-TN6251), to prepare the operating tests required by Section 55.45, “Operating tests,” and to evaluate the operating tests prepared by power reactor facility licensees.

The regulations in Section 55.59, “Requalification,” require licensed operators to complete a requalification program developed by the facility licensee and to pass a comprehensive requalification written examination and an annual operating test. In accordance with paragraph 50.54(i-1), facility licensees must establish the operator requalification program within 3 months after either the issuance of an operating license (OL) or the date that the Commission makes the finding under paragraph 52.103(g) for a combined license (COL), as applicable.

1.2 Guidance

NUREG-1021, Revision 11, establishes the policies, procedures, and practices for examining licensees and applicants for operator licenses at nuclear power reactor facilities in accordance with Part 55. NUREG-1021, ES-202, C.1.c, contains guidance for meeting the experience requirements of paragraph 55.31(a)(5). NUREG-1021, ES-202, D.4, defines cold licensing as “the licensing process used before the first refueling outage that provides a consistent method for operations personnel to acquire the knowledge and experience required for licensed operator duties up to the first refueling outage.” The cold licensing process is described in Appendix A, “Cold License Training Plan,” of Nuclear Energy Institute (NEI) 06-13A, “Template for an Industry Training Program Description,” Revision 1 (NEI 2008-TN6252). “Final Safety Evaluation for Topical Report NEI 06-13A, ‘Template for an Industry Training Program Description,’ Revision 1,” dated December 5, 2008 (NRC 2008-TN6249), documents the NRC’s approval of NEI 06-13A for use in COL applications.

NUREG-1021, ES-301, “Preparing Initial Operating Tests,” describes the procedure for developing operating tests that meet the requirements of Section 55.45, including the conduct of the plant walkthrough. ES-301 explains that the walkthrough examinations are commonly referred to as “job performance measures,” and these two terms are used interchangeably throughout NUREG-1021. Each applicant for an operator license must complete a set of in-plant job performance measures as part of the initial operator licensing examination to meet the plant walkthrough requirement.

Regulatory Guide 1.149, “Nuclear Power Plant Simulation Facilities for Use in Operator Training, License Examinations, and Applicant Experience Requirements,” Revision 4 (RG

1.149; NRC 2011-TN6250), describes methods acceptable to the NRC for complying with the portions of the Commission's regulations associated with approval or acceptance of a nuclear power plant simulation facility for use in operator training and license examination operating tests and for meeting applicant experience requirements. RG 1.149 also explains that the NRC accepts and endorses American National Standards Institute/American Nuclear Society (ANSI/ANS)-3.5-2009, "Nuclear Power Plant Simulators for Use in Operator Training and Examination" (ANSI/ANS 2009-TN6263). RG 1.149 states, "ANSI/ANS-3.5-2009 provides methods acceptable to the NRC staff for a facility licensee to demonstrate that, through meeting the criteria of the standard, a plant-referenced simulator will be sufficiently complete and accurate to meet the requirements of 10 CFR 55.46. Although the scope statement of ANSI/ANS-3.5-2009 is limited to the use of full-scope nuclear power plant simulators in operator training and examination, the staff has concluded that simulators meeting this standard should also be satisfactory for meeting the applicant experience requirements described in 10 CFR 55.31(a)(5)."

2.0 REGULATORY ISSUES

The NRC established the "Charter for Enhancing the Nuclear Regulatory Commission Cold Operator Licensing Process" (NRC 2017-TN6244), which directed the staff to formulate recommendations to enhance the operator licensing process for cold plants. The NRC also established the "Charter for Declaration of Plant-Referenced Simulators and Qualification of Commission-Approved Simulation Facilities to Support the Cold Operator Licensing Process" (NRC 2017-TN6245), which directed the staff to develop recommendations for (1) the steps and activities necessary for a facility licensee to declare a simulator as a PRS and (2) the application and evaluation process used to qualify a simulation facility as a Commission-approved simulator (CAS). The establishment of these charters was motivated by lessons learned from the cold licensing efforts at VEGP 3&4 and Virgil C. Summer Nuclear Station Units 2 and 3 (VCSNS 2&3). The staff's recommendations (NRC 2018-TN6253, NRC 2018-TN6254, NRC 2017-TN6264, and NRC 2019-TN6385), developed to address the two charters, include those related to rulemaking for the following topics: criteria for simulation facilities used to administer the operating test, to meet experience requirements, and for requalification training; the plant walkthrough portion of the operating test; and continuing training for operator license applicants after completion of the NRC's initial operator licensing examination. The basis for the staff's recommendations related to rulemaking for these three topics is discussed below.

2.1 Criteria for Simulation Facilities

In paragraph 55.31(a)(5), the NRC requires, in part, operator license applicants to provide evidence that the applicant, as a trainee, has successfully manipulated the controls of either the facility for which a license is sought or a PRS that meets the requirements of paragraph 55.46(c), including using models related to nuclear and thermal-hydraulic characteristics that replicate the most recent core load in the nuclear power reference plant for which a license is being sought. Prior to initial fuel loading, it is not possible for operator license applicants at new nuclear power reactors under construction to meet the existing requirement because the plant cannot yet be used, and a simulator cannot yet "replicate the most recent core load." The Commission has previously granted two exemptions from the control manipulation requirement, allowing operator license applicants at the facility to satisfy the control manipulation requirement on a CAS in lieu of the plant or a PRS ("Vogtle Electric Generating Plant Units 3 and 4; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia," (81 FR 20690, April 8, 2016;

TN6246); and “South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Units 2 and 3,” (81 FR 55237, August 18, 2016; TN6248). Future facility licensees at cold plants may need to request a similar exemption.

In addition, when paragraph 55.46(c) was established, development of a PRS occurred after the reference plant was built and operated. Terms used in the existing regulations such as “reference plant” and “plant-referenced simulator” assume that the plant systems and control room have been constructed prior to the establishment of a simulation facility that models the reference plant. However, the NRC has observed that vendors of new nuclear power reactor designs are now using plant simulators during the design process, and facility licensees at new reactors under construction are using plant simulators to train plant personnel well before the plant is constructed. It is possible to establish a simulation facility that models the design of the plant control room and the expected response of the plant systems during normal and abnormal events using data generated through engineering analyses, such as those analyses discussed in the transient and accident analysis section of a facility’s final safety analysis report; data from subject matter expert estimates; and other relevant data sources when data collected directly from the as-built plant are not yet available because the plant is under construction.

For example, a simulation facility was established at VEGP 3&4 while the plants were under construction. In accordance with paragraph 55.46(b), the facility licensee, Southern Nuclear Operating Company (SNC), requested Commission approval of this simulation facility for use in the administration of operating tests because the simulation facility did not yet meet the requirements for a PRS (SNC 2015-TN6241). Although the simulation facility modeled core physics, thermodynamic and heat transfer characteristics associated with integrated system operations, containment functions, and electrical, instrumentation, and control system functionality, the actual control room console and operating station designs were incomplete at the time of the request. Specifically, a proposed control room console and operating station design had been established and tested, issues in the operation of the simulator were identified during testing, and corrective actions to resolve these issues were in progress. Thus, the simulation facility did not meet the definition of a PRS in Section 55.4.

As discussed in the safety evaluation documenting the Commission approval of the simulation facility at VEGP 3&4 (NRC 2016-TN6266), the NRC reviewed SNC’s request using the criteria in ANSI/ANS-3.5-2009 and RG 1.149 that are also applicable to PRSs. Once the corrective actions were completed, the NRC concluded that the simulation facility for VEGP 3&4 demonstrated sufficient scope and fidelity with the reference plant as described in the design control document to support approval of the simulation facility at VEGP 3&4 for the equitable and consistent administration of operator licensing examinations and for control manipulations. Upon receiving approval of the simulation facility at VEGP 3&4 as a CAS, and upon receiving an exemption that allowed operator license applicants at VEGP 3&4 to perform the control manipulations on the CAS, the CAS at VEGP 3&4 was able to be used for the same purposes as a PRS that meets the criteria in paragraphs 55.46(c)(1) and (2). The Commission approved a similar approach at VCSNS 2&3.

2.2 Plant Walkthrough

The plant walkthrough was the subject of exemption requests for VEGP Unit 3 and for VCSNS Unit 2. In the *Federal Register* notice (FRN) granting approval of the exemption for VEGP Unit 3 (“Vogtle Electric Generating Plant Unit 3; Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia”; 81 FR 42745,

June 30, 2016; TN6247) and in the FRN granting approval of the exemption for VCSNS Unit 2 (“South Carolina Electric & Gas Company and South Carolina Public Service Authority; Virgil C. Summer Nuclear Station Unit 2”; 81 FR 56704, August 22, 2016; TN6240), the NRC also approved alternatives to the in-plant methods of testing described in NUREG-1021. Specifically, the NRC approved the use of discussion and performance evaluation methods in combination with plant layout diagrams, maps, equipment diagrams, pictures, and mock-ups while the plant is under construction.

A substantial number of the plant systems must be constructed before performing a plant walkthrough during the NRC initial licensing examination so that the plant walkthrough portion of the operating test is not predictable. Predictable examinations may prevent the examiner from distinguishing applicants who have mastered the required knowledge and skills from those who have not. The completion of plant construction occurs relatively close in time to the scheduled date for fuel loading and subsequent operation of the facility. Thus, administration of the NRC initial licensing examinations would need to occur relatively close in time to the scheduled date for fuel loading at the cold plant. In its recommendations for Part B of the Operator Licensing Process for Cold Plants Charter, the staff stated that

. . . delaying the administration of the NRC operating test, which includes in-plant JPMs [job performance measures], until construction is complete at cold plants is not desirable for the following reasons:

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

2.3 Continuing Training for Operator License Applicants

For operating plants, an applicant who meets all the requirements to receive an operator’s license receives his or her license within approximately 30 days after passing the NRC’s operator licensing examination. NUREG-1021, ES-605, “License Maintenance, License Renewal Applications, and Requests for Administrative Reviews and Demands for Hearings,” Section C.1.b states that newly licensed operators must enter the requalification training and examination program required by Section 55.59 promptly upon receiving their licenses. Accordingly, newly licensed operators typically enroll in the facility licensee’s requalification training program within approximately 8 weeks after receiving an operator’s license. The facility licensee’s licensed operator requalification program must meet the requirements in Section 55.59, which includes the requirement for the requalification program to be conducted for a continuous period not to exceed two years, and upon conclusion must be promptly followed,

pursuant to a continuous schedule, by successive requalification programs. In addition to keeping licensed operators informed of facility design changes, procedure changes, and facility license changes, the requalification program helps to ensure that licensed operators maintain the knowledge, skills, and abilities obtained during the initial license training program. Participation in a requalification program helps to provide assurance that those personnel who are licensed to operate the facility retain the essential skills necessary to safely operate the plant and maintain awareness of design and procedure changes that affect the tasks that licensed operators perform. Accordingly, by the establishment of the requalification training and examination requirements of Section 55.59, the Commission has acknowledged that knowledge and skills are perishable, and it is necessary for operators to receive periodic re-training and examination of their skills and knowledge.

However, the NRC has observed that in some cases, because of construction schedules, months and years may pass after an applicant for an operator's license passes the NRC examination and before he or she can complete all of the experience requirements for an operator's license. For example, at VEGP Unit 3, some applicants took and passed an NRC examination in 2015, but as of the end of calendar year 2019, they had not been issued an operator's license because they had not yet been able to complete all of the experience requirements (e.g., participation in preoperational testing, etc.). Because operator license applicants are not yet licensed, they are not required to be enrolled in a continuing training program that meets the requirements of Section 55.59 to retain their knowledge, skills, and abilities and to remain cognizant of design and procedure changes. The NRC has observed at VEGP Unit 3 that the facility licensee made changes to the plant design and procedures since 2015, some of which directly affected the tasks that licensed operators will perform at the plant. The NRC has also observed that the facility licensee has voluntarily established and implemented a continuing training program based on a systems approach to training (SAT) that closely models a requalification program for applicants that have passed the NRC initial licensing examinations administered to date at VEGP Unit 3, and that these applicants are participating in that program.

The current regulatory framework could foster a decline in applicants' level of knowledge, skill, and ability to safely operate the plant when there will be a significant amount of time that passes between when the applicant successfully completes the NRC initial licensing examination and when the applicant can complete all the other requirements to be licensed. Applicants for operator licenses at cold plants also may not be trained on the design and procedure changes that may affect tasks that they will be licensed to perform when the plant commences operation and they have completed all the other requirements to be licensed.

3.0 DISCUSSION OF ALTERNATIVES

3.1 Alternative 1: No-Action

3.1.1 Description of Alternative 1

This alternative would maintain the approach used most recently at VEGP 3&4 and VCSNS 2&3, which was to rely on the use of regulatory exemptions as necessary to support operator licensing activities at cold plants. As such, no changes to the current requirements in Part 55 and no NRC efforts to develop additional guidance related to these topics would be implemented.

3.1.2 *Assessment of Alternative 1*

This option would retain the current provisions in Part 55. An advantage of this option is that NRC resources would not be spent to conduct rulemaking and to develop the related guidance documents within the current planning horizon.

However, Alternative 1 has several disadvantages. Facility licensees would continue to need to request an exemption from the plant walkthrough requirement in paragraph 55.45(b) to conduct operator licensing examinations at the facility prior to the completion of construction. Also, facility licensees would continue to need to request an exemption from the experience requirement in paragraph 55.31(a)(5) for applicants to complete the required control manipulations. Therefore, Alternative 1 would not relieve the burden imposed on both the facility licensees and the NRC resulting from a case-by-case exemption process.

Also, there would be continued lack of clarity about whether and how a simulation facility at a cold plant may be used in the administration of operating tests, for requalification, and for the performance of control manipulations. The current regulations allow for the licensee to request Commission approval of a simulator that does not meet the definition of a PRS for use on initial license examinations. However, this approach is not well defined, and although the NRC has developed draft guidance and criteria to improve the efficiency of the process of requesting Commission approval of a simulation facility, it has not yet been incorporated into the applicable guidance document.

In addition, this alternative would not ensure that applicants for an operator license maintain the knowledge, skills, and abilities gained during initial training and remain cognizant of any plant design and procedure changes that may occur prior to when they would otherwise be enrolled in the requalification program. Although a facility licensee may voluntarily establish a continuing training program for applicants who have passed the initial NRC operator licensing examination, there would continue to be no requirement to do so. Also, a continuing training program for applicants that may be established voluntarily by a facility licensee would continue to not be subject to any of the existing regulatory requirements for SAT-based training programs and, therefore, the quality and content of such programs may not be adequate to retain essential knowledge, skills, and abilities and ensure that applicants are trained in plant design and procedure changes. As a result, a voluntarily established continuing training program may not adequately maintain the knowledge, skills, and abilities of the personnel that the facility licensee intends to be licensed to operate the plant after initial fuel load. If a facility licensee of a cold plant chooses not to enroll its applicants for an operator license in an SAT-based continuing training program that closely models a requalification program after the applicants' successful completion of the NRC examination, and if a significant amount of time passes before the applicants receive licenses and commence the requalification program, then the applicants may not retain knowledge from the initial training program or learn new information related to operationally important topics.

Per Section 55.51, "Issuance of licenses," "If the Commission determines that an applicant for an operator license ... meets the requirements of the Act and its regulations, it will issue a license in the form and containing any conditions and limitations it considers appropriate and necessary." For the reasons provided above, when the NRC receives the final operator license applications, the NRC may determine that it is necessary to issue licenses with conditions or limitations necessary to ensure that the applicants have retained knowledge and learned new information related to operationally important topics during the time between completion of the examination and the issuance of the license (e.g., administer additional operating tests or

examinations to ensure that the personnel who would be licensed to operate the facility have the knowledge, skills, and abilities necessary to do so safely). However, administering additional operating tests and or examinations would likely require expenditure of the NRC's resources and the facility licensee's resources just prior to operating the facility when it is anticipated that NRC and facility licensee resources will be in high demand. Also, the case-by-case nature of assessing these situations could lead to inconsistent license conditions for operators.

3.2 Alternative 2: Rulemaking and Guidance to Address Simulation Facilities (with only minor changes to current requirements for simulation facilities), the Plant Walkthrough Portion of the Operating Test, and Continuing Training at Cold Plants

3.2.1 Description of Alternative 2

In this alternative, the NRC would pursue rulemaking to address simulation facilities at cold plants to allow for suitable alternatives to the plant walkthrough portion of the operating test while the plant is under construction, and to establish a new requirement for facility licensees at cold plants to maintain the knowledge, skills, and abilities of operator license applicants who have successfully completed the NRC initial licensing examination.

To address simulation facilities at cold plants, the NRC would amend paragraph 55.46(c)(2)(i) to allow applicants for operator licenses to perform the control manipulations required by paragraph 55.31(a)(5) on a simulation facility that uses a suitable alternative to "models relating to nuclear and thermal-hydraulic characteristics that replicate the most recent core load," such as using models related to nuclear and thermal-hydraulic characteristics that replicate the intended first core load for the plant. The NRC would also amend two definitions in Section 55.4. The definition of "reference plant" in Section 55.4 would be amended to state that it is not necessary for the "reference plant" to be physically constructed. The definition of "plant-referenced simulator" would be amended to state that for a cold plant, a PRS means a simulator modeling the systems of the reference plant with which the operator would interface in the as-built control room.

To allow for suitable alternatives to the plant walkthrough portion of the operating test while the plant is under construction, the NRC would amend paragraph 55.45(b) to give facility licensees of new reactors under construction the option of developing plant walkthrough test items (i.e., job performance measurements used for the in-plant portion of the operating test), using suitable alternatives to in-plant testing while the plant is under construction.

To establish a new requirement for facility licensees at cold plants to maintain the knowledge, skills, and abilities of operator license applicants who have successfully completed the NRC initial licensing examination, the NRC would amend paragraph 55.31(a)(4) to require facility licensees of new reactors under construction to provide information on NRC Form 398 to explain how the knowledge, skills, and abilities of applicants for an operator license would be maintained when the facility licensee requests an NRC examination to be administered well before the applicants would be expected to complete all requirements to receive operator licenses.

3.2.2 *Assessment of Alternative 2*

Alternative 2 would accomplish several objectives. First, this alternative would eliminate the need for certain exemption requests. Specifically, it would eliminate the need to use the exemption process to provide a means for operator license applicants to perform the required control manipulations and to provide an alternative to in-plant testing when the plant is under construction. This would reduce the administrative burden to facility licensees and the NRC associated with the processing of exemptions.

Second, Alternative 2 would eliminate the need for facility licensees to request Commission approval of a simulation facility at a cold plant if the simulation facility meets certain criteria, regardless of whether the simulation facility meets the definition of a PRS in Section 55.4. This would reduce the administrative burden on the licensees and the NRC associated with the processing of requests for Commission approval of the simulation facility. Alternative 2 would result in minor changes in the regulations governing simulation facilities that would only affect facilities that are under construction.

Third, because Alternative 2 would establish a new requirement for facility licensees at cold plants to maintain the knowledge, skills, and abilities of operator license applicants and keep them informed of significant design and procedure changes that affect licensed operator tasks in the time between when the applicants pass the NRC initial licensing examination and when they are enrolled in the licensed operator requalification program, the NRC would have assurance that the applicants have retained knowledge from the initial training program and learned information about new operationally important topics such that they would be prepared to operate the plant safely. The NRC expects that, with this change, it would not be necessary to impose conditions on the operator licenses related to additional training or examinations, which would help improve the efficiency and reliability of the operator licensing process.

The NRC would also develop guidance for implementing the amended regulations.

3.3 Alternative 3: Guidance Only

3.3.1 *Description of Alternative 3*

Alternative 3 does not involve any changes to NRC regulations. Instead, the NRC would prepare guidance to help improve the efficiency of processing requests for proposed alternatives or exemptions related to the plant walkthrough, and control manipulation requirements and requests for Commission-approved simulation facilities at cold plants. Alternatively, the NRC could review and approve guidance prepared by another party that the NRC can endorse in a safety evaluation or regulatory guide.

Also, the NRC could provide additional guidance in NUREG-1021 that would describe when and how to consider the imposition of appropriate conditions on operator licenses if future or current facility licensees choose not to enroll their applicants for operator licenses in continuing training programs that closely model Section 55.59 after the applicants' successful completion of the NRC initial licensing examinations.

3.3.2 *Assessment of Alternative 3*

An advantage of this alternative is that NRC resources would not be spent to conduct rulemaking. However, Alternative 3 only partially addresses the regulatory uncertainties

associated with these topics. This alternative would require a significant amount of resources to prepare guidance documents, but it would not provide the same degree of certainty or finality that would be provided by a rulemaking. Proceeding with guidance rather than a rulemaking would ultimately still require case-by-case decision-making, which is an inefficient method of addressing a generic concern.

In addition, issuing operator licenses with conditions, such as the need to pass additional operating tests or examinations prior to operating the facility, would require expenditure of the NRC's resources and the facility licensee's resources just prior to operating the facility when it is anticipated that NRC and facility licensee resources would be in high demand. The case-by-case nature of assessing these situations could lead to inconsistent license conditions for operators.

3.4 Alternative 4: Rulemaking and Guidance to Address Simulation Facilities (with moderate changes to current requirements for simulation facilities), the Plant Walkthrough Portion of the Operating Test, and Continuing Training at Cold Plants

3.4.1 Description of Alternative 4

Alternative 4 is identical to Alternative 2 except that instead of amending the definition in Section 55.4 of "plant-referenced simulator," the NRC would remove the terms "plant-referenced simulator" and "Commission-approved simulator" from Part 55. The term "simulation facility" would remain, and its definition in Section 55.4 would be revised to define it as a simulation device used for either the partial conduct of operating tests for operators, senior operators, and license applicants, or to establish on-the-job training and experience prerequisites for operator license eligibility. The NRC would not add any new requirements for simulation facilities; the performance-based requirements that a simulation facility must meet in order to be used for operating tests, requalification, or meeting experience requirements would remain in Section 55.46.

As a result of deleting the terms "plant-referenced simulator" and "Commission-approved simulator," paragraph 55.46(b) would only address the requirements that must be met to use the plant in the administration of the operating test; the term "simulation facility" would replace the term "plant-referenced simulator" in paragraphs 55.46(c) and 55.31(a)(5). Paragraph 55.45(b) would be amended to state that the operating test may be administered during a plant walkthrough and in either a simulation facility that meets the requirements to be used for the operating tests specified in paragraph 55.46(c) or at the plant, if approved for use in the administration of the operating test by the Commission under paragraph 55.46(b).

3.4.2 Assessment of Alternative 4

The assessment of Alternative 4 is the same as that for Alternative 2 except that Alternative 4 would result in more revisions to the regulations in Part 55. Removing the terms "plant-referenced simulator" and "Commission-approved simulator" from Part 55 would clarify for facility licensees of new reactors under construction the requirements that a simulation facility must meet to be used for operating tests, requalification, or meeting experience requirements. As long as a simulation facility meets these requirements, it may be used for those purposes; there would be no need to determine whether the simulation facility is a PRS or if it instead must be approved as a simulation facility by the Commission. The NRC would confirm that a

simulation facility complies with regulatory requirements by inspecting simulator performance test results and other simulator data.

Similar to Alternative 2, the NRC would also develop guidance for implementing the amended regulations.

4.0 REGULATORY SCOPE

4.1 Criteria for Simulation Facilities

The NRC is considering amending the criteria in paragraph 55.46(c)(2)(i) to allow applicants for operator licenses to perform the control manipulations required by paragraph 55.31(a)(5) on a simulation facility that uses a suitable alternative to models relating to nuclear and thermal-hydraulic characteristics that replicate the most recent core load.

The NRC is also considering two alternatives (i.e., Alternatives 2 and 4) for additional changes to the regulations governing simulation facilities. The first alternative (i.e., Alternative 2) would be to add information to the definitions of a “plant-referenced simulator” and “reference plant” in Section 55.4 to explain how the terms apply to simulation facilities that model plants that are under construction. The second alternative (i.e., Alternative 4) would amend the regulations in Sections 55.4, 55.45, and 55.46 and paragraph 55.31(a)(5) to remove the terms “plant-referenced simulator” and “Commission-approved simulator.” The term “simulation facility” would remain, and its definition would be revised to include the statement that it is a simulation device.

Guidance would also be developed if the NRC implements Alternative 2, Alternative 3, or Alternative 4. The new guidance may be located in NUREG-1021 and RG 1.149.

4.2 Plant Walkthrough Requirements

The NRC is considering amending paragraph 55.45(b) to give facility licensees of new reactors under construction the option of developing plant walkthrough test items (i.e., job performance measurements used for the in-plant portion of the operating test) using suitable alternatives to in-plant testing while the plant is under construction. As the construction of plant systems, components, and structures is completed, the training program would need to adjust to use actual in-plant training and equipment. In addition, the NRC would develop guidance to provide examples of acceptable alternatives to in-plant testing.

4.3 Continuing Training for Operator License Applicants

The NRC is considering a new requirement in Section 55.31 to require facility licensees of new reactors under construction to provide information on NRC Form 398 to explain how the knowledge, skills, and abilities of applicants for an operator license would be maintained when the facility licensee requests that an NRC examination be administered well before the applicants would be expected to complete all requirements to receive operator’s licenses.

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

5.1 NRC Guidance

If the NRC conducts rulemaking, the NRC would develop new regulatory guidance to describe an acceptable approach for facility licensees and operator license applicants to use to implement the amended requirements in Part 55. Under Alternative 3, the NRC could develop guidance without conducting rulemaking. Under Alternatives 2-4, the NRC would make the draft regulatory guidance available for public comment.

5.2 Policy Issues

No specific policy issues are associated with any of the alternatives.

6.0 IMPACTS

This section provides an analysis of the alternatives discussed in Section 3.0.

6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing operator licensing process as described in the current regulations and guidance. The NRC would not pursue any changes to the current process.

6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees of plants that have been constructed or that are under construction. However, future and current facility licensees of plants that have not yet commenced construction could incur expenditures associated with the preparation of exemption requests related to requirements for plant walkthroughs and for performing control manipulations. In addition, these licensees could incur expenditures associated with the preparation of any requests for Commission approval of a simulation facility and any exemptions related to proficiency requirements.

Also, facility licensees of new reactors under construction would not be required to maintain the knowledge, skills, and abilities of operator license applicants after their completion of the NRC operator licensing examination. However, a facility licensee may choose to establish a continuing training program that closely models a requalification program for operator license applicants after their successful completion of the NRC initial licensing examination; doing so would help to ensure that the personnel who are selected to operate the facility maintain their skills such that they would be ready to operate the facility safely after initial fuel loading. If the NRC determines that no or insufficient continuing training was provided for the applicants during the time between the completion of the initial licensing examination and when licensing requirements are met, and that a significant amount of time had passed, then the NRC may need to review and administer additional operating tests and or examinations prior to issuing operator licenses to ensure that the applicants have the necessary skills, knowledge, and ability

to operate the facility safely. The facility licensee would need to provide resources to prepare the applicants for these additional operating tests or examinations and develop the additional operating tests or examinations for NRC review.

6.1.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC; however, the NRC would continue to expend resources associated with the reviews of exemptions and requests for Commission approval of a simulation facility on a case-by-case basis. The NRC would review submittals using existing procedures and guidance. In addition, the NRC would still likely need to expend resources to administer additional tests or examinations to applicants who have not been enrolled in a sufficient continuing training program for a significant amount of time after their completion of the NRC initial licensing examination. If the NRC determines that additional testing or examination is required, then the NRC would need to expend resources to develop or review, as well as administer, the necessary tests or examinations.

6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.1.5 *Summary of Benefits and Costs*

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 **Alternative 2: Rulemaking (Minor Changes to Current Requirements for Simulation Facilities)**

Under this alternative, the NRC would undertake a rulemaking to amend Part 55 to improve the efficiency and effectiveness of the operator licensing program at cold plants.

6.2.1 *Impacts on Public Health, Safety, and Security*

The regulatory changes are aimed at improving the efficiency, consistency, and clarity of the operator licensing process at cold plants and would ensure that applicants for operator licenses maintain up to date knowledge, skills, and abilities. Thus, rulemaking would have no impacts on public health and safety or the common defense and security.

6.2.2 *Impacts on Licensees*

Alternative 2 would eliminate the need to request exemptions to use alternatives to the in-plant method of testing and to perform the required control manipulations. Also, future facility licensees and current facility licensees of plants that have not yet commenced construction would incur savings because Alternative 2 would eliminate the need to seek Commission approval of the simulation facility if the simulation facility meets the criteria in paragraph 55.46(c), as amended by the rulemaking. Rulemaking is also the option that is most likely to create predictable regulatory outcomes for facility licensees because it avoids the case-by-case processing of exemptions and or conditioning of operator licenses. Because the changes in requirements for simulation facilities would be limited to only those changes necessary to clarify application of the requirements to simulation facilities at cold plants, the NRC does not intend for the changes to have any impact on facility licensees of operating reactors.

In addition, facility licensees of new reactors under construction would incur increased annual costs associated with maintaining the knowledge, skills, and abilities of operator license applicants in the time between when they complete the initial operator licensing examination and when they receive operator licenses. The NRC estimates the cost of administering a continuing training program for operator license applicants that closely models an operator requalification program to be approximately \$1–1.3 million annually. This estimate is based on the following assumptions: (1) 7–10 training staff personnel, including instructors, supervisors, and simulator engineers, earning an average of \$90,000 per year; (2) costs associated with operating and maintaining the control room simulator, estimated to be approximately \$400,000 per year; and (3) an approximate cost of \$20,000 per year to maintain facilities and other training resources.

The NRC estimates the cost to facility licensees of developing additional tests and examinations to be approximately \$1.23 million. This estimate assumes that 3–4 examinations would need to be developed for 3–4 classes of 12–20 applicants. The cost to the facility licensee associated with developing additional tests and examinations would be averted if the facility licensee implements a continuing training program for operator license applicants that closely models the operator requalification program. The above costs were used as the baseline for the cost estimate shown in Table E-1.

Table E-1 Licensee and NRC Costs and Benefits, Alternative 2

Year	Activity	Count	Labor Hours	Duration	Rate	Cost		
						Undiscounted	7% NPV	3% NPV
2024-2025	Averted exemption request from licensee	2	1483		\$134	\$398,392	\$256,782	\$328,788
2024-2025	Averted NRC review of exemption request	2	713		\$131	\$186,893	\$120,461	\$154,241
2026	Continuing training staff (Aggregated)	8	1420	2.3	\$134	(\$3,503,950)	(\$2,182,084)	(\$2,849,032)
2026	Control Room Simulator (Aggregated)	1		2.3	\$416,667	(\$937,500)	(\$583,828)	(\$762,273)
2026	Other training resources (Aggregated)	1		2.3	\$20,833	(\$46,875)	(\$29,191)	(\$38,114)
2027	Averted Ramp-Up Training	7	1420	0.5	\$134	\$683,310	\$397,693	\$539,411
2027	Averted Second OLA cost	1			\$20,833	\$20,833	\$12,125	\$16,446
2027	Averted cost to licensees of additional written examinations	1	582		\$134	\$78,089	\$45,449	\$61,644
2027	Averted cost to licensees of additional operating re-tests	1	1186		\$134	\$159,312	\$92,721	\$125,762
2027	Averted cost of NRC overseeing examinations and re-tests	1	2742		\$131	\$359,158	\$209,033	\$283,523
2027	Averted NRC travel and per diem costs of exams and re-tests					\$21,933	\$12,765	\$17,314
Total:						(\$2,580,404)	(\$1,648,074)	(\$2,122,289)
Per Operator Per year:						(\$20,003)		

OLA = operator license application.
Calculations are on a per-facility-licensee basis

The NRC estimates a cost per future facility licensee of Alternative 2 of approximately (\$1.65 million) using a 7 percent net present value (NPV) and (\$2.12 million) using a 3 percent NPV. For each new facility licensee, the costs would increase by approximately (\$1.65 million). The regulatory changes to the simulators and walkthroughs represent a savings to licensees of \$377,000 using a 7 percent NPV. The continuing training portion of Alternative 2 would result in additional costs to the facility licensee compared to the regulatory baseline. Reviewing Table E-1 line by line, the NRC assumed one averted exemption request per year, per facility licensee, and the associated NRC review (also averted). The continuing training staff is described above and, based on experience, this continuing training could be necessary for up to 4 years, at an average of 2.3 years. The term “Aggregated” in Table E-1 refers to the costs that would occur across those 2.3 years on average (the training staff, simulator use, and other resources) were summed and assumed to occur in 1 year, which simplified the calculation. The

year 2026 was selected for these aggregated values because it would be the midpoint year of the continuing training of an applicant that applied to the NRC right after this rulemaking is scheduled to become final, in 2024, and is used to calculate the NPV.

The averted costs in Table E-1 are also described above. If a facility licensee did not provide continuing training allowed by the regulatory baseline, then prior to fuel loading (estimated to occur in 2027 per the above timeline), the operator license applicants would have to be retrained and reexamined. This would involve ramp-up training prior to written examinations, a second operating license application review, and operating retests. Both the licensee and the NRC would be involved in the process of generating those examinations and retests and administering them. Finally, the NRC would have per diem costs associated with these activities. The staff notes that the facility licensee controls the duration of the continuing training program for its applicants. If the duration is one year, then the costs are comparable to the costs of the regulatory baseline.

The NRC chose to estimate this on a per-facility-licensee basis because of the many uncertainties involved (beyond those presented in the cost estimate above). The cost estimate above is the most conservative, or worst-case scenario, where all of the continuing training costs are accounted for, and the status quo averted costs of the retests and reexaminations are calculated assuming no failures (best case), as further described below. The number of future applicants is not known, leading to further uncertainty that is avoided by using cost estimate on a per-facility-licensee basis. Because the NRC considers the potential additional averted costs and the qualitative benefits, the NRC concluded it would overestimate the costs of this alternative to attempt to predict future facility licensees and estimate costs for those expected future facility licensees. For these reasons, the cost estimate was calculated on a per-facility-licensee basis.

While Alternative 2 would result in net costs to facility licensees estimated as described above, several factors make rulemaking more attractive. Though the current regulatory baseline allows for the cost estimate shown in Table E-1 to reflect reality, facility licensees are instead seeing the value of continuing training programs, as evidenced by the approach taken by VEGP 3&4, which is currently under construction. This analysis assumes several years of continuing training, but the length of time between when applicants take the initial operator licensing examination and when they complete all of the other requirements to be licensed is highly variable and, depending on the construction schedule, the average plant may need far less continuing training than the average in this cost estimate of 2.3 years. Implementing a continuing training program for applicants provides more control for facility licensees because applicants who pass the initial NRC operator licensing examinations and enroll in the continuing training program would not need to return to the NRC for the reexaminations and operating retests.

Implementing a Section 55.59-like continuing training program for operator license applicants following completion of the initial operator licensing examination reduces risk for the facility licensee. Without a continuing training program, the NRC would require additional tests or examinations prior to operation of the facility. There is a possibility that some applicants would not pass the tests or examinations, and they would need to retake them prior to operating the facility. This could result in the facility not having available the expected number of licensed operators prior to fuel loading. In a worst-case scenario, fuel loading and subsequent operation of the facility could be delayed if a sufficient number of licensed operators are not available by the scheduled date for fuel load. In addition, if operator license applicants needed to participate in ramp-up training and additional tests and examinations, then they would not be available to

conduct preoperational testing and other activities that must occur prior to fuel loading (e.g., procedure validations and plant system walkdowns). For these two reasons it is efficient for facility licensees to implement a continuing training program for operator license applicants when there would be a significant amount of time between the NRC initial licensing examination and issuance of operator licenses. Furthermore, this alternative is consistent with how facility licensees are currently operating under the regulatory baseline (Alternative 1) and codifying it in the regulations is consistent with the NRC's Principles of Good Regulation (NRC 2014-TN6227), specifically, clarity and efficiency.

6.2.3 Impacts on the NRC

By amending the regulations as discussed in Section 4.0 of this appendix, the NRC would reduce the number of exemption requests and requests for Commission approval of simulation facilities (for use in the operating test and performance of experience requirements) at cold plants. This would result in a more efficient process and save the NRC time and resources. In addition, because the applicants participated in a continuing training program, the NRC would not have to perform the reexamination and operating retests and associated costs, which would be averted. These are reflected in Table E-1 above.

The NRC also would review the licensee's program for continuing training requirements for operator license applicants provided in the license applications. This cost to the NRC would be averted if the facility licensee implemented a continuing training program for operator license applicants that closely models the operator requalification program. The NRC made this assumption for the purposes of this cost estimate.

The NRC would incur rulemaking costs of approximately (\$211,000) using a 7 percent NPV and (\$243,000) using a 3 percent NPV, as shown in Table E-2.

Table E-2 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
Total:					(\$270,836)	(\$211,478)	(\$242,925)

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 Summary of Benefits and Costs

The NRC would incur rulemaking costs of approximately (\$211,000) using a 7 percent NPV, in Alternative 2. For each future facility licensee, the NRC estimates a net cost to the licensee and to the NRC of (\$1.65 million), as described above. These licensee costs amount to approximately (\$20,000) per operator applicant per year, for the continuing training program.

The changes in the simulator and plant walkthrough regulations represent a savings to facility licensees; the continuing training portion of Alternative 2 would result in additional costs to the facility licensee compared to the regulatory baseline.

6.3 Alternative 3: Develop Guidance

Under this alternative, the NRC would continue with the existing operator licensing process as described in the current regulations; however, the NRC would revise guidance in NUREG-1021 and NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," Chapter 13, "Conduct of Operations" (NRC 2007/2019-TN6221), to more efficiently evaluate exemption requests and requests for Commission approval of simulation facilities.

6.3.1 Impacts on Public Health, Safety, and Security

This alternative would not change the current regulations; however, Section 55.40 requires use of the criteria in NUREG-1021 to prepare and administer examinations. NUREG-1021 is the primary guidance document governing operator licensing. Any impacts on public health and safety resulting from changes to NUREG-1021 would be evaluated on a case-by-case basis depending on the nature of the change in the guidance document. The NRC does not anticipate any appreciable impacts on public health and safety, because the goal of any guidance changes would be to improve the efficiency and consistency of the operator licensing process at cold plants.

6.3.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees of plants that have been constructed or that are under construction; however, facility licensees of new reactors under construction and current facility licensees of plants that have not yet commenced construction would incur expenditures associated with the preparation of exemption requests related to plant walkthrough requirements and requirements for performing control manipulations. In addition, future facility licensees and current facility licensees of plants that have not yet commenced construction would also incur expenditures associated with the preparation of any requests for Commission approval of a simulation facility and any exemptions related to proficiency requirements.

Facility licensees of new reactors under construction would continue to not be required to maintain the knowledge, skills, and abilities of operator license applicants; however, they may choose to establish a continuing training program that closely models a requalification program because doing so would help to ensure that the personnel who are selected to operate the facility maintain their skills and would be ready to operate the facility after initial fuel loading. If the NRC determines that no or insufficient continuing training was provided for the applicants during the time after completion of the NRC initial licensing examination and when licensing requirements are met, and if a significant amount of time had passed, then the NRC may need to review and administer additional tests or examinations. The facility licensee would need to provide resources to prepare the applicants for these additional tests or examinations and develop the additional tests or examinations.

The development of guidance would not avoid the case-by-case processing of exemptions and/or conditioning of operator licenses and, therefore, the implementation of this alternative

would be less likely to create predictable regulatory outcomes for facility licensees and operator license applicants.

6.3.3 *Impacts on the NRC*

This alternative would result in the costs of guidance development to the NRC; moreover, the NRC would continue to expend resources associated with the reviews of exemptions and requests for Commission approval of a simulation facility on a case-by-case basis in a fashion similar to Alternative 1. The NRC would review submittals using existing procedures and the newly developed guidance, which would help improve the efficiency of the NRC’s reviews of these submittals.

In addition, if a significant amount of time passes after the completion of the NRC initial licensing examination, then the NRC would need to determine whether to expend resources to administer additional tests or examinations if applicants had not been voluntarily enrolled in a sufficient continuing training program. If the NRC determines that additional testing or examinations are required, then the NRC would expend resources to develop or review, as well as administer, the necessary tests or examinations similar to Alternative 1.

The cost to modify guidance in Alternative 3 is estimated to be approximately (\$90,000) using a 7 percent NPV and (\$99,000) using a 3 percent NPV, as shown in Table E-3.

Table E-3 NRC Guidance Development Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	408	\$131	(\$53,481)	(\$46,712)	(\$50,411)
2022	Finalize/Issue Reg Guide independently	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
Total:					(\$106,962)	(\$90,368)	(\$99,353)

6.3.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.3.5 *Summary of Benefits and Costs*

The costs associated with Alternative 3 would be related to guidance development by the NRC, estimated to be approximately (\$90,000) using a 7 percent NPV, as shown in Table E-3.

6.4 Alternative 4: Rulemaking (Moderate Changes to Current Requirements for Simulation Facilities)

6.4.1 *Impacts on Public Health, Safety, and Security*

The regulatory changes are aimed at improving the efficiency, consistency, and clarity of the operator licensing process at cold plants and would ensure that applicants for operator licenses maintain up to date knowledge, skills, and abilities. Thus, rulemaking would have no impacts on public health and safety or the common defense and security.

6.4.2 *Impacts on Licensees*

Future facility licensees and current facility licensees of plants that have not yet commenced construction would incur savings because Alternative 4 would eliminate the need to request exemptions to use alternatives to the in-plant method of testing and to perform the required control manipulations. Also, future facility licensees and current facility licensees of plants that have not yet commenced construction would incur savings because Alternative 4 would eliminate the need to seek Commission approval of the simulation facility if the simulation facility meets the criteria in paragraph 55.46(c), as amended by the rulemaking. Rulemaking is also the option that is most likely to create predictable regulatory outcomes for facility licensees because it avoids the case-by-case processing of exemptions and or the conditioning of operator licenses. Although the NRC is considering eliminating the terms “plant-referenced simulator” and “Commission-approved simulator” from the NRC’s regulations, the NRC does not intend for the changes to have any impacts on facility licensees of operating reactors because requirements for simulation facilities to conduct operating tests and requalification would remain as they are.

In addition, facility licensees of new reactors under construction would incur increased annual costs associated with maintaining the knowledge, skills, and abilities of operator license applicants prior to establishing and implementing the licensed operator requalification program. (The associated costs are the same as those discussed in Section 6.2.2, “Impacts on Licensees” of this appendix.)

As detailed in Section 6.2.2, the estimated net cost from these rulemaking changes to each future facility licensee from Alternative 4 is approximately (\$1.65 million) using a 7 percent NPV and (\$2.12 million) using a 3 percent NPV, as shown in Table E-1. Further explanations of this cost estimate and justifications of this burden increase are also described above under Alternative 2.

6.4.3 *Impacts on the NRC*

By amending the regulations as discussed in Section 4.0, “Regulatory Scope,” of this appendix, the NRC would reduce the number of exemption requests and requests for Commission approval of simulation facilities (for use in the operating test and performance of experience requirements) at cold plants. This would result in a more efficient process and save the NRC time and resources.

In addition, the NRC would incur administrative burden associated with reviewing the new information provided on the license applications addressing continuing training requirements for operator license applicants. This cost to the NRC would be minimized if the facility licensee implemented a continuing training program for operator license applicants that closely models the operator requalification program.

The estimated net implementation cost to the NRC would be approximately (\$232,000) using a 7 percent NPV and (\$267,000) using a 3 percent NPV, as shown in Table E-4. The NRC burden would be greater than that in Alternative 2 because of the additional regulatory guide development that would occur in Alternative 4.

Table E-4 NRC Rulemaking Costs, Alternative 4

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	510	\$131	(\$66,851)	(\$54,570)	(\$61,178)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	510	\$131	(\$66,851)	(\$47,664)	(\$57,666)
Total:					(\$297,577)	(\$231,925)	(\$266,693)

6.4.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.4.5 Summary of Benefits and Costs

The NRC would incur rulemaking costs of approximately (\$232,000) using a 7 percent NPV, in Alternative 4. For each future facility licensee, the NRC estimates a net cost to the facility licensee of (\$1.65 million) as described above. The changes to the simulator and plant walkthrough regulations represent a savings to facility licensees; the continuing training portion of Alternative 4 would result in additional costs to the facility licensee compared to the regulatory baseline.

7.0 BACKFITTING AND ISSUE FINALITY

None of the alternatives described in this appendix, if implemented by the NRC, would constitute backfitting under Section 50.109, “Backfitting,” or affect the issue finality of an approval issued under Part 52. Alternative 1 would not impose a change in requirements or NRC staff positions. Under Alternatives 2 and 4, the NRC would provide non-mandatory options for facility licensees to address simulation facilities and the plant walkthrough portion of the operating test at plants under construction. A new requirement for licensees to maintain the knowledge, skills, and abilities of operator license applicants, and revisions to the Part 55 definitions, would not meet the definition of backfitting because these changes would involve operator license applicants and licensed operator training, respectively, and thus would not involve a procedure or organization required to operate a facility. The guidance development in Alternatives 2, 3, and 4 would not impose requirements or staff positions.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor operator license applications and to solicit comments on the rulemaking (NRC 2019-TN6224). At that meeting, NEI provided a list of suggested items to be addressed by the rulemaking (NRC 2019-TN6228). Item 14 on the “Suggestions for 10 CFR 52 Lessons Learned Rulemaking – January 2019” is to “clarify definitions and use of Commission-approved simulators.” According to the transcript from the meeting, SNC stated that there is an opportunity to improve clarity on the use of a Commission-approved simulator and how that compares to what the rules allow for PRSs. The licensee also suggested that the regulations

governing control manipulations be adjusted. These topics are related to the staff's recommendations for amending the regulations governing the use of simulation facilities for administration of the operating tests and performance of control manipulations.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, "Rulemaking and Guidance to Address Simulation Facilities (with only minor changes to current requirements for simulation facilities), the Plant Walkthrough Portion of the Operating Test, and Continuing Training at Cold Plants," because rulemaking would provide for a more efficient and effective operator licensing process at cold plants. This would be accomplished by reducing the need for certain exemptions from existing regulations and requests for Commission approval of simulation facilities and assuring that operator license applicants' knowledge, skills, and abilities are maintained up to date when there would be a significant amount of time between when the applicants successfully pass the NRC initial licensing examination and complete all requirements to be licensed. Alternative 2 is not cost-effective, resulting in rulemaking costs of approximately (\$211,000) using a 7 percent NPV, and incremental costs to each facility licensee of approximately (\$1.65 million) using a 7 percent NPV. These costs to facility licensees are associated with the recommended continuing training requirement; the other recommended changes that are part of Alternative 2 would result in net cost savings to licensees.

However, the staff recommends Alternative 2 based on the qualitative benefits of regulatory certainty, efficiency, clarity, and reliability. The current regulatory framework allows significant length of time between passing the initial licensing examination and issuance of the license and subsequent participation in the requalification program. As more time passes without refresher or continuing training, previously gained knowledge and skills decrease. Prior to fuel load and operation of the plant, knowledge and skills would need to be restored. Implementing a continuing training program at cold plants for applicants provides more control for facility licensees because applicants who pass the initial NRC operator licensing examinations and enroll in the continuing training program would not need to return to the NRC for the reexaminations and operating retests. Accordingly, the implementation of Alternative 2 supports the NRC's Principles of Good Regulation, including efficiency, clarity, and reliability.

The NRC staff recommends Alternative 2 instead of Alternative 4 because the NRC would incur greater rulemaking costs with the implementation of Alternative 4, with no additional benefit to offset the costs.

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APPENDIX F – PHYSICAL SECURITY AND FITNESS-FOR-DUTY REQUIREMENTS

1.0 PHYSICAL SECURITY

The U.S. Nuclear Regulatory Commission (NRC) has identified an issue in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, “Physical Protection of Plants and Materials,” (TN423) paragraphs 73.55(a)(4) and 73.56(a)(3) that may result in an unnecessary burden on power reactor applicants and licensees under 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities” (TN249), and 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251). Paragraphs 73.55(a)(4) and 73.56(a)(3) require applicants for a power reactor operating license (OL) under Part 50 or holders of a combined license (COL) under Part 52 to implement the requirements of Sections 73.55, “Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage,” and 73.56, “Personnel access authorization requirements for nuclear power plants,” respectively, before unirradiated fuel is allowed onsite at nuclear power reactors (i.e., within the protected area). The NRC is considering amending these requirements to clarify that applicants and licensees may bring unirradiated nuclear fuel onsite and protect it in accordance with Section 73.67, “Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate and low strategic significance,” before implementing the requirements of Sections 73.55 and 73.56. In addition, the NRC is considering changes to the language in paragraphs 70.22(k) and 73.67 to clarify the appropriate security requirements for Category II and III quantities of special nuclear material (SNM) brought onsite at nuclear power reactors.

1.1 Existing Regulatory Framework

Under paragraphs 50.34(c)(2) and (c)(3), each Part 50 applicant for an OL must have, among other security-related plans, a physical security plan that describes how the applicant will meet the physical security requirements of Part 73. Similarly, paragraphs 52.79(a)(35)(i) and (ii) require an applicant for a COL under Part 52 to include in its final safety analysis report (FSAR) a physical security plan that describes how the applicant will meet the physical security requirements of Part 73 and a description of the implementation of the physical security plan. For applicants or licensees under Parts 50 and 52, their physical security plans must implement the requirements in Section 73.55, including the requirements in paragraph 73.55(a)(4), governing physical protection at the site and the requirements governing access authorization at the site in accordance with Section 73.56, including the requirements in paragraph 73.56(a)(3).

Both Parts 50 and 52 licensees have applied for and been issued a license under Part 70, “Domestic Licensing of Special Nuclear Material,” (TN4883) authorizing them to possess and use SNM, typically in the form of unirradiated reactor fuel but also in non-fuel SNM such as intermediate range detectors and other devices. A typical Part 50 OL contains a license condition that authorizes the licensee to receive, possess, and use SNM. The typical Part 52 COL contains two license conditions. The first license condition authorizes the licensee to receive and possess but not use SNM as reactor fuel subject to certain limitations and as described in the FSAR. The second license condition authorizes the licensee to use SNM as reactor fuel after the Commission has made its paragraph 52.103(g) finding.

Consistent with the requirements in paragraph 70.22(k), licensees possessing SNM of moderate strategic significance (also known as a Category II quantity of SNM) or licensees possessing SNM of low strategic significance (also known as a Category III quantity of SNM), as defined in Sections 70.4, "Definitions," and 73.2, "Definitions," must have a security plan that identifies how the licensee will meet the applicable security requirements in paragraphs 73.67(d), (e), (f), and (g) for the protection of the SNM. However, paragraph 70.22(k) contains a specific exception for a license for possession or use of SNM in the operation of a nuclear power reactor licensed pursuant to Part 50. Similar exception language is found in paragraphs 73.67(d) and 73.67(f) for a Category II and a Category III quantity of SNM, respectively. Therefore, consistent with these exceptions, the need for a security plan in paragraph 70.22(k) and the security requirements in paragraphs 73.67(d) and (f) do not apply to Part 50 licensees.¹ There is no such exception for Part 52 licensees. Therefore, they are subject to the requirement to have a security plan as well as the applicable security requirements in Section 73.67. Both licensees are subject to the same requirements in Sections 73.55 and 73.56.

The security requirements in Section 73.67 consider the risk significance of the material being protected. Unirradiated fuel brought onsite at commercial nuclear power reactors typically constitutes a Category III quantity of SNM. Because of its low enrichment, unirradiated fuel poses no significant risk to the common defense and security. Consistent with Section 73.67, a licensee possessing a Category III quantity of SNM must store or use the material within a controlled access area (CAA), monitor the CAA with an intrusion alarm or other device or procedures that detect unauthorized penetrations or activities, ensure that a watchman or offsite response force will respond to all unauthorized penetrations or activities, and establish and maintain response procedures for dealing with threats. These security requirements are much less stringent than the Section 73.55 security requirements to protect irradiated fuel from sabotage events at nuclear power reactors.

1.2 Regulatory Issue

The regulatory language in paragraphs 73.55(a)(4) and 73.56(a)(3) potentially subjects a Category III quantity of SNM brought onsite at nuclear power reactors to the security requirements in Sections 73.55 and 73.56. The language in paragraph 73.55(a)(4) states that Parts 50 and 52 applicants "shall implement the requirements of this section [10 CFR 73.55] before fuel is allowed onsite (protected area)." There is identical language in paragraph 73.56(a)(3) requiring that licensees implement the Section 73.56 access authorization program before "fuel is allowed onsite (protected area)." These more stringent security requirements are inconsistent with the regulatory regime developed by the NRC for the protection of Category III quantities of material and with the security risk associated with Category III quantities of material.

In the Statement of Considerations to the March 27, 2009, Power Reactor Security Requirements final rule (74 FR 13926, March 27, 2009; TN6300), the Commission addressed the intent of paragraph 73.55(a)(4):

Section 73.55(a)(4) establishes when an applicant's physical protection program must be implemented. The Commission concluded that the receipt of special

¹ Most 10 CFR Part 50 licensees that store SNM in the owner-controlled area (OCA) (outside of an operating protected area) voluntarily comply with the 10 CFR 73.67 security requirements. There have been instances where licensees storing detectors and other devices in the OCA have not implemented 10 CFR 73.67 security requirements.

nuclear material (SNM) in the form of fuel assemblies onsite, i.e., in the licensee's protected area, is the event that subjects a licensee to the requirements of § 73.55. It is the responsibility of the applicant/licensee to implement an effective physical protection program before SNM in the form of fuel assemblies is received in the protected area.

Presumably, given that identical language is included in paragraph 73.56(a)(3), the same rationale would apply to implementation of the licensee's access authorization program.

A plain reading of the language in paragraphs 73.55(a)(4) and 73.56(a)(3) would arguably require licensees to implement the full physical security program required by Section 73.55 and the access authorization program required by Section 73.56 before bringing a Category III quantity of SNM onsite. An alternative reading of the regulatory language in these two provisions would prevent the storage of a Category III quantity of SNM in the site's protected area (PA) prior to implementing the security requirements in Section 73.55 and the access authorization requirements in Section 73.56, but would allow storage in the owner-controlled area (OCA). Either situation would subject these licensees to unnecessary regulatory burdens and costs, as discussed below.

Both Parts 50 and 52 licensees could seek an exemption from the requirements in paragraphs 73.55(a)(4) and 73.56(a)(3) to avoid these regulatory burdens and costs. Alternatively, licensees could seek NRC approval for an alternative measure for implementing these requirements in accordance with the requirements in paragraph 73.55(r). Having to develop and submit an exemption under Section 73.5, "Specific exemptions," or conduct the analysis necessary to support a proposed alternative measure under paragraph 73.55(r) imposes an unnecessary burden and costs on licensees. It also forces the NRC to spend time and effort evaluating the exemption request or proposed alternative measure, despite the fact that the NRC has already established appropriate security requirements in Section 73.67 that could adequately protect Category III quantities of SNM brought onsite at a nuclear power reactor prior to full implementation of Section 73.55 security requirements or the licensee's access authorization program.

1.2.1 Requiring Implementation of the Section 73.55 and 73.56 Requirements before Fuel Is Brought Onsite

Some stakeholders, focusing on the term "onsite," have interpreted the language in paragraphs 73.55(a)(4) and 73.56(a)(3) to mean that Category III SNM unirradiated reactor fuel may not be brought and stored anywhere onsite until the security requirements in Sections 73.55 and 73.56 are fully implemented. This interpretation creates an unnecessary regulatory and financial burden on applicants and licensees.

As noted above, this interpretation is inconsistent with the rationale underlying the physical security requirements for the protection of SNM of moderate and low strategic significance. Unirradiated nuclear fuel poses a low sabotage risk. The NRC determined that Section 73.67 establishes sufficient security requirements for this type of material. Accordingly, prematurely imposing the security requirements in Sections 73.55 and 73.56 serves no significant safety or security purpose.

This interpretation of the language in paragraphs 73.55(a)(4) and 73.56(a)(3) would also have other potential adverse consequences for licensees. It could force licensees to incur the regulatory burdens and costs associated with prematurely implementing Section 73.55 and

73.56 security requirements to take advantage of favorable market conditions for the purchase of unirradiated nuclear fuel during construction of the reactor. Alternatively, it could force licensees to forgo taking advantage of favorable market conditions to avoid incurring the regulatory burdens and costs associated with prematurely implementing an operational PA or a full access authorization program.

1.2.2 Prohibiting Storage of Unirradiated Nuclear Fuel in the PA but Allowing Storage in the OCA

Other stakeholders, focusing on the parenthetical “protected area,” have interpreted the language in paragraph 73.55(a)(4) and 73.56(a)(3) to apply only to the storage of unirradiated reactor fuel or other Category III SNM in the PA. Under this interpretation, unirradiated nuclear fuel or other Category III SNM could be brought onsite and stored in the OCA and protected in accordance with the applicable security requirements in Section 73.67. It could not be stored in the PA until the security requirements in paragraph 73.55(a)(4) and 73.56(a)(3) are fully implemented. This interpretation also creates an unnecessary regulatory and financial burden on applicants and licensees.

Unirradiated nuclear fuel received onsite at a commercial nuclear power plant is stored in a fuel receiving facility. Parts 50 and 52 applicants and licensees construct a fuel receiving facility in the site’s PA. This facility is often completed long before the licensee is ready to fully implement the security requirements in Sections 73.55 and 73.56. However, the existing language in paragraphs 73.55(a)(4) and 73.56(a)(3) would prevent a licensee from using this facility to store unirradiated fuel because it is located in the PA. Consequently, the fuel receiving facility constructed in the PA could potentially sit unused for extended periods of time.

Adopting the interpretation that unirradiated nuclear fuel may be brought onsite but not stored in the PA fuel receiving facility forces an applicant or licensee to make one of three choices: (1) delay receiving unirradiated nuclear fuel onsite until the licensee is ready to implement all of the Section 73.55 and 73.56 security requirements; (2) seek an exemption from the requirements in paragraphs 73.55(a)(4) and 73.56(a)(3) or propose an alternative measure to enable use of the completed fuel receiving facility in the PA and protect that facility in accordance with the security requirements in Section 73.67; or (3) build a second fuel receiving facility in the OCA and protect it in accordance with the security requirements in Section 73.67. The NRC has determined that all of these options impose costs and burdens on Parts 50 and 52 applicants or licensees with no compensating increase in security for the onsite unirradiated nuclear fuel.

1.2.3 Clarifying Inconsistent Application of Section 73.67

The NRC has instituted a regulatory regime that protects all SNM in a manner commensurate with the risk associated with the material. The NRC has determined that it is appropriate to protect all unirradiated nuclear fuel and other non-fuel SNM brought onsite at an NRC licensed commercial nuclear power reactor in accordance with Section 73.67 until that material is protected in accordance with Section 73.55. The NRC is aware of instances where Part 50 licensees have stored non-fuel SNM at operating power reactors outside the PA without protecting the SNM in accordance with Section 73.67. The NRC does not believe this practice is appropriate. Also, the regulations should be clarified to better define, commensurate with the risk associated with the material, which physical protection regulations should apply for COL holders. The NRC is unable to determine the basis for the inconsistency in how Parts 50 and 52 licensees are treated when it comes to the application of the Section 73.67 security requirements. There is nothing in the regulation, applicable regulatory guides, or regulatory

history that explains why a Part 50 licensee is excepted from the requirements in paragraphs 73.67(d) and (f) but a Part 52 licensee is not excepted. The NRC also believes that when Part 52 was issued, not including a similar exception for Part 52 licensees in paragraphs 70.22(k) and 73.67(d) and (f) was an oversight. Notwithstanding this, the NRC further believes that the exception should be clarified to also except Part 52 licensees when the material is protected in accordance with Section 73.55.

1.3 Discussion of Alternatives

1.3.1 *Alternative 1: No-Action*

1.3.1.1 *Description of Alternative 1*

Under this alternative, the NRC would make no changes to the existing regulatory language in paragraphs 73.55(a)(4) or 73.56(a)(3). Therefore, Parts 50 and 52 applicants and licensees would have to fully implement the physical security requirements in Section 73.55 and the access authorization requirements in Section 73.56 before unirradiated nuclear fuel could be stored in the PA. Alternatively, if adopting the interpretation that unirradiated nuclear fuel could be stored onsite outside the PA, licensees would have to construct a temporary fuel receiving facility in the OCA and protect the fuel in accordance with Section 73.67, or request an exemption from, or propose an alternative measure to, the requirements in paragraphs 73.55(a)(4) and 73.56(a)(3). The exceptions in paragraphs 70.22(k) and 73.67(d) and (f) would not be clarified to address the disparate treatment of Parts 50 and Part 52 licensees discussed in Sections 1.1, “Existing Regulatory Framework” and 1.2.3, “Clarifying Inconsistent Application of Section 73.67” of this appendix.

1.3.1.2 *Assessment of Alternative 1*

The requirement to protect unirradiated nuclear fuel in the PA in accordance with the Section 73.55 and 73.56 security requirements is not justified by the security risks associated with SNM of moderate or low strategic significance. The fact that the unirradiated nuclear fuel is stored onsite either inside the PA or in the OCA during construction does not increase the security risk associated with Category II or III SNM brought onsite. That risk only increases once the material is irradiated. Applying the Section 73.55 and 73.56 security requirements to the protection of unirradiated nuclear fuel stored onsite, even within the PA, is inconsistent with the regulatory scheme established by the NRC for the protection of SNM of moderate or low strategic significance. There are no security considerations or other factors that justify imposing on licensees the regulatory burdens and costs that result from requiring the premature implementation of the more stringent Section 73.55 and 73.56 security requirements on unirradiated Category III quantities of SNM brought onsite prior to fuel loading.

1.3.2 *Alternative 2: Rulemaking to Provide Appropriate Security Requirements for SNM Brought on Site*

1.3.2.1 *Description of Alternative 2*

The NRC would undertake rulemaking to amend paragraphs 73.55(a)(4) and 73.56(a)(3). This rulemaking would replace the current rule language, “before fuel is allowed onsite (protected area),” with new rule language, “before initial fuel load into the reactor.” The rulemaking would also add new language to paragraph 70.22(k) and new language to paragraphs 73.67(d) and (f) to clarify the applicability of the security requirements in Section 73.67 to both Parts 50 and 52

licensees. Specifically, the rulemaking would amend paragraph 70.22(k) to replace “other than a license for possession or use of this material in the operation of a nuclear power reactor licensed pursuant to 10 CFR Part 50 of this chapter,” with “other than a license for possession or use of this material in the operation of a nuclear power reactor licensed pursuant to 10 CFR Part 50 or 52 of this chapter, provided that the SNM is located within a protected area and protected pursuant to 10 CFR 73.55.” The NRC would revise Section 73.67 to clarify that the existing exception applies to both Parts 50 and 52 licensees when the SNM is protected in accordance with the appropriate security requirements in Section 73.55. The NRC also considered a request from stakeholders to provide clarification regarding the timing for implementation of the PA to meet the requirements of Section 73.55.

This rulemaking may also require a revision to appropriate guidance to make it clear that licensees should provide the NRC with sufficient time to conduct the necessary inspections of the licensee’s facility to determine that the licensee has fully implemented the security requirements in Section 73.55.

1.3.2.2 Assessment of Alternative 2

This change in rule language would make clear that Category II or III SNM, including unirradiated nuclear fuel, could be stored anywhere onsite and protected in accordance with Section 73.67 before fuel loading. This would apply the appropriate requirements to unirradiated nuclear fuel. However, licensees would still be required to have a fully operational PA prior to loading fuel into the reactor.

Modifying the rule language in paragraph 73.55(a)(4) would (1) eliminate the need for applicants or licensees to implement two separate sets of security requirements to protect SNM onsite, (2) reduce unnecessary regulatory burden and costs on applicants or licensees, (3) clarify the security requirements for the PA, and (4) permit licensees or applicants to complete construction, security systems tests, train and certify appropriate security personnel, and ensure that operational readiness milestones for plant operations are fully completed prior to implementation of the security requirements for an operational PA.

Modifying the rule language in paragraph 73.56(a)(3) would eliminate the need for applicants or licensees to prematurely implement requirements for unescorted access to personnel during construction and make implementation of this regulatory provision consistent with the requirements in paragraph 73.55(a)(4).

The rulemaking would also address the inconsistency between the treatment of Parts 50 and 52 licensees in paragraph 70.22(k) and clarify that the security requirements and associated exception in paragraph 73.67(d) and (f) apply to both classes of licensees.

1.4 Regulatory Scope

Alternative 2 would change the requirements in paragraphs 73.55(a)(4), 73.56(a)(3), 70.22(k), and 73.67(b), (d), and (f) and may result in a revision to existing guidance documents.

1.5 NRC Guidance, Policy, and Implementation Issues

1.5.1 NRC Guidance

Regulatory Guide (RG) 5.59, “Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance” (NRC 1983-TN6381), provides guidance on the implementation of the requirements in Section 73.67. Regulatory Guide 5.66, “Access Authorization Program for Nuclear Power Plants” (NRC 1991-TN6380), provides guidance on the implementation of the NRC’s access authorization requirements in Section 73.56. Regulatory Guide 5.76, “Physical Protection Programs at Nuclear Power Reactors,”² provides guidance on the implementation of the NRC’s physical protection requirements in Section 73.55. Alternative 2 would require revisions to these guidance documents to reflect the changes implemented by the rulemaking.

1.5.2 Policy Issue

Alternative 2 does not involve any changes to policy that require Commission approval. Furthermore, Alternative 2 does not establish any new or revised procedure, perspective, or strategy that could be considered a new policy. Alternative 2 would not result in an unresolved policy issue affecting the initiation or completion of the rulemaking.

1.6 Impacts

1.6.1 Alternative 1: No-Action

Under this alternative, there would be no change to NRC regulations or guidance. Licensees who are authorized to operate a nuclear power reactor under Section 50.57, as well as holders of COLs issued under Part 52 (after the Commission has made the finding under paragraph 52.103(g)) would continue to comply with the requirements of paragraph 73.55(a)(4) and 73.56(a)(3).

1.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change current regulatory requirements, there would be no increase or reduction in public health, safety, or security.

1.6.1.2 Impacts on Licensees

Because this alternative would not change current regulatory requirements, the alternative would have no impact on licensees. Parts 50 and 52 licensees would potentially have to expend resources to support a case-by-case exemption to the requirements in paragraph 73.55(a)(4) and 73.56(a)(3) if they wanted to bring unirradiated nuclear fuel onsite in the protected area before implementing these requirements. Without such an exemption, licensees would be subject to the regulatory burdens and costs identified in Section 1.2 above.

1.6.1.3 Impacts on NRC

This alternative would have no incremental impacts on the NRC.

² Regulatory Guide 5.76, “Physical Protection Programs at Nuclear Power Reactors,” contains safeguards and security information and therefore is not publicly available.

1.6.1.4 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking to Provide Appropriate Security Requirements for SNM Brought on Site

This alternative would modify the language in paragraph 73.55(a)(4) and 73.56(a)(3) to make clear unirradiated nuclear fuel could be stored onsite and protected in accordance with Section 73.67 prior to fuel being loaded into the reactor. This alternative would also modify the language in paragraph 70.22(k) and 73.67(b), (d), and (f) to clarify the applicability of the security requirements in Section 73.67 to both Parts 50 and 52 licensees.

1.6.2.1 Impacts on Public Health, Safety, and Security

The alternative would establish appropriate requirements for the protection of SNM brought onsite at a nuclear power reactor prior to fuel being loaded into the reactor. This alternative would not result in any change to the licensee's overall security posture. Therefore, this alternative would have no impact on and would still maintain adequate protection of the public health and safety and would not be inimical to the common defense and security.

1.6.2.2 Impacts on Licensees

This alternative would provide cost savings by reducing the need for requests for exemptions under Section 73.5 or alternative measures under paragraph 73.55(r), construction costs associated with a temporary fuel receiving facility, and operating costs associated with security staffing to implement the requirements in Section 73.55 and 73.56. The NRC must consider the potential benefits and costs of the other options for COL, early site permit (ESP), and OL holders. The NRC has not performed detailed analysis of cost and benefit impacts for all of these entities, in particular for the temporary fuel receiving facility. However, the NRC notes that the benefits could be substantial in terms of improvement in the flexibility in the construction planning of COL holders and the elimination of the need to unnecessarily construct a second fuel receiving facility.

The NRC was able to estimate averted costs associated with security protection for the temporary fuel receiving facility of approximately \$5 million per year added to the operating costs of a nuclear power plant, not including administrative and maintenance cost to the licensees or applicants. This estimated averted cost assumes 50 armed responders (full-time equivalent employees [FTEs]) being required to provide the minimum number of 10 responder FTE coverage per shift with an estimated labor cost of \$100,000 per responder.

One licensee is currently constructing two new units and is affected by the existing regulatory requirements of paragraph 73.55(a)(4). This licensee is currently operating a multi-unit site and protects its SNM under the requirements of Section 73.55. The licensee is expanding its security protected footprint to include the new reactor construction area. As a result, the NRC believes that this licensee would augment its existing armed responders with additional security personnel to cover the new construction area. The staff discounts the industry's provided averted cost discussed above and estimates that Alternative 2 would reasonably provide an averted cost of approximately 30 FTEs (3 million dollars) for additional armed security personnel and 400 to 500 labor hours to prepare and submit an exemption request for each reactor unit

from implementing prematurely the full physical protection program. As discussed, the NRC has not estimated the averted cost saving associated with constructing a temporary fuel receiving facility and operational costs. If this averted cost materialized, the total averted cost savings for the recommended Alternative 2 would be substantial.

This alternative would also provide averted cost savings by eliminating the need for licensees to implement the paragraph 73.56(a)(3) access authorization requirements for site personnel when unirradiated fuel is stored in the area designated as the PA during construction but prior to fuel load. The NRC estimated 2,000 to 2,500 individuals would be subject to the access authorization requirements when the PA is prematurely established. The licensee could currently avoid this requirement by submitting a license amendment request.

Therefore, the NRC estimated an additional averted cost of approximately 200 labor hours for the licensee to prepare and submit for NRC review an exemption or alternative request associated with paragraph 73.55(a)(4) and 73.56(a)(3) for each reactor unit. For this cost estimate, the NRC assumed one applicant every 3 years, beginning with expected issuance of the final rule.

Alternative 2 would result in averted costs to licensees of approximately \$5.62 million (7 percent net present value [NPV]) and \$7.54 million (3 percent NPV), as shown in Table F-1.

Table F-1 Licensee and NRC Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted exemption request from licensee	1	318	\$134	\$42,685	\$30,434	\$36,820
2027	Averted exemption request from licensee	1	318	\$134	\$42,685	\$24,843	\$33,696
2030	Averted exemption request from licensee	1	318	\$134	\$42,685	\$20,279	\$30,836
2024	Averted security forces for temporary refueling facility	31	1420	\$72	\$3,134,722	\$2,235,014	\$2,704,039
2027	Averted security forces for temporary refueling facility	31	1420	\$72	\$3,134,722	\$1,824,437	\$2,474,579
2030	Averted security forces for temporary refueling facility	31	1420	\$72	\$3,134,722	\$1,489,284	\$2,264,590
Total:					\$9,532,221	\$5,624,290	\$7,544,560

1.6.2.3 Impacts on NRC

The NRC would incur incremental costs to undertake rulemaking to make changes to paragraphs 73.55(a)(4), 73.56(a)(3), 70.22(k), and 73.67(b), (d), and (f), and associated regulatory guides.

By revising the requirements of paragraph 73.55(a)(4) and 73.56(a)(3), the NRC would reduce the need to review exemptions under Section 73.5 or alternative measures under paragraph 73.55(r). The revised regulation would clarify that SNM of moderate or low strategic significance during construction may be protected in accordance with the security requirements in Section 73.67. The revised regulation would also clarify that during operation of a Part 50 or 52 licensed nuclear power reactor, SNM located in the OCA may be protected in accordance with the security requirements in Section 73.67. In addition to the quantitative benefits below, these changes would increase the clarity and effectiveness of regulations for the review of future new reactor license applications.

Alternative 2 would result in rulemaking costs to the NRC of approximately (\$256,000) using a 7 percent NPV and (\$289,000) using a 3 percent NPV, as shown in Table F-2.

Table F-2 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guides for Proposed Rule	4	204	\$131	(\$106,962)	(\$87,312)	(\$97,885)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guides for Final Rule	4	204	\$131	(\$106,962)	(\$76,262)	(\$92,266)
2024	Averted NRC review of exemption request	1	159	\$131	\$20,820	\$14,844	\$17,959
2027	Averted NRC review of exemption request	1	159	\$131	\$20,820	\$12,117	\$16,435
2030	Averted NRC review of exemption request	1	159	\$131	\$20,820	\$9,891	\$15,041
Total:					(\$315,339)	(\$256,413)	(\$288,565)

1.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 Summary of Benefits and Costs

Alternative 2 would remove the regulatory requirements in paragraph 73.55(a)(4) and 73.56(a)(3) applicable to the receipt and storage of unirradiated fuel in the PA. This alternative would clarify that unirradiated nuclear fuel could be stored onsite, including in a fuel receiving facility in the site's PA. Unirradiated fuel would be protected in accordance with Section 73.67 before initial fuel loading. This alternative would provide cost savings by reducing the need for requests for alternative or exemption, construction costs associated with a temporary fuel receiving facility, evaluation of the initial access authorization for an individual, and operating costs associated with security staffing.

Alternative 2 would result in net averted costs to industry and the NRC of approximately \$5.37 million (7 percent NPV) and \$7.26 million (3 percent NPV).

1.7 Backfitting and issue Finality Considerations

None of the alternatives described in this appendix section, if implemented by the NRC, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would not impose a change in requirements or NRC staff positions. Alternative 2 would involve changes to regulations affecting power reactor applicants and licensees. However, these applicants and licensees could continue to wait to bring unirradiated fuel onsite or protect the fuel onsite under Section 73.67 until a Section 73.55 physical security plan and a Section 73.56 access authorization program are fully implemented. Thus, Alternative 2 would not involve the imposition of requirements on the applicants and licensees. Alternative 2 may also revise guidance, and the NRC changes to guidance documents would not impose new requirements or staff positions.

1.8 Stakeholder Feedback

1.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). At that meeting, the Nuclear Energy Institute (NEI) made a presentation about its suggestions for this rulemaking (NRC 2019-TN6228). The NRC included NEI's feedback regarding the need to modify Section 73.67 to allow a COL holder the option during construction to use its Section 73.55 security plan to receive fuel as part of its proposed alternatives in the discussion above in Section 1.3 along with lessons learned discussed in SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications" (NRC 2015-TN6209).

1.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The staff recommends Alternative 2, "Rulemaking to Provide Appropriate Security Requirements for SNM Brought on Site," to clarify the regulatory language in paragraph 73.55(a)(4) so licensees or applicants could store unirradiated nuclear fuel onsite in accordance with Section 73.67. In addition, the NRC would change language in paragraphs 73.67(b), (d), and (f) and paragraph 70.22(k) and 73.56(a)(3). The recommended rulemaking would reduce the regulatory burden and enhance consistency and ensure the appropriate protection of SNM in accordance with the security risk associated with the material.

2.0 FITNESS FOR DUTY

The NRC is considering several amendments to Part 26, "Fitness-for-Duty Programs" (TN5451), to address lessons learned from implementation of fitness-for-duty (FFD) programs at the Vogtle Electric Generating Plant (VEGP) and Virgil C. Summer Nuclear Station (VCSNS) construction sites. These amendments would address issues concerning access to the construction site, Medical Review Officer (MRO) procedures, clarifications to regulatory language, and a change to Part 26 implementation based on risk insights learned from operating experience.

2.1 Existing Regulatory Framework

The scope of licensees and other entities subject to Part 26 is defined in Section 26.3, "Scope," and includes entities described in paragraph 26.3(a) who are authorized to operate a nuclear power reactor or hold a COL under Part 52 for constructing and operating a commercial nuclear power plant, and paragraph 26.3(b) who are authorized to possess, use, or transport formula quantities of strategic special nuclear material under Part 70. Under paragraph 26.3(c), certain holders of approvals under Part 50 or Part 52 must implement an FFD program that meets the requirements of Part 26, except for Subpart I, "Fatigue Management," before the receipt of special nuclear material (SNM) in the form of fuel assemblies and all Part 26 requirements no

later than the receipt of SNM in the form of fuel assemblies. These entities are (1) COL applicants under Part 52 who have been issued a limited work authorization (LWA) under paragraph 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the LWA; (2) COL holders under Part 52 before the Commission has made the finding under paragraph 52.103(g); (3) construction permit (CP) applicants under Part 50 who have been issued an LWA under paragraph 50.10(e), if the LWA authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA; (4) CP holders under Part 50; and (5) ESP holders who have been issued an LWA under paragraph 50.10(e), if the LWA authorizes the ESP holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the LWA.

The licensees and other entities listed in paragraph 26.3(c) must implement an FFD program that meets the requirements in Part 26, except Subparts I and K, “FFD Program for Construction,” for the categories of individuals listed in paragraph 26.4(e), who perform specific construction-related activities described in paragraphs 26.4(e)(1) through (e)(6). The individuals described in paragraph 26.4(f), who construct or direct the construction of safety- or security-related SSCs, are subject to either the same FFD program as the individuals listed in paragraph 26.4(e) or an FFD program for a construction site that meets the requirements of Part 26, Subpart K.

This existing regulatory framework in Part 26 provides reasonable assurance that individuals onsite during construction are trustworthy and reliable, and fit to safely and competently fabricate, erect, integrate, and test safety- and security-related SSCs in accordance with design specifications so that these SSCs will be operable to support safe and secure reactor operation. The rule takes “a graded approach to FFD requirements, by imposing requirements that are commensurate with the potential risks to public health and safety and the common defense and security that the results of construction activities may pose when a plant begins operations . . .” by requiring “two different levels of FFD requirements for workers in different job roles” (“Fitness for Duty Programs; Final Rule” [73 FR 16995, March 31, 2008; TN6302]). When construction activities have the potential to become risk significant, then the licensee must implement an FFD program that meets all Part 26 requirements, except those in Subpart K. For licensees constructing commercial nuclear power plants under Part 50, this occurs when the licensee receives authorization to operate, and for licensees constructing under Part 52, this occurs after the Commission has made the finding under paragraph 52.103(g) and before the receipt of SNM in the form of fuel assemblies (see paragraph 26.3(a) and (c)).

Section 26.5, “Definitions,” defines a “reviewing official” as “an employee of a licensee or other entity specified in § 26.3(a) through (c), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information [PDI] 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.”

Paragraph 26.183(c), “Responsibilities,” describes the MRO’s primary role as reviewing and interpreting positive, adulterated, substituted, invalid, and, at the licensee’s or other entity’s discretion, dilute test results obtained through the licensee’s or other entity’s testing program, and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

Section 26.401, “General,” provides requirements that a licensee or other entity must satisfy if the licensee or other entity elects to implement the requirements of Part 26, Subpart K, for an FFD program for a construction site. Paragraphs 26.401(a) and (c) refer to a “licensee or other entity” whereas paragraph 26.401(b) refers to only “Entities.”

Section 26.405, “Drug and alcohol testing,” provides the drug and alcohol testing requirements for licensees and other entities subject to Subpart K. Paragraph 26.405(g) states that licensees and other entities must provide for an MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results to determine whether the donor has violated the licensee’s or other entity’s FFD policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under Section 26.419.

Section 26.419, “Suitability and fitness evaluations,” describes the requirements for a licensee or other entity that implements an FFD program at a construction site to develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- and security-related SSCs. Under Section 26.419, these procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse.

Part 26, Subpart A, “Administrative Provisions,” provides descriptions and requirements associated with, in part, Part 26 applicability, definitions, interpretations, exemptions, and communications.

Part 26, Subpart B, “Program Elements,” provides requirements for, in part, policy, procedures, training, drug testing, behavioral observation, employee assistance, and FFD policy violations.

Part 26, Subpart C, “Granting and Maintaining Authorization,” describes the requirements for licensees and other entities who desire to grant individuals initial authorization, authorization update, authorization reinstatement, or authorization with PDI.

Part 26, Subpart G, “Laboratories Certified by the Department of Health and Human Services,” provides the requirements for, in part, laboratory testing of drugs and drug metabolites, personnel, qualifications, quality assurance, documentation, and reporting.

Part 26, Subpart H, “Determining Fitness-for-Duty Policy Violations and Determining Fitness” describes the requirements for MROs, substance abuse professionals, evaluation of drug test results, and conduct of determinations of fitness.

Part 26, Subpart N, “Recordkeeping and Reporting,” describes the recordkeeping and reporting requirements for licensees and other entities, Department of Health and Human Services-certified laboratories, licensee testing facilities, and FFD performance data.

The NRC has issued one guidance document to support implementation of Part 26, Subpart K: RG 5.84, “Fitness-for-Duty for New Nuclear Power Plant Construction Sites,” dated July 2015 (NRC 2015-TN6807). This RG endorses (with one exception not relevant here) NEI 06-06, “Fitness-for-Duty Program Guidance for New Nuclear Plant Construction Sites,” revision 6, dated April 2013 (NEI 2013-TN6311).

On September 16, 2019, as part of the “Fitness for Duty Drug Testing Requirements” proposed rule (84 FR 48750, September 16, 2019; TN6312), the NRC issued draft regulatory guide (DG)

5040, “Urine Specimen Collection and Test Result Review Under 10 CFR Part 26, ‘Fitness-for-Duty Programs.’ ” This DG would provide guidance on methods and procedures the NRC considers acceptable to demonstrate compliance with the NRC’s Part 26 regulations regarding the collection of urine specimens and the review of test results. The NRC expects to issue the final version of this RG when it issues the “Fitness for Duty Drug Testing Requirements” final rule.

2.2 Regulatory Issues

2.2.1 *Escorting Construction Workers*

Under the Part 26 requirements for a licensee described in paragraphs 26.3(a) and (b), an individual who would otherwise be subject to the licensee’s FFD program can be escorted at the licensee’s site and not be subject to the licensee’s FFD program. The regulations applicable to a licensee described in paragraph 26.3(c) do not allow for certain individuals to be escorted onsite. Paragraph 26.4(f) requires individuals who construct or direct the construction of safety- or security-related SSCs to be subject to a licensee’s FFD program. If these individuals are performing those duties at a power reactor construction site, then the individuals must be subject to the FFD program and cannot be escorted. This can unnecessarily restrict a licensee’s work planning and execution. If an individual will be onsite for only a short period of time, then escorting the individual can save time and allow for scheduling flexibility.

The burden that this requirement places on a licensee’s work planning and execution became evident during Southern Nuclear Operating Company’s (SNC’s) construction of VEGP Units 3 and 4 (VEGP 3&4). By letter dated December 6, 2018 (SNC 2018-TN6315), as supplemented by letter dated March 8, 2019 (SNC 2019-TN6316), SNC requested that the NRC approve an exemption from paragraph 26.4(f). The licensee claimed that the burden of requiring these individuals to be subject to the SNC FFD program, such as pre-assignment drug testing, would be costly and unnecessary when an equivalent, less burdensome alternative was available. The licensee requested approval to exclude from paragraph 26.4(f) individuals who would construct or direct the construction of safety- or security-related SSCs as long as they would perform their duties for 30 days or less in a 60-day period and would be under the control of an escort at VEGP 3&4.

In granting the exemption, the NRC found, in part, that the exemption affords the licensee increased flexibility in its management of its construction workforce and the conduct of construction activities by enabling SNC to implement process and procedural changes in a manner that leverages immediately available workers for short-duration construction activities. This flexibility could enable SNC to implement methods to use public finances more effectively and efficiently to construct the facility while maintaining reasonable assurance that the escorted construction workers would be trustworthy and reliable and fit to safely and competently perform assigned duties and responsibilities. The NRC wrote the exemption to automatically terminate before the establishment of a PA because, under paragraph 73.55(a)(4), with the establishment of the PA, the visitor-escort provisions of paragraphs 73.55(g)(7) and (8) would apply.

2.2.2 *Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction*

Based on operating experience and associated insights learned from the construction of VEGP 3&4 and VCSNS Units 2 and 3 (VCSNS 2&3), the NRC reassessed the risks presented during the construction of these commercial nuclear power reactors and finds that

implementation of paragraphs 26.3(a) and (c) is not commensurate with current risk insights. Paragraph 26.3(a) requires licensee implementation of an FFD program that meets all Part 26 requirements, except those in Subpart K, after the licensee is authorized to operate the commercial power reactor plant. Paragraph 26.3(c) and (a) require holders of a COL to implement an FFD program that meets all Part 26 requirements, except those in Subpart K, after the Commission has made the finding under paragraph 52.103(g) and before the receipt of SNM in the form of fuel assemblies. These provisions are therefore associated with the risk created by reactor operation in the first case, and receipt of unirradiated nuclear fuel onsite (after the Commission has made its finding under paragraph 52.103(g)) in the second case.

The security risk associated with unirradiated fuel does not increase when the fuel is onsite because its engineered safety features, storage, and configuration have not changed from when the fuel was in transit. For transit and receipt onsite, the same physical protection requirements are applied to protect the fuel.³ The unirradiated reactor fuel also does not present a safety risk because of its engineered features designed to contain the nuclear fuel, and the lack of SSCs to support criticality. Therefore, safety and security risks associated with unirradiated nuclear fuel only begin to increase after the nuclear fuel begins to be placed in the reactor vessel following the authorization to operate or the Commission's finding under paragraph 52.103(g). There is also some operational risk as the nuclear fuel is moved from transit, dry storage, and finally to the reactor vessel, but this risk is mitigated by security, operator training and qualification, and the safety-related and security-related SSCs designed to provide for safe wet storage and safe transfer of fuel into the reactor vessel.

The conduct of construction activities after the authorization to operate (or the Commission's Paragraph 52.103(g) finding) and before initial fuel load would also be expected to present a very low risk. This very low risk is based on a significant reduction in the number, type, and complexity of construction activities being performed during this period. As such, extending the implementation milestone of an FFD program that meets all Part 26 requirements except Subpart K, would not present an undue risk to safety and security. For example, although individuals may continue fabricating, erecting, integrating, and testing safety- and security-related SSCs in accordance with licensee-approved procedures that ensure design requirements are met, these activities will have a significantly low chance of causing an unreviewed safety question, a condition adverse to quality, an adverse safety impact, a security impact, an environmental impact, or an unreviewed change to an NRC-approved plan (such as quality assurance, security, fire protection, or emergency preparedness). This assessment is based on the defense-in-depth regulatory frameworks established in Parts 26, 50, 52, and 73; licensee procedures and controls; NRC reviews conducted to support the authorization to operate and the Commission's paragraph 52.103(g) finding; and NRC oversight of licensee activities as the licensee transitions from construction to reactor operation.

The NRC finds that the implementation of an FFD program that is not based on risk is inconsistent with one of the NRC's Principles of Good Regulation (NRC 2014-TN6227), "Reliability," which states, in part, that NRC regulations should be based on the best available knowledge from research and operational experience, and the NRC's Strategic Plan (NUREG-1614, Volume 7, "Strategic Plan, Fiscal Years 2018-2022," NRC 2018-TN6382), Safety Strategy 2, which states as a Contributing Activity, the NRC uses "risk-informed . . .

³ The NRC's physical protection requirements for unirradiated commercial reactor fuel are in 10 CFR 73.67, "Licensee fixed site and in-transit requirements for the physical protection of special nuclear material of moderate to low strategic significance."

approaches to enhance the effectiveness and efficiency of the regulatory framework that appropriately consider defense-in-depth, risk insights, and margins of safety.”⁴ In addition, requiring implementation of a more robust FFD program without a corresponding regulatory need is inconsistent with the graded approach incorporated into FFD requirements, which imposes requirements that are commensurate with the potential risks to public health and safety and the common defense and security that construction activities may pose when a plant begins operations.

Implementation of an FFD program that meets all Part 26 requirements except those in Subpart K during this period of construction would also place an unnecessary burden and cost on the licensee or other entity if they elect to receive nuclear fuel onsite very shortly after the paragraph 52.103(g) finding but before any significant change in risk warranting the need to implement an FFD program that meets all Part 26 requirements, except those in Subpart K. This burden and cost occur because a more comprehensive FFD program would be implemented on a larger population of construction workers for a longer period.

2.2.3 *Medical Review Officer Evaluation of a Donor’s Urine Specimen*

Under paragraph 26.401(a), a licensee has the option to implement two FFD programs on its construction site—one applicable to individuals who perform the duties specified in paragraph 26.4(e) and one applicable to individuals who perform the duties specified in paragraph 26.4(f). Based on operating experience gained from FFD program implementation at nuclear power plant construction sites, the NRC identified a process difference between the protections afforded to these two groups of individuals if a drug testing laboratory reports a donor’s urine specimen as “dilute.” Even though all these individuals are subject to essentially the same FFD drug and alcohol testing program requirements and sanctions under Part 26, individuals described in paragraph 26.4(f) are not afforded the same protection as those individuals described in paragraph 26.4(e) because, under a Subpart K FFD program applicable to paragraph 26.4(f) individuals, the MRO is not provided the option to review a dilute urine specimen, whereas under an FFD program applicable to paragraph 26.4(e) individuals who are subject to an FFD program that implements all Part 26 requirements except Subpart K, the MRO can review a dilute urine specimen at the licensee’s discretion under paragraph 26.183(c). The MRO’s review of a dilute specimen benefits the tested individual because laboratory identification of dilute urine could indicate an adverse physiological condition related to the donor’s muscular metabolism or kidney function. Further, for paragraph 26.4(e) individuals, urine specimens can be subject to an additional evaluation, which informs the licensee’s or other entity’s assessment of the donor’s trustworthiness, reliability, and FFD. Regulatory consistency would therefore benefit individuals subject to the licensee’s Subpart K FFD program, because these individuals could then be afforded equivalent worker protection from an unjustified Part 26 sanction that could originate from an incomplete MRO evaluation of a drug testing result involving a dilute urine specimen.

This is also important because a dilute urine specimen is an indication that the individual may have attempted to subvert the drug test through excessive hydration (prior to providing the urine specimen) in an attempt to lower *in situ* drug metabolite concentrations to below Part 26 cutoff levels and testing for dilute urine specimens is only one of a few tests that are conducted to determine if someone has attempted to subvert the drug test.⁵ This is significant for licensees

⁴ NUREG-1614, Volume 7, Strategic Plan, Fiscal Years 2018-2022.

⁵ A subverted drug test may also be identified by, for example, temperature, adulteration, substitution, and validity testing.

and other entities who are constructing a commercial power reactor have a higher incidence of subversion attempts than operating facilities. For example, from 2012 to 2017, approximately 42 percent per year on average of all subversion attempts in the commercial nuclear industry occurred at a power reactor construction site (VCSNS 2&3 and VEGP 3&4).

2.2.4 Clarifying Regulatory Language

Operating experience learned from the industry and from NRC inspection has not suggested that the issues discussed in Sections 2.2.4.1, “Use of the word ‘Entities,’” 2.2.4.2, “Individuals Directing the Construction of Safety- and Security-related SSCs,” and 2.2.4.3, “ ‘Reviewing Official’ in Part 26, Subpart K” of this appendix, have resulted in safety or security concerns. However, clarifying regulatory language would be consistent with the NRC’s Principles of Good Regulation.

2.2.4.1 Use of the Word “Entities”

Unlike paragraph 26.401(a), which uses a form of the phrase “licensee or other entity” three times and paragraph 26.401(c), which also uses the phrase “licensee or other entity,” paragraph 26.401(b) refers to only “entities.” As described in the Statement of Considerations (SOC) for paragraph 26.401(b) of the 2008 Part 26 final rule, the NRC intended for the paragraph 26.401(b) provision to apply to “licensees and other entities,” and not just “entities.” Consequently, the rule text is inconsistent with related provisions and the stated intent of the Commission.

2.2.4.2 Individuals Directing the Construction of Safety- or Security-related SSCs

The NRC has learned that Section 26.419 is not clear. Under Section 26.419, licensees and other entities must develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- or security-related SSCs. However, Section 26.419 does not address those individuals who direct the construction of safety- and security-related SSCs. In the 2008 Part 26 Final Rule SOC, the Commission explained that Section 26.419 is supposed to require licensees and other entities to have the procedures for evaluating individuals for assignment to “the duties specified in § 26.4(f).” The only duties specified in paragraph 26.4(f) are “constructing or directing the construction of safety- or security-related SSC.” Consequently, the rule text is inconsistent with related rule provisions and the stated intent of the Commission regarding individuals who direct the construction of safety- and security-related SSCs. Furthermore, the unclear language in Section 26.419 could have an adverse impact on licensees or other entities because, depending on the types of construction activities being performed, a significant population of the construction site workforce (i.e., those individuals who direct the construction of safety- and security-related SSCs) would not be subject to fitness determinations.

2.2.4.3 “Reviewing Official” in Part 26, Subpart K

Based on operating experience, the NRC has learned of a regulatory inconsistency regarding a “reviewing official” as defined in Section 26.5. This definition states that the reviewing official is an “employee of a licensee or other entity specified in § 26.3(a) through (c), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in 10 CFR 26.189, in order to determine whether the individual may be granted or maintain authorization.” A licensee or other entity specified in

paragraph 26.3(c) that implements a Subpart K FFD program is not required to use a reviewing official to disposition PDI or evaluate an individual's fitness to safely and competently perform their duties. However, these licensees or other entities must also implement an FFD program that meets all of Part 26, except Subparts I and K, for those individuals who perform the construction-related activities specified in paragraph 26.4(e), and licensees or other entities must use a reviewing official in an FFD program that meets all of Part 26, except Subparts I and K. There is no regulatory basis for requiring the use of a reviewing official in one FFD program but not the other.

NEI 06-06, as endorsed by RG 5.84, correctly uses the reviewing official terminology in that it provides for the licensee or other entity to rely on a reviewing official to make FFD authorization determinations for individuals specified in paragraph 26.4(e) and, at the licensee's or other entity's discretion, as per paragraph 26.4(f). The FFD programs at the VEGP and VCSNS construction sites demonstrated this use. These licensees and other entities implemented the guidance in RG 5.84 and used the phrase "reviewing official" whether referring to construction site access adjudications under an FFD program for construction and the collocated operating reactor FFD program that implements all Part 26 requirements, except Subpart K.

2.3 Discussion of Alternatives

2.3.1 *Alternative 1: No-Action*

2.3.1.1 *Description of Alternative 1*

This alternative would maintain the current regulatory framework.

2.3.1.2 *Assessment of Alternative 1*

This alternative would not incorporate lessons learned from the VEGP 3&4 and VCSNS 2&3 construction sites. Therefore, future licensees and other entities would have to request regulatory relief from the NRC to enhance the flexibility afforded to construction planning and execution that was approved for the VEGP construction site. In addition, implementation of an FFD program that meets all Part 26 requirements, except Subpart K, by future licensees and other entities would not be commensurate with risk and would result in unnecessary burden and costs unless the licensee requests an exemption. This alternative also would not improve worker protections associated with MRO review of dilute urine specimens or clarify rule language.

2.3.2 *Alternative 2: Limited-Scope Rulemaking and Guidance*

2.3.2.1 *Description of Alternative 2*

Under Alternative 2, the NRC would pursue rulemaking to address the regulatory issues discussed in Section 2.2.1, "Escorting Construction Workers," and Section 2.2.2, "Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction."

The NRC would address the escorting of construction workers who perform the duties specified in paragraphs 26.4(e) and (f) by amending paragraph 26.4(e) to add a new requirement that the escort shall be subject to an FFD program that meets all Part 26 requirements, except Subparts I and K; paragraph 26.4(f) to state that individuals who are escorted need not be subject to the

licensee's FFD program; Section 26.5 to define "escort" potentially as a person who is designated by the licensee or other entity and is trained and responsible for directly observing assigned individuals and helping ensure that those individuals under escort can safely and competently perform assigned duties; and paragraphs 26.403(a) and (b) to require the licensee or other entity to establish, implement, and maintain procedures for escorts and individuals under escort. The NRC would also propose a conforming change to regulatory guidance.

The NRC would require implementation of an FFD program that meets all Part 26 requirements, except Subpart K, at initial fuel load by amending paragraphs 26.3(a) and (c) to replace the words "before the receipt of special nuclear material in the form of fuel assemblies" with "before initial fuel load."

2.3.2.2 Assessment of Alternative 2

This alternative would incorporate lessons learned from the construction of the VEGP 3&4 commercial power reactors. Alternative 2 would allow licensees constructing new nuclear reactors to escort workers to perform or supervise those duties and responsibilities described in paragraphs 26.4(e) and (f). This option would afford these licensees and other entities enhanced flexibility in construction planning, scheduling, and conduct, and to respond to exigent construction and maintenance issues. The changes under this alternative would have no impacts on public health and safety because the NRC would have reasonable assurance that these escorted individuals would be able to perform their duties safely and competently while being observed by licensee-trained individuals.

This alternative would also defer the time by which licensees or other entities must implement an FFD program that meets all Part 26 requirements, except Subpart K. Alternative 2 would reduce licensee burden and costs by maintaining Subpart K FFD program requirements for a longer period of time than is currently required.

2.3.3 Alternative 3: Full-Scope Rulemaking and Guidance

2.3.3.1 Description of Alternative 3

Under Alternative 3, the NRC would address the issues in Alternative 2 and the regulatory issues in Section 2.2.3, "Medical Review Officer Evaluation of a Donor's Urine Specimen," and Section 2.2.4, "Clarifying Regulatory Language."

The regulatory issue in Section 2.2.3, "Medical Review Officer Evaluation of a Donor's Urine Specimen," would be addressed by amending paragraph 26.405(g) in a manner that is consistent with MRO review of dilute specimens under paragraph 26.183(c); this would enhance worker protections and licensee or other entity assessment of the individual's trustworthiness, reliability, and fitness. The regulatory issue in Section 2.2.4, "Clarifying Regulatory Language," would also be addressed by amending paragraph 26.401(b) to replace "entities" with "licensees and other entities"; Section 26.419 to include the category of individuals who direct the construction of safety- and security-related SSCs; and Section 26.5 and paragraph 26.405(g) to clarify that suitability and fitness evaluations required under Section 26.419 would be performed by a licensee's or other entity's designated reviewing official.

2.3.3.2 Assessment of Alternative 3

The NRC assessment provided in Section 2.3.2.2, “Assessment of Alternative 2,” also applies to Alternative 3, to the extent that Alternative 3 addresses the issues in Alternative 2. In addition, Alternative 3 would align how the MRO performs his or her review of drug testing results in a Subpart K FFD program with how they are conducted for individuals specified in paragraphs 26.4(a)–(e). This also affords reasonably equivalent worker protections to all individuals subject to Part 26 and helps identify individuals attempting to subvert a drug test.

Alternative 3 would clarify Sections 26.5 and 26.419 and paragraph 26.401(b). These changes would be administrative and would benefit future licensees, other entities, and NRC assessment of licensee performance. In addition, the changes would be simple and straightforward because they would not require conforming changes to other requirements and would only require non-substantial changes to procedures. Licensee or NRC training would not be necessary.

2.4 Regulatory Scope

Alternatives 2 and 3 would affect the requirements in Sections 26.3, 26.4, and 26.5; the requirements in Part 26, Subpart K; and regulatory guidance.

2.5 NRC Guidance, Policy, and Implementation Issues

2.5.1 *NRC Guidance*

Alternatives 2 and 3 could involve changes to guidance to address the escorting of individuals and MRO review of dilute urine specimens. This guidance would be provided in RG 5.84 and DG-5040.

2.5.2 *Policy Issues*

Alternatives 2 and 3 would not involve any changes to policy. These alternatives would not establish any new or revised procedure, perspective, or strategy that could be considered a new policy. The NRC also finds that Alternatives 2 and 3 would not result in an unresolved policy issue affecting the initiation or completion of the rulemaking.

2.6 Impacts

2.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would continue with the existing new reactor licensing process as described in the current regulations and guidance. This would include the processing of site-specific exemptions and amendments to address the regulatory issues described in Section 2.2.1, “Escorting Construction Workers,” and Section 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction.” The NRC would review existing regulatory guidance and propose revisions, if needed, based on the NRC’s schedule for reviewing existing guidance.

2.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current regulatory framework, there would be no increase or decrease in public health, safety, and security.

2.6.1.2 Impacts on Licensees or Other Entities

Because this alternative would not change the current regulatory framework, there would be no incremental impacts on licensees or other entities unless they voluntarily act to request relief from NRC requirements.

2.6.1.3 Impacts on NRC

Because this alternative would not change the current regulatory framework, there would be no incremental impacts on NRC, unless a licensee or other entity voluntarily acts to request relief from NRC requirements.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Limited-Scope Rulemaking and Guidance

Under this alternative, the NRC would amend the current regulations and issue guidance to benefit future licensees and other entities by enhancing regulatory flexibility and reducing burden and costs. Licensees and other entities would not have to request relief to resolve the regulatory issues described in Section 2.2.1, “Escorting Construction Workers,” and Section 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction.”

2.6.2.1 Impacts on Public Health, Safety, and Security

Because the NRC recommendations in Alternative 2 are administrative and do not change how a licensee or other entity constructs, operates, or maintains a nuclear power facility and Parts 26, 50, 52, and 73 regulatory frameworks are currently risk-informed and provide defense-in-depth, there would be no adverse impacts on public health, safety, and security.

2.6.2.2 Impacts on Licensees or Other Entities

The flexibility afforded by addressing the regulatory issues in Sections 2.2.1, “Escorting Construction Workers,” and 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction,” would result in cost savings for licensees and other entities – escorting individuals may improve the management of the workforce in response to short-duration or exigent construction activities and changing Part 26 implementation based on risk insights could reduce programmatic burden and costs. The improved flexibility would be realized through enhanced planning, scheduling, and execution and a stable Part 26 regulatory framework until radiological risk increases prior to initial core load. A cost savings to future construction licensees could also occur because site-specific relief requests would not be required.

The rulemaking costs to address escorting could exceed the cost of future site-specific relief requests if there are few new construction sites and these licensees and other entities elect to implement an escorting program. However, this cost is expected to be relatively low and a one-time cost. This low cost would occur because the Alternative 2 amendment is relatively simple and straightforward to implement; instruction would be required for individuals who are assigned as escorts. These changes do not require conforming changes in other requirements. Furthermore, once the regulatory framework has been revised, implementation costs will be dependent upon whether the licensee and other entity elect to implement changes to its program. The NRC would propose changes to two NRC RGs.

The burden and cost for Alternative 2 would be less than that incurred with Alternative 3, Full-Scope Rulemaking and Guidance, principally because the scope of the NRC’s action would be smaller.

In this rulemaking alternative, the cost averted would be the cost to develop and request an exemption to allow an escort program and to delay the implementation of an FFD program that meets all Part 26 requirements, except those in Subpart K. The NRC estimates that each licensee would no longer need to submit two licensing actions taking approximately 160 hours each with an averted cost estimated at approximately \$45,000 per new reactor construction site. Because the NRC expects future licensees and other entities to request this relief because the benefits outweigh the costs, amending the regulation to enable escorting would result in a cost to the licensee (e.g., procedures and training) covered under the exemption request.

Amending paragraphs 26.4(a) and (c) to replace “before the receipt of special nuclear material in the form of fuel assemblies” with “initial fuel load” is not a burden or cost for the VEGP Unit 3 construction site because issuance of a final rule will occur after initial core loading. If the amended rule is issued in time to benefit VEGP Unit 4, the averted cost would be the cost to develop and request an exemption and implement procedure and schedule changes. In addition, the VEGP Unit 4 burden and cost would be inconsequential compared to the potential cost savings incurred because the licensee or other entity could delay implementation of an FFD program that implements all Part 26 requirements, except for those in Subpart K, until later in the construction schedule.

Table F-3 shows the net averted costs for Alternative 2 are estimated to be approximately \$78,000 (7 percent NPV), and \$104,000 (3 percent NPV), using the assumption of one impacted applicant every 3 years through 2030. Beyond that, a cost estimate for future licensees would be too speculative to include in the cost estimate.

Table F-3 Licensee Averted Costs, Alternative 2 [Part 2]

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted exemption request from licensee	2	163	\$134	\$43,868	\$31,277	\$37,841
2027	Averted exemption request from licensee	2	163	\$134	\$43,868	\$25,532	\$34,630
2030	Averted exemption request from licensee	2	163	\$134	\$43,868	\$20,841	\$31,691
Total:					\$131,604	\$77,650	\$104,162

2.6.2.3 Impacts on NRC

This alternative would require a change in the current regulatory framework; consequently, there would be an incremental impact on the NRC. These impacts would be more than those for Alternative 1 and less than those for Alternative 3, principally because the scope of rulemaking

and guidance would be smaller than for Alternative 3. The NRC may incur some long-term quantitative benefit because it would not need to process future licensing actions that would enable escorting of individuals specified in paragraphs 26.4(e) and (f) and changing the implementation deadline for an FFD program that meets all Part 26 requirements, except Subpart K, to before initial core loading. The NRC estimates that the two averted licensing actions above each would result in approximately 80 hours of review time for the NRC; therefore, the rulemaking alternative would result in averted costs to the NRC.

The NRC would need to implement the rulemaking process, propose changes to two RGs, and conduct outreach with external stakeholders. The regulatory changes would be relatively simple and straightforward. Minor changes to NRC inspection program procedures may be required; however, NRC inspector training would not be necessary because the Alternative 2 changes are within the skill and knowledge of NRC inspectors. The NRC costs and averted costs listed in Table F-4 show an estimated cost to the NRC of Alternative 3 of (\$68,000) using a 7 percent NPV and (\$71,000) using a 3 percent NPV.

Table F-4 NRC Costs and Benefits, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2024	Averted exemption request review	2	82	\$131	\$21,397	\$15,256	\$18,457
2027	Averted exemption request review	2	82	\$131	\$21,397	\$12,453	\$16,891
2030	Averted exemption request review	2	82	\$131	\$21,397	\$10,165	\$15,457
Total:					(\$71,228)	(\$67,865)	(\$70,657)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Benefits and Costs

This alternative would present a substantial planning and scheduling benefit and an expected low cost for licensees and other entities. Rulemaking is a benefit because it establishes clear and consistent requirements to address the regulatory issues described in Sections 2.2.1, “Escorting Construction Workers,” and 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction.” This alternative would allow future licensees to avoid burden and costs because they would not need to request NRC approval of licensing actions to enhance flexibility in the planning and scheduling of construction activities and avoid the FFD costs discussed and shown above.

The rulemaking would result in a one-time cost to the NRC, and averted costs of licensing actions for future licensees. Alternative 2 would result in a net benefit to industry and the NRC of \$9,800 (7 percent NPV) and \$33,500 (3 percent NPV).

2.6.3 *Alternative 3: Full-Scope Rulemaking and Guidance*

Under this alternative, the NRC would implement rulemaking and guidance to address the regulatory issues in Alternative 2 and two additional recommendations described in Section 2.2.3, “Medical Review Officer Evaluation of a Donor’s Urine Specimen,” on the MRO evaluation of dilute urine specimens, and Section 2.2.4, “Clarifying Regulatory Language,” about the clarification of three regulatory requirements.

2.6.3.1 *Impacts on Public Health, Safety, and Security*

Because the two additional NRC recommendations are administrative and do not change how a licensee constructs, operates, or maintains a nuclear power facility, there would be no adverse impacts on public health, safety, and security. The two additional recommendations also would not affect public health, safety, and security.

2.6.3.2 *Impacts on Licensees or Other Entities*

The impacts on licensees and other entities are those described in Section 2.6.2.2, “Impacts on Licensees or Other Entities,” for Alternative 2 and the impact caused by the recommended MRO review of dilute urine specimens and the clarification of three regulatory requirements.

The Alternative 2 recommendations to enable escorting and delay implementation of an FFD program that meets all Part 26 requirements, except those in Subpart K, are applicable to Alternative 3. These recommendations would result in a substantial planning and scheduling benefit and an expected low cost for licensees and other entities. Additionally, rulemaking would be a benefit because it would establish clear, consistent, and requirements to address the regulatory issues described in Sections 2.2.1, “Escorting Construction Workers,” and 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction.” Alternative 3 costs for these two recommendations are equivalent to those for Alternative 2. The licensee’s development and implementation of changes to its procedures is a burden and cost, yet this cost is expected to be small. If the NRC recommendations are implemented, future licensees and other entities would not incur burden and costs because they would not need to request NRC approval of licensing actions to enhance flexibility in the planning and scheduling of construction activities. Similarly, Alternative 3 averted costs are the same as the Alternative 2 averted costs for the regulatory issues in Sections 2.2.1 and 2.2.2 detailed above.

Medical Review Officer evaluation of dilute urine specimens would represent a burden and cost on licensees and other entities because of MRO time spent to evaluate the dilute specimen, the donor’s lost time from work, and cost associated with licensee administration of Part 26-required sanctions (e.g., administrative time and worker replacement costs of the individual who subverted the drug test). However, the NRC recommends that this review would be at the discretion of the licensees and other entities like that currently enabled by paragraph 26.183(c).

From 2013 to 2019, an annual average of 6,937 individuals were subject to the FFD program at the VEGP 3&4 construction site, with a maximum of 9,294 individuals. Of this population, SNC conducted 11,583 Part 26-required drug and alcohol tests on average per year. The NRC estimates between 0.1 to 0.5 percent of all drug tests will indicate a dilute urine specimen (42 tests per year as a mean estimate). The cost to evaluate each dilute urine specimen is estimated to be 1 hour for the MRO, with no additional cost incurred from the drug testing laboratory. Additionally, the cost to the individual is estimated to be about 2 hours to have a

discussion with the MRO and obtain medical records. Using the low, average, and high number of individuals tested at the construction site, the annual cost to the licensee or other entity could range from \$3,048 to \$47,237, with a mean cost estimate of \$20,554. Regarding small modular reactors (SMRs), the NRC estimates that SMR construction will take one-third as long and the number of individuals subject to a Part 26 drug and alcohol testing program would be about 10 to 15 percent of that of the VEGP 3&4 construction site. Therefore, the burden associated with MRO evaluation of dilute specimens at an SMR will be significantly smaller than the costs estimated for the VEGP 3&4 construction site.

Training is not required because the assessment of dilute urine specimens is within the MRO training syllabus. The licensee or other entity would be required to change its FFD policy and procedures; however, these changes would be simple and straightforward and would not require staff training or any read-and-sign material. This change would result in a minor change to two RGs.

The NRC estimates that the cost to implement procedural changes for the clarification of regulatory language by licensees and other entities is small. The cost to implement changes to procedures to resolve the regulatory issue in Section 2.2.4, “Clarifying Regulatory Language,” would include technical staff, management, and administrative time based on loaded hourly rates. The changes are considered simple and easy to understand and implement. Training would not be required. This estimated cost ranges from \$7,750 to \$8,370. Licensee resources would incur a one-time cost to assess the impact of a change to a rule or guidance and change their procedures; they would not incur annual costs. Licensees and other entities could voluntarily propose changes to their industry guidance (e.g., NEI 06-06) to enhance unclear regulatory language and could request the NRC to endorse this guidance.

Alternative 3 would result in costs to licensees of approximately (\$15,500) using a 7 percent NPV and (\$25,300) using a 3 percent NPV, as shown in Table F-5.

Table F-5 Industry Costs and Averted Costs, Alternative 3

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted exemption request from licensee	2	163	\$134	\$43,868	\$31,277	\$37,841
2027	Averted exemption request from licensee	2	163	\$134	\$43,868	\$25,532	\$34,630
2030	Averted exemption request from licensee	2	163	\$134	\$43,868	\$20,841	\$31,691
2024-2030	Additional dilute urine specimen analysis	7		\$20,554	(\$143,879)	(\$78,979)	(\$110,464)
2024	Licensee procedure update	1		\$8,020	(\$8,020)	(\$5,718)	(\$6,918)
2027	Licensee procedure update	1		\$8,020	(\$8,020)	(\$4,668)	(\$6,331)
2030	Licensee procedure update	1		\$8,020	(\$8,020)	(\$3,810)	(\$5,794)
Total:					(\$36,335)	(\$15,525)	(\$25,345)

2.6.3.3 Impacts on NRC

The impacts described for Alternative 2 would be applicable for Alternative 3.

The NRC rulemaking and guidance recommendations to address regulatory issues in Sections 2.2.3, “Medical Review Officer Evaluation of a Donor’s Urine Specimen,” and 2.2.4, “Clarifying Regulatory Language,” would result in an increase in cost and burden above that for Alternative 2, due to greater modification of regulatory and guidance language. However, consistency and clarity of regulatory requirements could help reduce the possibility of any future NRC internal staff discussions and discussions with licensees that may result from a misunderstanding or misinterpretation of the rule. Qualitative benefits would also be gained

from knowing that the NRC requirements are clear and that the licensees and other entities would have the option to direct their MRO to review dilute urine specimens similar to that performed in an FFD program that implements all Part 26 requirements, except those in Subpart K.

Alternative 3 would result in net costs to the NRC of approximately (\$68,000) using a 7 percent NPV and (\$71,000) using a 3 percent NPV, as shown in Table F-6.

Table F-6 NRC Costs and Benefits, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2024	Averted exemption request review	2	82	\$131	\$21,397	\$15,256	\$18,457
2027	Averted exemption request review	2	82	\$131	\$21,397	\$12,453	\$16,891
2030	Averted exemption request review	2	82	\$131	\$21,397	\$10,165	\$15,457
Total:					(\$71,228)	(\$67,865)	(\$70,657)

2.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments. These impacts would be equivalent to those of Alternative 2.

2.6.3.5 Summary of Benefits and Costs

The summary of benefits and costs would be equivalent to those for Alternative 2, except additional benefit and cost would occur because the regulatory issues in Sections 2.2.3, “Medical Review Officer Evaluation of a Donor’s Urine Specimen,” and 2.2.4, “Clarifying Regulatory Language,” would be addressed.

For the regulatory issues in Sections 2.2.3, “Medical Review Officer Evaluation of a Donor’s Urine Specimen,” and 2.2.4, “Clarifying Regulatory Language,” qualitative benefits would be gained by enhancing personal protections through an additional MRO evaluation and clarifying the regulations, respectively. The MRO evaluation of dilute urine specimens is expected to be of low burden and cost because the evaluation is not technically complex, is within the skill of an MRO, and based on large construction site experience, there are approximately 42 occurrences of dilute urine specimens per year on average. Furthermore, the NRC recommendation is to enable an MRO, if directed by the licensee or other entity, to review dilute specimens, not to require the review. The benefit to the individual and to public health and safety is considered substantial when compared to cost. For the regulatory issue in Section 2.2.4, “Clarifying Regulatory Language,” there would be qualitative benefits if the regulatory language is clarified. Regulatory clarity reduces the chance of licensee implementation errors and may result in an NRC benefit because the NRC staff would not need to spend time conversing with licensees, other entities, and other NRC staff to ascertain the meaning of the requirement. Clarifying regulatory language could prevent a violation of NRC requirements.

Alternative 3 would result in minor net costs to industry and the NRC of approximately (\$83,000) using a 7 percent NPV and (\$96,000) using a 3 percent NPV.

2.6.4 Other Impacts and Regulatory Considerations

2.6.4.1 Regulatory Efficiency

If Alternative 2 or 3 is pursued, then future paragraph 26.3(c) licensees and other entities would benefit from improved regulatory effectiveness and efficiency presented in the regulations, and the NRC would not have to process the site-specific actions described in Sections 2.2.1, “Escorting Construction Workers,” and 2.2.2, “Changing Part 26 Implementation Based on Risk Insights Learned from Reactor Plant Construction.” This should result in an improvement in regulatory efficiency.

2.7 Backfitting and Issue Finality Considerations

Alternative 1 would not impose a change in requirements or NRC staff positions, so it would not constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52.

Alternative 2 would not constitute backfitting or affect the issue finality of an approval issued under Part 52. Alternative 2 would provide non-mandatory alternative requirements and would not result in backfitting or affect issue finality.

Alternative 3 would include the changes in Alternative 2 plus four other changes, none of which would constitute backfitting or affect issue finality. The four additional changes would affect licensees constructing a nuclear power plant, and the NRC does not expect any licensees to be constructing nuclear power plants at the time this rulemaking’s final rule goes into effect.

2.8 Stakeholder Feedback

2.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to FFD programs.

2.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The NRC staff recommends Alternative 3, “Full-Scope Rulemaking and Guidance,” because it is within the scope defined by the Commission, requirements would be clarified, and this alternative should result in a substantial improvement in regulatory flexibility for future licensees and other entities. Alternative 3 is not cost beneficial, resulting in net costs to industry and the NRC of (\$83,000) using a 7 percent NPV, due to rulemaking and conduct and evaluation of

dilute urine specimen tests. However, Alternative 3 is the staff's recommendation because of two principal reasons. First, Alternative 3 implements the recommendations described in Alternative 2, which do result in a net benefit. Second, enabling licensees and other entities to conduct and evaluate a urine specimen as dilute results in the following qualitative benefits: (1) aligning the Subpart K drug testing program with that of an FFD program that implements all subparts, except Subpart K, enables a more seamless transition of drug testing information between the two programs to support authorization determinations and it subjects all individuals onsite to the same drug testing evaluation process (providing consistency and worker protection considerations); and (2) testing an individual's urine specimen to ascertain whether it is diluted could identify a physiological condition that may require medical treatment and is one of only a few methods that could identify individuals who have attempted to subvert the drug test. This is significant for licensees and other entities who are constructing a commercial power reactor because construction sites have a relatively high number of subversion attempts.

APPENDIX G – EMERGENCY PLANNING

The potential alignment and updating of the language describing the U.S. Nuclear Regulatory Commission's (NRC's) policies related to the initial emergency classification and action level scheme, emergency plan change process, emergency preparedness exercises, significant impediments to development of emergency plans, and offsite contacts, arrangements, and certifications are addressed in the following sections of this appendix.

1.0 INITIAL EMERGENCY CLASSIFICATION AND ACTION LEVEL SCHEME

In the NRC's regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249), Appendix E, "Emergency Planning Preparedness for Production and Utilization Facilities," Section IV.B establishes the requirements for the contents of emergency plans with respect to the emergency classification and action level scheme (EALs or EAL scheme). An applicant for a combined license (COL) under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), is required to submit a complete EAL scheme despite certain information not being available at the time it submits its application. An early site permit (ESP) applicant under Part 52 may also seek approval of an EAL scheme as part of a major features plan or as a requirement of a complete and integrated plan. The NRC is considering clarifying the NRC approval process for the initial EAL scheme that is submitted for a COL or ESP under Part 52.

1.1 Existing Regulatory Framework

Section 52.17, "Contents of applications; technical information," and Section 52.79, "Contents of applications; technical information in final safety analysis report," provide the requirements for the contents of ESP and COL applications, respectively. Specifically, paragraphs 52.17(b)(2) and 52.79(a)(21) require COL applicants and ESP applicants (that choose to include major features of emergency plans or complete and integrated emergency plans in their applications) to comply with the pertinent requirements of Section 50.47, "Emergency plans," and Part 50, Appendix E. Paragraph 50.47(b) provides the planning standards for nuclear power plant emergency plans, including an EAL scheme under paragraph 50.47(b)(4). Appendix E to Part 50 provides emergency planning (EP) requirements for production and utilization facilities licensed under Parts 50 and 52. Section IV.B of Appendix E requires each emergency plan to contain an NRC-approved EAL scheme and a general description of EAL schemes.

The EAL scheme, as part of an NRC-approved emergency plan, is necessary to ensure adequate protection of public health and safety from the potential consequences of a radiological event. Emergency action level schemes are inherently complex and critically important as triggers for protective action decisions to mitigate the consequences of the event for the public. As a direct result of this safety significance, the NRC must review and approve EAL schemes as part of the licensing process for an operating license under Part 50 or for a COL under Part 52 to ensure that they are comprehensive and effective.

1.2 Regulatory Issues

There is a disparity in the timing and level of site-specific information available to Part 50 applicants and COL (and certain ESP) applicants under Part 52 regarding when they are

required to provide a complete EAL scheme for NRC approval. Part 50 applicants are not required to have a complete NRC-approved EAL scheme at the time a construction permit (CP) is issued under Section 50.35, "Issuance of construction permits." In contrast, Part 52 applicants are required to have a complete NRC-approved EAL scheme prior to being issued a COL or else are required to have included in their license a condition that prescribes a methodology for developing a complete EAL scheme, as discussed in more detail below. Submitting a complete EAL scheme requires sufficient detail to support the necessary findings by the NRC. Applicants for either an ESP or COL may not be able to provide a complete EAL scheme at the time of application because development of a complete EAL scheme relies on plant-specific inputs and variables that may not be available until the facility is partially, or fully, constructed. Despite not having site-specific as-built inputs, Part 52 applicants must still be able to show that the EAL scheme contained in the emergency plan can and will be implemented when warranted.

In 2011 and 2012, NRC held numerous public meetings to discuss certification and licensing of advanced reactor designs. In response to the uncertainties related to EAL scheme approval, the NRC developed an acceptable method by which applicants can meet the current requirement in Appendix E and be issued a COL. The method provides for both finality when the COL is issued and a reasonable assurance determination prior to operation. COL applicants submit "near complete" EAL schemes that were developed using an NRC-endorsed EAL scheme development guidance document without deviations. The only "unknowns" in a "near-complete" EAL scheme reflect specific plant information that the applicant has identified as being dependent on site-specific, as-built, conditions. In addition, the specific methodology that will be used for calculating each unknown once the plant is built must be in accordance with the selected NRC-endorsed guidance or contained within the near-complete EAL scheme. For COLs issued to date, the NRC has included a license condition that requires the licensee to submit a fully developed EAL scheme to the NRC no later than 180 days before initial fuel load. For an ESP that is approving an EAL scheme, the NRC has included a permit condition that has the same requirement, which carries forward into a subsequent COL as a license condition. This time period has proven to be adequate for the NRC to confirm that the licensee has finalized the EAL scheme in accordance with the license.

The NRC determined that there is a lack of clear NRC guidance addressing submittal and approval of initial EAL schemes for ESP and COL applicants. Although the method described herein has been implemented on a case-by-case basis and has proven successful in each application, it has not yet been clearly adopted such that the regulatory approach is communicated to COL and ESP applicants.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

This alternative would maintain the regulations and guidance in their current states.

1.3.1.2 Assessment of Alternative 1

This alternative would not address the identified regulatory issue. The NRC would continue to require an approved EAL scheme prior to issuance of either a COL or ESP (that addresses EALs), and the exact process by which this can be achieved would remain unclear.

1.3.2 *Alternative 2: Rulemaking to Amend Regulations for EAL Scheme Approvals*

1.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking and develop associated guidance to amend the regulations in Part 52 and Appendix E to Part 50 to better define the requirements for an EAL scheme that is submitted with an ESP or COL application.

1.3.2.2 *Assessment of Alternative 2*

Because a COL is issued prior to construction, the Parts 50 and 52 licensing processes cannot be perfectly aligned on this issue. Revising the regulations and developing associated guidance could provide added clarity to the process for Part 52 COL and ESP applicants. However, because a proven method to meet the existing regulations exists, the benefits of rulemaking would be minimal.

1.3.3 *Alternative 3: Guidance Development*

1.3.3.1 *Description of Alternative 3*

Under this alternative, the NRC would revise guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (NRC 2007/2019-TN6221) and Regulatory Guide (RG) 1.101, "Emergency Response Planning and Preparedness for Nuclear Power Reactors," (NRC 2005-TN6303), to provide a clear and consistent approach for Part 52 COL and ESP applicants' use to meet the existing regulations.

1.3.3.2 *Assessment of Alternative 3*

Revising guidance under this alternative would clarify what the NRC considers to be an acceptable "near-complete" EAL scheme for NRC approval prior to issuance of the COL or ESP (that addresses EALs), as well as the criteria that must be established by an associated license or permit condition. Because the guidance would provide a level of detail and clarity that does not currently exist in the regulations or in guidance, this alternative would serve to enhance the accessibility of the current regulations and be of significant benefit to future applicants and licensees.

1.4 **Regulatory Scope**

Alternatives 1 and 3 would not result in any changes to the regulations. Alternative 2 would require amendments to regulations in Part 52 and Section IV.B of Appendix E to Part 50 to clarify the processes for NRC approval of a COL or ESP applicant's initial EAL scheme. Under Alternative 3, the NRC would revise guidance in NUREG-0800 and RG 1.101 to clarify how Part 52 COL and ESP applicants can meet the existing requirements to obtain an approved EAL scheme.

1.5 **NRC Guidance, Policy, and Implementation Issues**

There are no policy or implementation issues. Alternative 3 would involve revision of existing guidance documents or the development of a new guidance document.

1.6 **Impacts**

1.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue to use license conditions to address the issues related to EAL scheme submittal and approval. The NRC would not pursue any changes to the current process.

1.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees.

1.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would revise the regulations in Part 52 and Section IV.B of Appendix E to Part 50 to clarify the process for NRC approval of a Part 52 COL or ESP applicant's initial EAL scheme. The NRC would also develop or revise associated guidance.

1.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would only clarify an existing regulatory process, there would be no increase or reduction in public health, safety, and security.

1.6.2.2 Impacts on Licensees

This alternative would have a limited incremental impact on licensees. Regulatory efficiency would be enhanced, which could result in minor cost savings to licensees associated with a decreased likelihood of needing to revise and resubmit EAL schemes. Cost savings would likely be minimal, because the regulations would be amended to clarify the existing process. Therefore, the NRC did not quantify these savings.

1.6.2.3 Impacts on the NRC

An initial cost would be incurred by the NRC to conduct rulemaking and associated guidance; however, there could be ongoing cost savings. The NRC could benefit from a reduction in staff review time. This alternative could eliminate the need to issue requests for additional information on this topic. However, the NRC believes these staff requests would be limited in scope and number; therefore, the NRC did not quantify these potential, minor burden reductions. This alternative would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent net present value (NPV) and (\$121,000) using a 3 percent NPV, as shown in Table G-1.

Table G-1 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

1.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 Summary of Costs and Benefits

This alternative would result in net costs to the NRC of (\$106,000) using a 7 percent NPV, due to rulemaking costs.

1.6.3 Alternative 3: Guidance Development

Under this alternative, the NRC would revise guidance.

1.6.3.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current regulations, there would be no increase or reduction in public health, safety, and security.

1.6.3.2 Impacts on Licensees

This alternative would have a limited incremental impact on licensees. Similar to Alternative 2, licensees could realize minor cost savings associated with a decreased likelihood of needing to revise and resubmit EAL schemes. Because the cost savings would be minimal, the NRC did not quantify these savings. Alternative 3 would describe the existing process in guidance; it would not alter this process. The benefit of this alternative is that the NRC would document an acceptable method of meeting the regulatory requirements.

1.6.3.3 Impacts on the NRC

An initial cost would be incurred by the NRC to revise the guidance; however, there could be ongoing cost savings. The NRC could benefit from a reduction in staff review time and response to submittals that need to be revised to meet the requirements. Alternative 3 would result in guidance development costs to the NRC of approximately (\$45,000) using a 7 percent NPV and (\$50,000) using a 3 percent NPV, as shown in Table G-2.

Table G-2 NRC Guidance Development Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
Total:					(\$53,481)	(\$45,184)	(\$49,677)

1.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.3.5 Summary of Costs and Benefits

This alternative would result in net costs to the NRC of (\$45,000) using a 7 percent NPV, due to guidance development costs.

1.7 Backfitting and Issue Finality

None of the alternatives presented in this section of Appendix G, if implemented by the NRC, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no changes to requirements or staff positions. Alternative 2 would clarify the existing regulatory pathway for COL and ESP applicants and would have no effect on existing Part 52 approvals. Alternative 3 would result in guidance development and would not impose any new requirements or staff positions.

1.8 Stakeholder Feedback

1.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The staff recommends pursuing Alternative 3, “Guidance Development,” to clarify the licensing process for future Part 52 COL and ESP applicants. Under Alternative 3, the NRC staff would issue guidance for EAL scheme approval for COL and ESP applicants under Part 52 that provides a clear and consistent approach for future applicants to meet the existing regulations. Because the guidance would provide a level of detail and clarity that does not currently exist in the regulations or in guidance, this alternative would serve to enhance the accessibility of the current regulations and be of significant benefit to future applicants and licensees at relatively low cost.

2.0 EMERGENCY PLAN CHANGE PROCESS

The NRC is considering whether the NRC regulations clearly convey the applicability of the emergency plan change process in paragraph 50.54(q) as it pertains to COL applicants and licensees under Part 52.

2.1 Existing Regulatory Framework

After a COL is issued under Section 52.97, “Issuance of combined licenses,” the Commission and licensee are bound by the regulations in Section 52.98, “Finality of combined licenses; information request,” regarding making changes to the COL. Section 52.98 requires COL holders to make changes to facilities and procedures (e.g., emergency plans), as described in the updated final safety analysis report, under the applicable Part 50 change processes. The applicable emergency plan change process is located in paragraph 50.54(q).

For changes to an emergency plan, Part 50 licensees and COL holders follow the requirements in paragraph 50.54(q). Section 50.54, “License conditions,” sets forth conditions that must be met by all nuclear power reactor license holders, including COL holders under Part 52. The introduction to Section 50.54 explains the applicability of many of the provisions within Section 50.54 to COL holders. Almost every provision, including paragraph 50.54(q), is a condition in a COL. Multiple provisions, but not paragraph 50.54(q), are identified as being applicable to COL holders only after the Commission has made a finding under paragraph 52.103(g). However, paragraph 50.54(q)(2) excepts a COL holder from the paragraph 50.54(q)(2) requirements to follow and maintain the effectiveness of the licensee’s emergency plan prior to a paragraph 52.103(g) finding. The other requirements in paragraph 50.54(q) apply to COL holders regardless of whether the Commission has made a finding under paragraph 52.103(g). So, although a COL holder has an approved emergency plan, that plan cannot be implemented or “in effect” at the time the COL is issued. For example, the plan may state that the licensee will have a fully staffed and trained fire brigade. The licensee likely will not have the fire brigade established when the COL is issued. However, if the licensee, prior to a finding under paragraph 52.103(g), decides to eliminate the fire brigade and rely on a local fire department, then the licensee would need to evaluate that change under paragraphs 50.54(q)(3) and (4).

2.2 Regulatory Issues

At a January 15, 2019, Category 3 public meeting, representatives from the Nuclear Energy Institute (NEI) discussed the lack of clarity on whether the emergency plan change process applies to Part 52 licensees prior to the Commission’s paragraph 52.103(g) finding. The NRC found that the applicability of the emergency plan change process in paragraph 50.54(q) is

unambiguous within the regulations. However, the regulations could be confusing to some COL holders because paragraph 50.54(q)(2) provides an exception for holders of a COL before the paragraph 52.103(g) finding, but the introductory text of Section 50.54, which lists the paragraphs within Section 50.54 that are excepted for COL holders before the paragraph 52.103(g) finding, does not include any portion of paragraph 50.54(q). Not identifying this exception in the introduction was an oversight during the 2011 EP rulemaking (76 FR 72560, November 23, 2011; TN5999), and could introduce some confusion regarding whether other paragraphs of paragraph 50.54(q) are applicable prior to the paragraph 52.103(g) finding.

2.3 Discussion of Alternatives

2.3.1 Alternative 1: No-Action

2.3.1.1 Description of Alternative 1

This alternative would maintain the regulations in Section 50.54 as written.

2.3.1.2 Assessment of Alternative 1

The “no-action” alternative would not address the regulatory issue. The regulations would continue to lack clarity.

2.3.2 Alternative 2: Rulemaking to Amend Section 50.54

2.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to amend the introduction of Section 50.54 to reference paragraph 50.54(q)(2) as being inapplicable before the Commission makes a paragraph 52.103(g) finding.

2.3.2.2 Assessment of Alternative 2

This alternative would amend the introductory text of Section 50.54 to include paragraph 50.54(q)(2) among the provisions listed as only being applicable after the Commission makes a paragraph 52.103(g) finding. This change would clarify when requirements under Section 50.54 are applicable.

2.4 Regulatory Scope

The scope of regulatory changes would be limited to the introductory text of Section 50.54.

2.5 NRC Guidance, Policy, And Implementation Issues

There would be no guidance, policy, or implementation issues related to this change. No regulatory guidance would need to be revised or developed.

2.6 Impacts

2.6.1 Alternative 1: No-Action

Under this alternative, the NRC would not make changes to existing regulations.

2.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees.

2.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Rulemaking to Amend Section 50.54

Under this alternative, the NRC would undertake rulemaking to amend the introduction to Section 50.54 to clarify its applicability.

2.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would only clarify when regulations are applicable and does not change the intent or effect of the regulations, there would be no impacts on public health, safety, and security.

2.6.2.2 Impacts on Licensees

Overall, this alternative would have a positive impact on licensees by clarifying the regulations. The current requirements would not change and licensees would benefit by removing any confusion regarding the applicability of the requirements in paragraph 50.54(q).

2.6.2.3 Impacts on the NRC

This alternative would have limited impact on the NRC. There would be costs associated with rulemaking. A non-quantified benefit may be the reduced number of applicant requests for the NRC to provide clarifications on a case-by-case basis. Alternative 2 would result in rulemaking costs to the NRC of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table G-3.

Table G-3 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Costs and Benefits

This alternative would result in net costs to the NRC of (\$32,000) using a 7 percent NPV, due to rulemaking.

2.7 Backfitting and Issue Finality

Neither of the two alternatives in this section of Appendix G, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect issue finality of an approval issued under Part 52. Alternative 1 would maintain Section 50.54 as written, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would amend the regulations to provide additional clarity but would not result in a change in requirements or NRC staff positions. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

2.8 Stakeholder Feedback

2.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, NEI made a presentation about its suggestions for this rulemaking. One industry representative from NEI mentioned a lack of certainty about whether the emergency plan change process applies to Part 52 licensees prior to the Commission's paragraph 52.103(g) finding.

2.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The NRC staff recommends pursuing Alternative 2, "Rulemaking to Amend Section 50.54," to clarify the applicability of paragraph 50.54(q)(2) prior to the Commission's paragraph 52.103(g) finding. Amending the introductory text of Section 50.54 by including a reference to paragraph 50.54(q)(2) to show that it is inapplicable to a COL holder until after the Commission's paragraph 52.103(g) finding would benefit both licensees and the NRC by providing additional clarity within the regulations.

3.0 EMERGENCY PREPAREDNESS EXERCISES

The NRC is considering rulemaking to address two separate issues related to the regulations in Section IV.F.2 of Appendix E to Part 50 as they apply to Part 52 applicants and licensees.

First, the NRC is analyzing whether there is a lack of clarity about the applicability of paragraph 50.54(gg) as a result of guidance in NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (Standard Review Plan or SRP) associated with developing inspections, tests, analyses, and acceptance criteria (ITAAC) that address low-power operations for testing.

Secondly, regarding Section IV.F.2.a.(iii) of Appendix E to Part 50, the NRC is considering whether to clarify when full participation exercises required by that provision are necessary for new reactors licensed under Part 52 at sites that have an existing nuclear power reactor. Exercises for each subsequent reactor at a site may not be needed if, for example, the new reactor is using the same technology, emergency response organization, and emergency response facilities as the existing reactor and the existing reactor has adequately demonstrated emergency plan capabilities in the required timeframe.

3.1 Existing Regulatory Framework

Section IV.F.2 of Appendix E to Part 50 provides specific requirements for the incorporation of emergency preparedness exercises into the emergency plans of both Parts 50 and 52 licensees. Section IV.F.2 of Appendix E to Part 50 provides requirements for the scope, timing, and outcomes of emergency preparedness exercises. Section 50.54 sets forth conditions that must be met by all nuclear power reactor license holders, including COL holders under Part 52.

Paragraphs IV.F.2.a.(ii) and (iii) of Appendix E to Part 50 state that paragraph 50.54(gg) applies when the Federal Emergency Management Agency (FEMA) identifies one or more deficiencies in the state of offsite emergency preparedness as a result of the exercises required by paragraphs IV.F.2.a.(ii) and (iii), 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 NRC will use the seven specific EP standards in paragraphs 50.54(gg)(1)(i) through (vii) to make the determination whether the Part 52 licensee can operate at up to 5 percent to conduct low-power testing. The regulations in paragraph 50.54(gg) for Part 52 licensees mirror those in paragraph 50.47(d) for Part 50 licensees.

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, then the holder of the COL may operate at up to 5 percent of rated thermal power.

Section IV.F.2.a.(ii) of Appendix E to Part 50 applies specifically to COL holders under Part 52 and details the timing and scope of exercises to be conducted prior to initial fuel load. Section IV.F.2.a.(iii) is applicable specifically to Part 52 applicants and licensees that currently have operating reactors at the site of the new Part 52 reactor and requires “an exercise, either full or partial participation, ... for each subsequent reactor constructed on the site.”

3.2 Regulatory Issues

3.2.1 *Paragraph 50.54(gg) Consistency*

The NRC identified an issue related to the guidance provided in NUREG-0800 that could adversely affect licensee understanding of paragraph 50.54(gg). NUREG-0800, Chapter 13.3 (Emergency Planning), and Chapter 14.3.10 (Emergency Planning – Inspections, Tests, Analyses, and Acceptance Criteria), address conditions for low-power operation in Table

14.3.10-1 (Emergency Planning – Generic Inspections, Tests, Analyses, & Acceptance Criteria [EP ITAAC]), ITAAC Acceptance Criterion 14.1.3. This criterion states:

The exercise is completed within the specified time periods of Appendix E to 10 CFR Part 50, offsite exercise objectives have been met, and there are either no uncorrected offsite exercise deficiencies or a license condition requires offsite deficiencies to be addressed prior to operation above 5 percent of rated power.

Previously issued COLs (as well as ESP applications that include complete and integrated emergency plans) have generally included application-specific versions of this generic ITAAC Acceptance Criterion 14.1.3. The language of ITAAC Acceptance Criterion 14.1.3 (“operation above 5 percent of rated power”) does not match the text of paragraph 50.54(gg) (“operate at up to 5 percent of rated thermal power”). This inconsistency could result in confusion about the application of paragraph 50.54(gg) for low-power testing.

3.2.2 *Subsequent Exercises*

The requirement in Section IV.2.a.(iii) of Appendix E to Part 50 for Part 52 applicants to conduct an emergency preparedness exercise for each new reactor constructed on a site with an operating reactor may not be necessary for certain licensees. The requirement may not be necessary if there are no significant differences between the operating reactor and the new reactor with respect to reactor technology and the EP and response resources, procedures, equipment, facilities, and emergency response organizations. In these circumstances, requiring a subsequent exercise may not provide any additional benefits to either regulatory oversight or the protection of public health and safety because previous exercises, conducted as part of the existing reactor’s exercise cycle, may be adequate to establish reasonable assurance.

Under paragraph 50.47(a)(2), FEMA’s findings and determinations regarding offsite emergency preparedness (i.e., whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented) focus on the offsite plans.

3.3 **Discussion of Alternatives**

3.3.1 *Alternative 1: No-Action*

3.3.1.1 *Description of Alternative 1*

Under this alternative, the NRC would take no action. Neither the current regulations nor guidance would be revised as a result of these regulatory issues.

3.3.1.2 *Assessment of Alternative 1*

This alternative would not address the identified regulatory issues. Under this alternative, neither the regulations nor the SRP would be revised to be consistent with paragraph 50.54(gg). Also, COL applicants would be subject to an exercise requirement.

3.3.2 *Alternative 2: Rulemaking and Guidance Development*

3.3.2.1 *Description of Alternative 2*

Under this alternative, existing guidance would be revised to clarify the applicability of paragraph 50.54(gg) to COL holders. Additionally, the NRC would pursue rulemaking in conjunction with revising existing guidance. The requirements in Section IV.F.2.a.(iii) of Appendix E to Part 50, would be revised to include provisions that, when met, would except COL holders from the requirement to conduct an emergency preparedness exercise for each subsequent reactor built at an operating reactor site.

3.3.2.2 *Assessment of Alternative 2*

Under this alternative, the NRC would also revise NUREG-0800. These minor revisions would add clarity and support reliability, which would also be aligned with the NRC's Principles of Good Regulation (NRC 2014-TN6227). Eliminating the requirement for a COL holder to conduct an exercise for each subsequent reactor built at an operating reactor site, when the exercise is redundant and of no incremental benefit to the NRC's oversight or to the protections afforded to the public, is aligned with the NRC's Principles of Good Regulation and strategic goals, objectives, and strategies. This alternative would provide for increased regulatory efficiency related to the conduct of emergency preparedness exercises for Part 52 applicants. It would also further enhance the risk-informed nature of the regulations.

3.4 **Regulatory Scope**

Rulemaking would focus on amending Section IV.F.2.a of Appendix E to Part 50, to include provisions that, when met, would except a Part 52 applicant from conducting emergency preparedness exercises for subsequent reactors built on the same site as an operating reactor. Along with rulemaking, the NRC would revise guidance to assist licensees in determining whether they meet the new provisions, and to address the identified issues in NUREG-0800.

3.5 **NRC Guidance, Policy, and Implementation Issues**

There are no policy or implementation issues. The revision of NUREG-0800 would clarify the guidance on the applicability of paragraph 50.54(gg). Rulemaking to provide exceptions for subsequent additional exercises, under certain circumstances, might require the development of new guidance but would not result in any policy or implementation issues.

3.6 **Impacts**

3.6.1 *Alternative 1: No-Action*

3.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

3.6.1.2 *Impacts on Licensees*

This alternative would have no incremental impacts on licensees.

3.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

3.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2 Alternative 2: Rulemaking and Guidance Development

Under this alternative, existing guidance would be revised to clarify the applicability of paragraph 50.54(gg) to COL holders. Additionally, the NRC would pursue rulemaking in conjunction with revising existing guidance.

3.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the intent or effect of the current regulations, there would be no impacts on public health, safety, or security.

3.6.2.2 Impacts on Licensees

Overall, this alternative has the potential to result in cost savings for Part 52 applicants. Significant time and expense are associated with conducting an emergency preparedness exercise. The NRC expects that applicants would seek an exemption as a less costly alternative, if they believe that they have already appropriately demonstrated meeting the emergency preparedness functions that would be demonstrated by conducting an exercise. By amending the regulations and creating provisions under which a licensee would not be required to conduct a subsequent exercise, the time and cost associated with requesting an exemption can be avoided. Based on the potential future applicants the NRC is aware of, an assumption of one applicant in 2026 and another in 2029 was used. After 2030, the prediction of future applicants becomes too speculative for this cost analysis. The NRC expects there will also be affected applicants after 2030; therefore, this cost estimate underestimates the benefits (averted costs) of Alternative 2.

Alternative 2 would result in averted costs to applicants of approximately \$75,000 (7 percent NPV) and \$103,000 (3 percent NPV), as shown in Table G-4.

Table G-4 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2026	Averted exemption request from licensee	1	494	\$134	\$66,399	\$41,350	\$53,988
2029	Averted exemption request from licensee	1	494	\$134	\$66,399	\$33,754	\$49,407
Total:					\$132,797	\$75,104	\$103,395

3.6.2.3 Impacts on the NRC

The NRC would incur minor costs associated with rulemaking, but by revising the regulations the NRC would reduce the number of future exemption and amendment requests. This would result in a more efficient process and save the NRC time and resources. These savings, while situational, would be realized on an ongoing basis because future reactor applicants would have an efficient path to meeting the regulations without the need for license amendments and

exemptions. Using the assumptions above, the NRC estimates Alternative 2 would result in costs of (\$176,000) using a 7 percent NPV and (\$194,000) using a 3 percent NPV, as shown in Table G-5.

Table G-5 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2026	Averted NRC review of exemption request	1	238	\$131	\$31,149	\$19,398	\$25,327
2029	Averted NRC review of exemption request	1	238	\$131	\$31,149	\$15,835	\$23,178
Total:					(\$208,538)	(\$176,246)	(\$194,420)

3.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net costs to industry and the NRC of approximately (\$101,000) using a 7 percent NPV and (\$91,000) using a 3 percent NPV.

3.7 Backfitting and Issue Finality

Neither of the alternatives presented in this section of Appendix G, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would not impose any new requirements on current Part 50 licensees and COL holders, and COL applicants that reference an NRC approval under Part 52 would not be required to comply with any new requirements. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality. Guidance changes under Alternative 2 would not impose new or changed requirements or NRC staff positions.

3.8 Stakeholder Feedback

3.8.1 *Feedback from the Public Meetings for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

3.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The staff believes that acting on these issues would result in significantly improved regulatory clarity and efficiency. The staff recommends pursuing Alternative 2, “Rulemaking and Guidance Development,” as described in Section 3.3.2.1, “Description of Alternative 2,” which is estimated to result in incremental costs to licensees and the NRC of (\$101,000) using a 7 percent NPV. These costs are due to the rulemaking process and are expected to be offset by the qualitative benefits above and from additional future applicants than the number estimated in this analysis.

4.0 SIGNIFICANT IMPEDIMENTS TO DEVELOPMENT OF EMERGENCY PLANS

As required by paragraph 52.17(b)(1), the site safety analysis report (SSAR) for an ESP application must include an evaluation of the physical characteristics of the proposed site, such as egress limitations from the area surrounding the site, that could pose a significant impediment to the development of emergency plans. Similar siting requirements are contained in Part 100, “Reactor Site Criteria.” However, the regulations and guidance are not clear how to determine the size and shape of the “site” or “area surrounding the site” that should be evaluated. The NRC is considering revisions to guidance to ensure a consistent approach to siting under Parts 50 and 52 for evaluating characteristics of the site that could pose a significant impediment to the development of emergency plans.

The regulations in paragraph 52.17(b)(1) further stipulate that if physical characteristics are identified that could pose a significant impediment to the development of emergency plans, then the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. This requirement has significance for EP and ESP applicants that may propose major features of emergency plans under paragraph 52.17(b)(2)(i) or complete and integrated emergency plans under paragraph 52.17(b)(2)(ii). For reviews of emergency plans, the NRC consults with FEMA on issues related to offsite radiological EP, as stated in paragraphs 52.17(b)(2)(i) and (ii). This consultation with FEMA is not part of the requirements of paragraph 52.17(b)(1). However, the regulations in Section 52.18, “Standards for review of applications,” state that such consultation with FEMA will occur. Therefore, the NRC is considering revising the regulations in Section 52.18 to clarify when consultation with FEMA is required.

4.1 Regulatory Framework

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

emergency plan under paragraph 52.17(b)(2)(i); or (3) complete and integrated emergency plans under paragraph 52.17(b)(2)(ii).

Siting requirements are contained in Part 100 (TN282). As stated in Section 100.1, "Purpose," siting factors and criteria are important in assuring radiological doses from normal operation and postulated accidents will be acceptably low, natural phenomena and potential manmade hazards will be appropriately accounted for in the design of the plant, site characteristics are such that adequate security measures to protect the plant can be developed, and physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans are identified. For the factors to be considered when evaluating sites for a power reactor, paragraph 100.20(a) requires that the applicant identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. In addition, under paragraph 100.21(g), applications for site approval of commercial power reactors must identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. This is similar to the language of paragraph 52.17(b)(1), except that under paragraph 52.17(b)(1), if physical characteristics are identified that could pose a significant impediment to the development of emergency plans, then the ESP application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. Paragraph 100.21(g) does not require the applicant to propose methods to mitigate or eliminate any identified significant impediments to the development of emergency plans.

Section 52.18 provides the standards of review for ESP applications. It generally incorporates into Part 52 all the relevant regulatory requirements for review from Parts 50 and 100. This includes the planning standards for emergency plans contained in paragraph 50.47(b) and for the content of emergency plans contained in Appendix E to Part 50. Section 52.18 further describes the review standards for the application in relation to the three distinct sets of requirements within paragraph 52.17(b) based on the level of emergency plan details that may be provided:

The Commission shall determine, after consultation with FEMA, whether the information required of the applicant by § 52.17(b)(1) shows that there is not significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with the applicable standards of § 50.47 of this chapter and the requirements of Appendix E to part 50 of this chapter, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Section 52.18 could be interpreted to require the NRC to consult with FEMA, even if the applicant, under paragraph 52.17(b)(1), did not identify any significant impediments to the development of emergency plans.

4.2 Regulatory Issues

4.2.1 *Extent of Siting Analysis*

In the Statement of Considerations for the Reactor Siting Criteria final rule ("Reactor Siting Criteria Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants; Final

Rule” [61 FR 65157, December 11, 1996; TN6305]), the Commission highlighted a concern that confusion may arise about the scope of the area surrounding the site:

It is sufficient that an applicant identifies any physical site characteristics that could represent a significant impediment to the development of emergency plans, primarily to assure that “A range of protective actions have been developed for the plume exposure pathway emergency planning zone for emergency workers and the public,” as stated in the planning standards.

Accordingly, appropriate sections of Part 100 (e.g., paragraph 100.21(g)) were modified to state that “physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans must be identified.” This language is identical to that in paragraph 52.17(b)(1), except paragraph 52.17(b)(1) also contains the phrase, “such as egress limitations from the area surrounding the site.” This phrase was removed from paragraph 100.21(g) in an attempt to eliminate any confusion that might arise regarding its scope.

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

Besides the regulations in paragraph 52.17(b)(1), the guidance associated with siting criteria does not define the site area under consideration. Regulatory Guide 4.7, “General Site Suitability Criteria for Nuclear Power Stations” (NRC 2014-TN3550), describes a method the NRC considers acceptable to implement the site suitability requirements for nuclear power stations:

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

However, “site” and “vicinity” are not defined in RG 4.7; rather, in RG 4.7 the NRC recommends that an evacuation time estimate be made for the entire plume exposure pathway EPZ. Similar guidance is provided in NUREG-0654/FEMA-REP-1, Revision 2, “Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants” (NRC and FEMA 2019-TN6306), which recommends that an ESP applicant identify unique physical characteristics of the site by performing a preliminary analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, noting major impediments to the evacuation or taking of other protective actions.

While this is one acceptable method of demonstrating the suitability of the site, both guidance documents assume a 10-mile EPZ is appropriate for the site. However, as described in NUREG-0396, “Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light-Water Nuclear Power Plants,” (NRC and EPA 1978-TN4441), the EPZ is only a planning tool to aid in the development and

implementation of predetermined prompt protective actions. In addition, EPZs are scalable in size, as appropriate to the facility (e.g., a site-boundary EPZ, a 5-mile EPZ), as allowed by the regulations in paragraph 50.33(g). Furthermore, as discussed in NUREG-0396, protective actions, in general, are not constrained to areas within the EPZ, nor does the capability for taking protective actions rely solely on the establishment of an EPZ. Thus, the EPZ may not necessarily be the same area under consideration for the siting requirements.

4.2.2 *Review of Early Site Permit Emergency Plans*

While the reactor siting criteria relate to components of the emergency plan, none of the siting factors and criteria are planning standards for emergency plans, such as those in paragraph 50.47(b). More importantly, the site characteristics are not material to findings on the adequacy of the emergency plan. This distinction was made in the Statement of Considerations for the Reactor Siting Criteria final rule, in which the Commission stated:

emergency planning is required as a matter of prudence and for defense-in-depth, and that the adequacy of an emergency plan was to be judged on the basis of its meeting the 16 planning standards given in 10 CFR 50.47(b). Hence, the characteristics of the site, which determine the evacuation time for the plume exposure pathway emergency planning zone, have not entered into the determination of the adequacy of an emergency plan. Emergency plans developed according to the above planning standards will result in reasonable assurance that adequate protective measures can be taken in the event of emergency.

An ESP applicant may propose major features of its emergency plan under paragraph 52.17(b)(2)(i) or propose a complete and integrated emergency plan under paragraph 52.17(b)(2)(ii). Paragraph 52.17(b)(2)(i) and (ii) require the NRC's review and approval to include consultation with FEMA.

Section 52.18 also requires consultation with FEMA during the NRC review of the acceptability of emergency plans. These consultation requirements are consistent with the regulations in paragraph 50.47(a) regarding how NRC and FEMA will make their findings and determinations on the adequacy of emergency plans. However, Section 52.18 could be interpreted to impose an additional requirement for consultation with FEMA regarding the information required by paragraph 52.17(b)(1), without clarifying whether the consultation is for purposes of siting or EP.

The NRC review conducted "in consultation with FEMA" is an explicit requirement of paragraph 52.17(b)(2)(i) and (ii), but it is not a requirement of paragraph 52.17(b)(1). The first part of paragraph 52.17(b)(1) is a siting criterion: "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." This is aligned with the siting criteria of Part 100. However, unlike Section 52.18, which requires consultation with FEMA regarding the information required by paragraph 52.17(b)(1), Part 100 does not require consultation with FEMA to support the NRC finding on the suitability of the site. Under Part 50, the mitigation of physical impediments would be addressed in the preliminary safety analysis report (PSAR) during the application for a CP. In accordance with Section II.G of Appendix E to Part 50, applicants are required to perform a preliminary analysis of the time required to evacuate various sectors and distances within the plume exposure pathway EPZ for transient and permanent populations, noting major impediments to the evacuation or implementation of protective actions. As stated in the introductory paragraph to Section II of

Appendix E, the PSAR must contain sufficient information to ensure the compatibility of proposed emergency plans for both onsite areas and the EPZs with respect to considerations such as access routes, surrounding population distributions, land use, and local jurisdictional boundaries for the EPZs. As such, any identified major impediments would be reviewed for compatibility with offsite plans and the NRC would consult with FEMA as required by paragraph 50.47(a)(2).

After the siting criteria, paragraph 52.17(b)(1) contains additional language stating that if significant impediments to the development of emergency plans are identified, then the applicant must identify the measures that would, when implemented, mitigate or eliminate the significant impediments. This part of paragraph 52.17(b)(1) relates directly to the development of emergency plans because, if significant impediments are identified, then consultation with FEMA would be needed in accordance with Section 52.18. But, Section 52.18 does not make the distinction between the two parts of paragraph 52.17(b)(1) or specify which part requires consultation with FEMA and why. Also, confusion may arise from the use of a double negative regarding the identification of significant impediments. Specifically, Section 52.18 states, in part:

The Commission shall determine, after consultation with FEMA, whether the information required of the applicant by § 52.17(b)(1) shows that there is not significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant....[emphasis added]

Consequently, Section 52.18 could be interpreted to impose a requirement to consult with FEMA on the ESP application that is not consistent with the review that would be performed under Part 100 for reactor siting.

4.3 Discussion of Alternatives

4.3.1 Alternative 1: No-Action

4.3.1.1 Description of Alternative 1

This alternative would maintain the regulations and guidance in their current states.

4.3.1.2 Assessment of Alternative 1

The “no-action” alternative would not address the identified regulatory issues and would be contrary to the agency’s goal to provide clear and consistent regulations. Taking no action and not pursuing, at a minimum, guidance development, would leave the licensing process in its current state, including when external consultation is needed and the area to be considered for siting purposes.

4.3.2 Alternative 2: Rulemaking and Guidance Development

4.3.2.1 Description of Alternative 2

Under this alternative, the NRC would revise existing guidance to clarify the extent of the analysis needed by the applicant to demonstrate compliance with the siting criteria for the

identification of physical characteristics of the proposed site that could pose significant impediments to the development of emergency plans.

In addition, the NRC would pursue rulemaking to align the ESP process in Part 52 with the Part 50 power reactor licensing process by revising Section 52.18 to align the siting requirements and EP requirements and to clarify when NRC consultation with FEMA is required.

4.3.3 *Assessment of Alternative 2*

4.3.3.1 *Extent of Siting Analysis*

Under Alternative 2, the NRC would clarify, in guidance, the area that ESP applicants should use in their siting analyses under paragraph 52.17(b)(1). Historically, the extent of the siting analysis has followed the size of the EPZ since this is the distance within which detailed radiological emergency plans are developed. In the event that the EPZ size has not yet been determined at the ESP stage, the NRC would provide guidance for the area that ESP applicants could use in their siting analyses under paragraph 52.17(b)(1). In the Statement of Considerations for the 1996 Reactor Siting Criteria Final Rule, the Commission incorporated basic reactor site criteria in Part 100 but relocated source term and dose calculations to Part 50 to represent a partial decoupling of siting from accident source term and dose calculations. For the same reasons, the EPZ size criteria, which are related to dose calculations, could be decoupled from siting to provide a generic site suitability determination that can inform the eventual development of emergency plans. This approach could provide a suitable method for the NRC to make findings on site suitability for an ESP when applicants choose not to include the optional EP information under paragraph 52.17(b)(2) or when the size of the EPZ appropriate to the facility has not yet been determined. This approach could also provide a consistent basis for comparing the suitability of one site to another. The NRC would revise existing guidance instead of conducting rulemaking because guidance can be used to define and clarify the area that should be considered when determining site suitability and to explain techniques acceptable for use in evaluating sites for significant impediments. Using guidance to address the issue would also allow applicants to propose alternate methods or solutions to meet the siting analyses under paragraph 52.17(b)(1).

As an example of the type of guidance that could be developed, the appropriate area surrounding the site might be demonstrated by a risk-informed consideration of the extrapolation of dose at the site boundary. This approach was used in Section D.1, "Siting," of Appendix 1 to NUREG-0396 to provide dose versus distance perspectives on the implication of Part 100 reactor siting criteria for EP. A similar argument could be applied to the U.S. Environmental Protection Agency (EPA) protective action guide (PAG) limits of 1-5 Roentgen equivalent man (rem), which are the trigger levels for initiating evacuation or sheltering in place. Considering that dose rates typically decrease with radial distance (r) from the source by an inverse-distance or inverse-distance-squared relationship, even if the upper PAG limit of 5 rem is reached at a 1-mile site boundary, the dose at 5 miles would be expected to be below EPA PAGs of 1 rem. This is not a justification for an EPZ of a particular size for a specific facility type; it is a potential justification of the distance one may need to travel away from the site to ensure that protective actions are effective at providing dose savings.

Additional consideration in this example could be given to the relationship between the EPZ size and implementation of protective actions. The initial protective action response within a 10-mile EPZ typically would not involve the entire EPZ. Supplement 3 to NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans

and Preparedness in Support of Nuclear Power Plants: Guidance for Protective Action Strategies,” (NRC and FEMA 2011-TN5965), suggests that licensees recommend evacuation or sheltering in place within a 2-mile radius and 5 miles downwind of the nuclear power plant as an initial protective action. As such, it may only be necessary to perform the siting analysis within the 5-mile area most at risk during a radiological release. Under this alternative, evaluation of the entire EPZ, such as a 10-mile plume exposure pathway EPZ, would also satisfy the siting analysis under paragraph 52.17(b)(1).

For a facility with a site-boundary EPZ, protective actions may only be warranted onsite, if at all. In NUREG-0396, a combined NRC and EPA Task Force considered the relationship between the design basis accidents analyzed for siting purposes and the extent to which beyond-design basis accidents should be considered in developing emergency plans. The Task Force concluded that it is not appropriate to develop specific plans for the most severe and most improbable accidents. The Task Force, however, did believe that consideration should be given to the characteristics of severe accidents in judging whether emergency plans based primarily on smaller accidents can be expanded to cope with larger events because this would provide assurance that some capability exists to minimize impacts of even the most severe accidents. For a facility that has a site-boundary EPZ, the siting criteria, evaluated in the area surrounding the site, would support the EP planning basis assumption that protective actions can be expanded to cope with the highly unlikely event of an accidental release offsite.

Guidance could specifically focus on the identification of physical characteristics unique to the site that would pose impediments to taking protective actions, including guidance for simplifying an evacuation time estimate (ETE) study used in support of this determination. Because an ETE study is typically used to demonstrate compliance with this siting requirement, the NRC would revise the ETE guidance in NUREG/CR-7002, “Criteria for Development of Evacuation Time Estimate Studies,” (Jones et al. 2011-TN5968), to provide guidance to ESP applicants on the extent of the analysis required when using an ETE for siting purposes. Conforming guidance would be provided in NUREG-0800 and RG 4.7.

4.3.3.2 Review of Early Site Permit Emergency Plans

Alternative 2 would also clarify (1) the alignment between siting requirements and EP requirements, and (2) when NRC consultation with FEMA is required. As discussed above in Section 4.2.2, “Review of Early Site Permit Emergency Plans,” paragraph 52.17(b)(1) contains siting criteria and criteria to aid in the development of emergency plans; however, paragraph 52.17(b)(1) is not a standard for determining the adequacy of emergency plans. As a source of siting criteria, this regulation provides assurance that assumptions supporting the planning basis for EP are valid for the specific site under consideration, and that any physical characteristics of the site that could pose a significant impediment to the development of emergency plans have been identified. Although the NRC has been able to issue ESPs and licenses under the existing regulatory framework, clarifying when the NRC reviews performed under Section 52.18 require consultation with FEMA would benefit applicants and the NRC by aligning the Parts 50 and 52 licensing processes, reducing the regulatory burden, and providing a needed alignment between siting criteria and the standards for determining the adequacy of emergency plans. The ESP application process, for licensees not seeking approval of emergency plans, would be better defined and more efficient than under the current regulatory framework.

4.3.4 *Alternative 3: Guidance Development*

4.3.4.1 *Description of Alternative*

Under this alternative, the NRC would develop additional guidance to clarify the NRC's position on siting requirements and EP requirements in Part 52 and to better define and clarify the area that could be considered when determining site suitability.

4.3.4.2 *Assessment of Alternative 3*

The desired clarifications could be acceptably addressed via guidance revision. Because the guidance would provide a level of detail and clarity that does not currently exist in the regulations or in guidance, this alternative would serve to enhance the accessibility of the current regulations and be of significant benefit to future ESP applicants. However, this alternative would not be consistent with the NRC's goal to provide clear and consistent regulations.

4.4 **Regulatory Scope**

Alternatives 1 and 3 would not result in any changes in the regulations. Alternative 2 would require revising Section 52.18. Alternatives 2 and 3 would involve developing or revising guidance.

4.5 **NRC Guidance, Policy, and Implementation Issues**

None of the alternatives would present guidance, policy, or implementation issues. The rulemaking under Alternative 2 would not substantively change the existing requirements; it would only align the Part 52 requirements with the Part 50 licensing process. Guidance development under Alternatives 2 and 3 would affect NUREG/CR-7002, NUREG-0800, and RG 4.7, and would be aligned with current agency policies.

4.6 **Impacts**

4.6.1 *Alternative 1: No-Action*

4.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

4.6.1.2 *Impacts on Licensees*

This alternative would have no incremental impacts on licensees.

4.6.1.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC.

4.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

4.6.2 Alternative 2: Rulemaking and Guidance Development

4.6.2.1 Impacts on Public Health, Safety, and Security

This alternative would have no incremental impacts on public health, safety, and security.

4.6.2.2 Impacts on Licensees

This alternative would have a net positive impact on applicants under Part 52 because standardization would clarify and simplify the current process. The NRC anticipates that rulemaking and guidance development could reduce burden on impacted applicants by 50 to 100 hours. Standardized approaches for determining whether significant impediments exist and simplified ETEs would reduce application costs. For example, if site characterizations were standardized to a 5-mile evaluation rather than a 10-mile evaluation, then in some cases, the ETE studies would not need to include elements needed to inform protective action strategies of the emergency plan, such as multiple scenarios. This would result in cost savings during initial ETE study development. In addition, this alternative would provide for approval of a site independent of the reactor technology to be selected for the site. Using the previously stated assumptions in Section 3.0 of this appendix, Alternative 2 would result in averted costs of \$11,400 (7 percent NPV) and \$15,700 (3 percent NPV), as shown in Table G-6.

Table G-6 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2026	Simplified ESP Application	1	75	\$134	\$10,072	\$6,272	\$8,189
2029	Simplified ESP Application	1	75	\$134	\$10,072	\$5,120	\$7,494
Total:					\$20,143	\$11,392	\$15,684

4.6.2.3 Impacts on the NRC

An initial cost would be incurred by the NRC for rulemaking and guidance development. However, the increased clarity in the requirements and guidance would result in ongoing savings, depending on the number of future applicants under Part 52. NRC reviews and subsequent licensing would be more efficient and consistent with clearly defined guidelines, and expenditure of resources to conduct external consultations, when they are not warranted, could be avoided. Alternative 2 would result in net costs to the NRC, due to rulemaking, of approximately (\$100,000) using a 7 percent NPV and (\$114,000) using a 3 percent NPV, shown in Table G-7.

Table G-7 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2026	NRC Review of Simplified ESP Application	1	38	\$131	\$4,913	\$3,059	\$3,994
2029	NRC Review of Simplified ESP Application	1	38	\$131	\$4,913	\$2,497	\$3,655
Total:					(\$125,593)	(\$100,183)	(\$113,813)

4.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net costs to industry and the NRC of approximately (\$89,000) using a 7 percent NPV and (\$98,000) using a 3 percent NPV, due to rulemaking costs.

4.6.3 Alternative 3: Guidance Development

4.6.3.1 Impacts on Public Health, Safety, and Security

There would be no increase or reduction in public health, safety, and security.

4.6.3.2 Impacts on Licensees

This alternative would likely result in cost savings for future ESP applicants. The guidance would clarify the regulations allowing the applicant to develop applications with increased regulatory certainty and potentially decreased development costs. For example, the guidance would clarify the “area surrounding the site” and standardize this value for all ESP applicants. However, the guidance-only approach would not result in the added burden reduction of the rulemaking alternative; therefore, the NRC did not quantitatively estimate the benefits of this alternative.

4.6.3.3 Impacts on the NRC

An initial cost would be incurred by the NRC to develop the guidance, but ongoing cost savings would be realized. Going forward, the availability of guidance would result in incremental cost savings for each new Part 52 applicant by reducing review and response to applications that need to be revised to meet the requirements. Alternative 3 would result in guidance development costs to the NRC of approximately (\$45,000) using a 7 percent NPV and (\$50,000) using a 3 percent NPV, as shown in Table G-8.

Table G-8 NRC Guidance Development Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
Total:					(\$53,481)	(\$45,184)	(\$49,677)

4.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.3.5 Summary of Costs and Benefits

Alternative 3 would result in net costs of approximately (\$45,000) using a 7 percent NPV, due to guidance development.

4.7 Backfitting and Issue Finality

None of the alternatives in this section of Appendix G, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no changes. Alternative 2 would include revisions to the requirements for ESP applications. With limited exceptions, applicants are not within the scope of Section 50.109 or any issue finality provision in Part 52. This is because these provisions were not intended to apply to every NRC action that substantially changes the expectations of current and future applicants. Two of those exceptions, an OL applicant or a COL applicant referencing an issued ESP, would not need to comply with the revised regulations. Alternative 2 and Alternative 3 would include guidance development, and guidance documents do not impose requirements or staff positions on licensees. For these reasons, none of the alternatives would constitute backfitting or affect issue finality.

4.8 Stakeholder Feedback

4.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

4.8.2 *Feedback from Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

4.9 Staff Recommendation

The staff recommends that the NRC pursue Alternative 2, “Rulemaking and Guidance Development,” to clarify the licensing process and ensure the regulations can be consistently implemented for future applicants and licensees. The regulations would be amended to clarify when the NRC will consult with FEMA. Alternative 2 would ensure consistency between Parts

50 and 52 licensing processes and reduce the regulatory burden on the licensee and NRC. Additional guidance development would act to provide further clarity about how applicants under both Parts 50 and 52 can meet siting and EP requirements. This alternative is estimated to result in incremental costs to licensees and the NRC of (\$89,000) using a 7 percent NPV. These costs are due to the rulemaking process and are expected to be offset by the qualitative benefits above.

5.0 OFFSITE CONTACTS, ARRANGEMENTS, AND CERTIFICATIONS

The NRC is considering revising the requirements in Section 52.17, "Contents of applications; technical information" related to establishing and describing contacts and arrangements made with Federal, State, and local governmental agencies that have EP responsibilities and the need for certifications from these agencies. The NRC is considering this change because it may be premature to request such detailed information during the ESP phase because there is no corresponding safety benefit. Within the context of this regulatory basis, "contacts and arrangements" is used to refer specifically to "contacts and arrangements made with Federal, State, and local governmental agencies with EP responsibilities" as provided in paragraph 52.17(b)(4).

5.1 Existing Regulatory Framework

Section 52.17 describes the required contents of applications for an ESP under Part 52. Specifically, the regulations in this section require that a SSAR be developed by the applicant and included in the ESP application. Applicants may request Commission approval and finality on certain elements of their emergency plans. Because the ESP phase of the licensing process is relatively early in the overall Part 52 licensing process, emergency plans are not always fully developed at the time of application and are not required at this stage. Three distinct sets of requirements are provided within paragraph 52.17(b) for the development of the SSAR and the application based on the level of emergency plan approval and finality sought by the applicant: (1) under paragraph 52.17(b)(1), no emergency plan is submitted, but the applicant must identify and, if applicable, describe plans to mitigate or eliminate, significant impediments to the development of emergency plans; (2) under paragraph 52.17(b)(2)(i), the applicant may submit the major features of an emergency plan; and (3) under paragraph 52.17(b)(2)(ii), the applicant may submit a fully developed emergency plan, generally referred to as a "complete and integrated" emergency plan.

Paragraph 52.17(b)(4) requires that SSARs complying with paragraph 52.17(b)(1) and (b)(2)(i) must describe the contacts and arrangements made with Federal, State, and local governmental agencies and include any certifications that have been obtained. As used in paragraph 52.17(b)(4), a certification is generally a letter that describes an offsite response organization's commitment to support EP and response in the event of an emergency (e.g., letter of agreement, memorandum of understanding). The offsite response organization also certifies that the proposed emergency plans are practicable. If a certification cannot be obtained, then the SSAR 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." In addition, paragraph 52.17(b)(4) describes information to be included in the SSAR if a complete and integrated emergency plan has been developed and submitted as part of the application package under paragraph 52.17(b)(2)(ii).

5.2 Regulatory Issues

The regulations in paragraph 52.17(b)(1) and 52.17(b)(4) may require revision regarding the descriptions of contacts and arrangements with Federal, State, and local governmental agencies that are required to be included in an ESP application. The NRC has identified two issues: (1) whether the regulations effectively differentiate between the level of emergency plan approval sought, and the corresponding contacts and arrangements that are necessary to support the review of the application; and (2) when certifications of these arrangements, including compensatory plans for certifications that cannot be obtained, should be required within the Part 52 licensing process.

Generally, contacts and arrangements are developed as necessary to support an applicant's emergency preparedness functions that depend on offsite agencies. The requirement that contacts and arrangements be described in the SSAR for an application with no emergency plan or major features of an emergency plan is subject to multiple interpretations. For example, does the applicant need to make contacts and arrangements in order to describe them, or does the applicant only need to describe any contacts and arrangements with offsite agencies that occurred while determining whether any significant impediments exist under paragraph 52.17(b)(1). If the applicant is not seeking approval of EP elements that involve offsite agencies, then requiring the applicant to develop contacts and arrangements that are not material to their application may present an undue regulatory burden. It also acts to limit the flexibility afforded to applicants and may have associated negative impacts. For example, it could be more efficient to establish contacts and arrangements in the development of a complete and integrated emergency plan as part of the COL application than to develop them for an application with no emergency plan or major features of an emergency plan.

The second issue concerns whether the current regulations appropriately address the need for certifications of offsite contacts and arrangements as part of the ESP application. Paragraph 52.17(b)(4) requires ESP applications complying with paragraph 52.17(b)(1) or (b)(2)(i) to include any certifications that have been obtained, and if they cannot be obtained, then an adequate compensatory utility plan must be included. The certifications requirement in paragraph 52.17(b)(4) can be broken down into two separate issues: when certifications should be required, and when compensatory plans should be required when certifications cannot be obtained.

The need for an applicant to provide certifications is clearly dependent on the need for contacts and arrangements. If contacts and arrangements are not needed to establish support from an agency or organization, then an applicant should not need a certification committing the offsite agency or organization to provide that support. Certifications are needed in two cases: (1) to show that any plans that were developed to mitigate a significant impediment to the development of emergency plans can be implemented; or (2) when the ESP application describes EP functions that rely on response from offsite organizations. As such, any amendments to the regulations to address the need for contacts and arrangements should clarify the requirements for when certifications and compensatory utility plans must be submitted with an ESP application.

Applications submitted under paragraph 52.17(b)(2)(ii) must provide complete plans such that the Commission can find that there is reasonable assurance that in the event of an emergency there will be adequate protection of the public health and safety. Complete and integrated plans in an ESP application must meet the same standards and regulations that are required of COL applications because the ESP would establish a similar amount of finality to the proposed

emergency plans as a COL. As such, all certifications and, when necessary, compensatory utility plans submitted under paragraph 52.17(b)(2)(ii), must be fully developed. This level of finality is not being sought by applications under paragraphs 52.17(b)(1) and 52.17(b)(2)(i), and compensatory utility plans may not be necessary as part of an ESP application. For applications submitted under paragraphs 52.17(b)(1) and 52.17(b)(2)(i), if certifications are not or cannot be obtained, then issuing an ESP without a compensatory plan could still be warranted, after which sufficient compensatory plans would have to be provided in the COL application.

5.3 Discussion of Alternatives

5.3.1 Alternative 1: No-Action

5.3.1.1 Description of Alternative 1

This alternative would maintain the current regulations and guidance.

5.3.1.2 Assessment of Alternative 1

The “no-action” alternative is not desirable because it would not address the regulatory issues described in Section 5.2 of this appendix, “Regulatory Issues.” The regulations would continue to lack the needed clarity about when and to what extent contacts and arrangements need to be described, and when certifications and utility plans are required of ESP and COL applicants.

5.3.2 Alternative 2: Rulemaking to Amend Paragraph 52.17(b)

5.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking and associated guidance. The requirements in paragraph 52.17(b) would be revised to properly differentiate when and to what extent descriptions of contacts and arrangements with Federal, State, and local governmental agencies are required, and when certifications (including compensatory utility plans as necessary) are required. The revisions would clarify that required contacts, arrangements, and certifications are contingent upon and commensurate with the level of emergency plan approval sought in the application.

5.3.2.2 Assessment of Alternative 2

Rulemaking would address the two primary issues described in Section 5.2, “Regulatory Issues,” of this appendix, and would result in a better defined, more consistent licensing process. The revisions under this alternative would provide added clarity about what contacts and arrangements with offsite organizations are needed commensurate with the level of EP content being provided in the ESP application. In addition, the revisions would clarify that for ESP applications complying with paragraphs 52.17(b)(1) and 52.17(b)(2)(i), any certifications that have been obtained, which are in addition to any other description of contacts and arrangements, must be included in the SSAR. However, if no certifications have been obtained at the ESP application stage, then they must be provided in the subsequent application for a COL under paragraph 52.79(a)(22).

5.4 Regulatory Scope

Rulemaking would be limited to revising paragraph 52.17(b) to clarify when and to what extent contacts and arrangements, certifications, and compensatory plans are required.

5.5 NRC Guidance, Policy, and Implementation Issues

There would be no NRC guidance, policy, or implementation issues. No guidance documents would be revised or developed.

5.6 Impacts

5.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing new reactor licensing process as described in the current regulations and guidance. The NRC would not pursue any changes to the current regulations or guidance.

5.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

5.6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees.

5.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

5.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.2 Alternative 2: Rulemaking

5.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would not involve changing the intent or effect of the current regulations, there would no impacts on public health, safety, or security.

5.6.2.2 Impacts on Licensees

This alternative has the potential to reduce unnecessary burden on ESP applicants. By clarifying the regulations, licensees would be afforded a higher degree of certainty regarding the descriptions of contacts and arrangement and certifications that are necessary to be included in their application. The effects of rulemaking would be ongoing and have incremental impacts, which could potentially save 50 to 100 labor hours of ESP application development for each applicant under paragraph 52.17(b)(1) that would no longer be required to make offsite arrangements and certifications for site-only ESP applications. Using the assumptions

previously stated, Alternative 2 would result in averted costs to applicants of approximately \$11,400 (7 percent NPV) and \$15,700 (3 percent NPV), as shown in Table G-9.

Table G-9 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2026	Simplified ESP Application	1	75	\$134	\$10,072	\$6,272	\$8,189
2029	Simplified ESP Application	1	75	\$134	\$10,072	\$5,120	\$7,494
Total:					\$20,143	\$11,392	\$15,684

5.6.2.3 Impacts on the NRC

The NRC would incur implementation costs for rulemaking. However, this alternative would benefit the NRC by simplifying the review process for ESP applications. The regulations would better define what needs to be included in an application, which could result in fewer requests for additional information and a reduction in associated staff hours for each affected ESP application. Alternative 2 would result in costs to the NRC (due to rulemaking) of approximately (\$100,000) using a 7 percent NPV and (\$114,000) using a 3 percent NPV, as shown in Table G-10.

Table G-10 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2026	NRC Review of Simplified ESP Application	1	38	\$131	\$4,913	\$3,059	\$3,994
2029	NRC Review of Simplified ESP Application	1	38	\$131	\$4,913	\$2,497	\$3,655
Total:					(\$125,593)	(\$100,183)	(\$113,813)

5.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net costs of approximately (\$89,000) using a 7 percent NPV and (\$98,000) using a 3 percent NPV, due to rulemaking costs.

5.7 Backfitting and Issue Finality

Neither of the alternatives in this section of Appendix G, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would not result in changes in the requirements or NRC staff positions. Alternative 2 would include revisions to the requirements for ESP applications. ESP applicants are not within the scope of any issue finality provision under Part 52.

5.8 Stakeholder Feedback

5.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

5.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

5.9 Staff Recommendation

The staff recommends the rulemaking be pursued as described under Alternative 2, "Rulemaking to Amend paragraph 52.17(b)." Conducting rulemaking to provide additional clarity in the regulations would benefit applicants and the NRC. It is an NRC goal to provide clear and consistent regulations. Clarifying the regulations to better define the expectations for contacts and arrangements, certifications, and compensatory utility plans would make the overall licensing process clearer and more efficient. This alternative is estimated to result in incremental costs to licensees and the NRC of (\$89,000) using a 7 percent NPV. These costs are dominated by NRC rulemaking costs and could be offset by the qualitative benefits above and if additional applicants choose to use the ESP process than those included in this analysis.

APPENDIX H – PART 52 LICENSING PROCESS

APPENDIX H.1 – DESIGN CERTIFICATION RENEWAL	H-1
APPENDIX H.2 – CHANGE PROCESS	H-23
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APPENDIX H.1 – DESIGN CERTIFICATION RENEWAL

The NRC establishes the duration of design certifications (DCs) in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251), Section 52.55, “Duration of certification,” and sets the requirements for applicants seeking to renew the DCs in Section 52.57, “Application for renewal.” The NRC is considering revisions to these regulatory provisions, based on lessons learned from implementing the DC renewal process, that would reduce unnecessary regulatory burden on applicants and the NRC.

1.0 EXISTING REGULATORY FRAMEWORK

In Section 52.55, the NRC sets a duration of 15 years from the date of issuance for DC rules. In the 1989 Part 52 final rule (54 FR 15372, April 18, 1989; TN6256), the NRC extended the DCs’ duration to 15 years from the proposed rule’s 10 years to permit more operating experience with a given design to accumulate before the certification would come up for renewal. The requirements for applicants for renewal of a DC rule are established in paragraph 52.57(a), which states, in part, “An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application.” The NRC established the criteria for renewal of a DC rule in Section 52.59, “Criteria for renewal.” Specifically, paragraph 52.59(a) states, in part, that:

The Commission shall 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 Atomic Energy Act and the Commission’s regulations applicable and in effect at the time the certification was issued....

Furthermore, in accordance with paragraph 52.59(b), the Commission may impose other requirements on a DC renewal 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 DC 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. Design certification renewal applicants can request an amendment to the certified design but must meet the criteria in paragraph 52.59(c). These criteria for an amendment to the design during the renewal proceeding are much more flexible than the criteria in paragraph 52.63(a) for making changes to a DC while it is in effect. Design certification renewal applications that include amendments to the certified design are not required to address the criteria in paragraph 52.63(a) (e.g., the advanced boiling-water reactor (ABWR) DC renewal applicants were not required to identify specific criteria in paragraph 52.63(a)(1) as the basis for proposing an amendment to the certified design). However, in accordance with paragraph 52.59(c), if the amendment request entails such an extensive change to the certified design that an essentially new standard design is being proposed, an application for a new certified design must be filed in accordance with Subpart B, “Standard Design Certifications,” of Part 52.

The NRC has not developed generic guidance on the format and content of DC rule renewal applications. However, on December 1, 2010, the NRC issued the “Advanced Boiling Water Reactor Design Certification Renewal Applications: Draft NRC Staff Views on Application

Content and Draft Staff Review Guidelines” (NRC 2010-TN6287) that contain the draft guidelines for NRC’s reviews of the format and content of ABWR DC rule renewal applications.

Each design certified by the NRC becomes an appendix to Part 52. Section IV of every DC rule appendix to Part 52 specifies additional requirements and restrictions, including requirements for combined license (COL) applicants wishing to reference the appendices. Section IV also states, “The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under 10 CFR Part 50.” To date, there is no case in which an applicant for a construction permit or operating license has sought to reference a DC rule. Therefore, the discussions in Appendix H.1 pertaining to applicants referencing DC rules is limited to COL applicants.

2.0 REGULATORY ISSUES

Design certification vendors have addressed the DC renewal requirements in Sections 52.57 and 52.59 or sought exemptions from these requirements as described below.

The Toshiba Corporation Power Systems Company and GE Hitachi Nuclear Energy (GE Hitachi) submitted applications to renew the ABWR DCs on October 27, 2010 (Toshiba 2010-TN6286),¹ and December 7, 2010 (GE Hitachi 2010-TN6284), respectively. These applications represented the first time that an applicant sought to renew a DC and hence, the first opportunity for the NRC to use the process in the DC rule renewal regulations. After the initial submittal of GE Hitachi’s application to renew the ABWR DC, GE Hitachi submitted a revised application on February 19, 2016, to implement changes in response to a letter in which the NRC identified design change issues considered to be regulatory improvements or changes that could meet the paragraph 52.59(b) criteria. The items in the NRC letter were derived from NRC experience in reviewing a COL application that referenced the certified ABWR design and implementation of the draft guidelines developed for the review of the ABWR DC renewal application. During the development of the draft ABWR review guidance, the NRC recognized that the 2007 Part 52 final rule (72 FR 49352, August 28, 2007; TN4796) did not define what constitutes “bringing up to date” as used in paragraph 52.57(a). Therefore, the NRC included discussions pertaining to this updating requirement in the draft guidance developed specifically for the review of the ABWR DC rule renewal applications. The NRC stated that the entire ABWR design control document (DCD) (i.e., the version of the ABWR DCD last approved for incorporation by reference) must be updated under paragraph 52.57(a) to include corrections of errors, typos, and defects (as defined in 10 CFR Part 21, “Reporting of Defects and Noncompliance”), which are known by the ABWR DC renewal applicant. In addition, the ABWR DCD must be updated to include the information necessary to demonstrate the technical qualification of the applicant, if different from the original applicant. The guidance also stated that the NRC would review the DC rule renewal application to ensure that it includes additional information pertaining to new information since the certification was issued for items such as high and medium priority unresolved safety issues, generic safety issues, generic letters and bulletins, and relevant domestic and international operating experience. Furthermore, the guidance stated that after the NRC’s initial use of these draft guidelines for the ABWR DC rule renewal applications, the NRC would develop generic guidance for DC renewal applications and staff reviews. This generic guidance would be based on lessons learned, including external stakeholder feedback, from the ABWR DC rule renewal review. The NRC has not developed

¹ Toshiba subsequently withdrew its application to renew the ABWR DC in a letter dated June 9, 2016 (Toshiba 2016-TN6285).

this generic guidance, so the inefficiencies encountered during the review of the ABWR DC renewal application due to the lack of clarity of the paragraph 52.57(a) requirements still exist.

An important lesson learned during the ABWR DC renewal review is that the 15-year certification period poses a problem if there is no customer referencing the design. In this situation, both the DC renewal applicant and the NRC are expending resources on reviewing a design that is not benefiting from customer insights that would reflect the actual design that would be constructed. Therefore, certain design review areas may have to be revisited during the review of license applications referencing the renewed DC. Because of the inflexibility of the DC renewal regulations, the design vendors are required to request renewal of the DC under the timely renewal provisions. Otherwise, the design vendor loses the benefits of certification if it does not submit a renewal application before the expiration of the DC. This situation is not addressed in the draft guidance discussed above.

By letter dated January 16, 2014, the Westinghouse Electric Company (Westinghouse) submitted three exemption requests for the Advanced Passive 600 (AP600) reactor DC (Westinghouse 2014-TN6294). The proposed exemptions would have (1) extended the date for which the AP600 is valid, and able to be referenced, from 15 to 20 years to expire on January 24, 2020; (2) extended the AP600 renewal application dates by 5 years, between January 24, 2017, and January 24, 2019; and (3) kept the AP600 valid (and able to be referenced) through expiration and until the NRC made a decision on a renewal application. The NRC denied the exemption requests (NRC 2014-TN6293) after concluding that Westinghouse did not demonstrate special circumstances in accordance with 10 CFR 50.12, "Specific exemption" and found its proposed basis to maintain the effectiveness of the AP600 DC past its expiration date to be insufficient. Therefore, the AP600 DC expired on January 24, 2015. The situation where the DC holder requested an exemption after missing the deadline for submittal of a DC renewal application highlighted the potential rigidity of DC renewal timelines and duration requirements. Now, however, with the benefit of more experience with Part 52 regulatory processes, including DC renewal, the NRC considers that creating greater flexibility for DC renewal applicants could provide for greater regulatory efficiency without any reduction in safety or security.

Separate from its revised DC renewal application discussed above, GE Hitachi submitted annual reports of emergency core cooling system (ECCS) evaluation model (EM) changes and errors for the ABWR standard plant design, pursuant to the requirements of Section 50.46, "Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors."² In a letter to GE Hitachi dated July 21, 2016, the NRC noted that GE Hitachi's reported changes and error corrections had not been adequately accounted for in GE Hitachi's ABWR DC renewal application (NRC 2016-TN6295). As a result, the DC renewal application revision failed to meet the requirements of paragraph 52.57(a), which specifies that the renewal application must contain all information necessary to bring up to date the information and data contained in the previous application. In a letter dated October 12, 2016, GE Hitachi proposed to add the reported changes and errors as a reference to the ABWR DCD (GE Hitachi 2016-TN6298). Furthermore, it proposed that resolution of EM changes or errors be incorporated at the time of a future COL application referencing the ABWR design and the results be reviewed by the NRC as part of the COL application proceeding. The NRC took the position that resolution of this matter could not be deferred to future COL applicants because it would have been contrary to the updating requirement in paragraph 52.57(a) and the requirement in

² The annual reports of ECCS EM changes and errors for the ABWR standard plant design were submitted on February 13, 2012 (GE Hitachi 2012-TN6292; TN6291; TN6290; TN6289; and TN6288).

paragraph 52.59(a) for the design to comply with the Atomic Energy Act (42 U.S.C. § 2011 *et seq.*; TN663) and the Commission's regulations applicable and in effect at the time the certification was issued. Therefore, the applicant revised its approach and implemented changes in the DCD to reflect the reported impacts on the cladding temperature values. The NRC found that this approach met the paragraph 52.57(a) and Section 52.59 requirements. However, based on the NRC's experience with operating reactors' compliance with Section 50.46, the NRC expects that ECCS EM changes and errors will accumulate as time goes by such that a COL applicant referencing a standard design will have to assess the need to reanalyze and or change the design. This situation is driven by the rigidity of the renewal regulations that, coupled with the absence of a customer, could result in a renewed design that may need to be revised by the customer as part of the licensing review.

By letter dated December 2, 2016, Westinghouse requested exemptions related to renewal of the Advanced Passive 1000 (AP1000) reactor DC, which will expire on February 27, 2021, under current regulations (Westinghouse 2016-TN6297). The requested exemptions would extend the period for which the AP1000 DC is able to be referenced by a COL applicant from 15 to 20 years, resulting in a new expiration date of February 27, 2026. The proposed exemptions would also defer by 5 years the time period during which Westinghouse could submit and the NRC could accept Westinghouse's renewal application. Under the requested exemption, this time period would occur between February 27, 2023, and February 27, 2025. In a letter dated February 14, 2018 (NRC 2018-TN6296), the NRC granted the request in part and denied it in part. Under the decision, the time period during which Westinghouse could submit and the NRC could accept Westinghouse's renewal application for the AP1000 DC was deferred by 5 years. The NRC denied the exemption requests from paragraph 52.55(a) and Part 52, Appendix D, Part VII, "Duration of this Appendix," that would have generically extended the period during which the current AP1000 DC could be referenced by future COL applicants. The 15-year duration of a DC established by paragraph 52.55(a) and Part 52, Appendix D, Part VII, addresses when a license applicant may reference the AP1000 design. These regulations pertain to future license applicants' ability to reference the AP1000 design certified by NRC rulemaking, and exemptions from them require consideration of the particular special circumstances of the "interested person" (i.e., the COL applicant), pursuant to the exemption criteria of paragraph 50.12(a). This is another example of an exemption request that seeks relief from the rigidity of renewal regulations pertaining to timing requirements.

3.0 DISCUSSION OF ALTERNATIVES

Alternatives 2, 3, 5, and 6 below were developed under the assumption that the requirement to renew DCs is retained and that there will always be an interest from vendors to apply for renewal of the DCs. Alternative 4 was developed under the assumption that once a design is certified, the vendor would be interested in maintaining the DC.

3.1 Alternative 1: No-Action

3.1.1 Description of Alternative 1

Under the "no-action" alternative, the NRC would not change or clarify the current design certification renewal requirements in Section 52.55 or paragraph 52.57(a) through rulemaking or guidance.

3.1.2 *Assessment of Alternative 1*

The requirements in paragraph 52.57(a) are not clear about what constitutes updating the information and data in the previous application for a DC. This lack of clarity is likely to create inconsistencies in the information submitted in DC renewal applications and inefficiencies in the NRC's reviews of DC renewal applications because the NRC must issue requests for additional information.

3.2 Alternative 2: Clarification of Paragraph 52.57(a) through Guidance

3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would issue generic guidance to clarify the update requirement in paragraph 52.57(a) consistent with NRC's interpretation described in the draft guidelines developed for the ABWR DC rule renewal review. This interpretation would define the requirement for an application for renewal to contain all information necessary to bring up to date the information and data contained in the previous application to include:

- clarifications and corrections of errors, typos, and defects (as defined in Part 21), and
- new information pertaining to high and medium priority unresolved safety issues and generic safety issues, generic letters and bulletins, and relevant domestic and international operating experience.

Renewal applicants could include a discussion of whether design changes are necessary as a result of this information in their applications.

3.2.2 *Assessment of Alternative 2*

As discussed above, this alternative would provide guidance to DC renewal applicants pertaining to the paragraph 52.57(a) update requirement. Therefore, this would result in establishing a clear understanding of information that should be included in applications for the DC renewals. However, vendors and the NRC could expend significant resources on the renewal for a design that might not be used if no COL applications reference the design that is being reviewed for renewal. Moreover, if no customer has referenced the design, the renewal application may not reflect a design that would be built in practice because it would not reflect insights from a COL applicant's implementation. Therefore, it may result in inefficiencies for COL applicants, holders and the NRC having to revisit design scope items.

3.3 Alternative 3: Removal of Paragraph 52.57(a) Update Requirements

3.3.1 *Description of Alternative 3*

Under this alternative, the NRC would conduct rulemaking to remove the sentence, "An application for renewal must contain all information necessary to bring up to date the information and data contained in the previous application," from paragraph 52.57(a).

3.3.2 *Assessment of Alternative 3*

Under this alternative, DC renewal applicants would not have to address new and applicable information since the design was certified. However, the NRC would be required to assess new information to determine whether changes are necessary to comply with the regulations in effect

at the time of the certification per paragraph 52.59(a) or whether additional conditions pursuant to paragraph 52.59(b) are warranted. This approach would require the NRC to consider the same type of information described in Section 3.2.1 of this appendix that was identified in the draft guidelines for updating the information in the previous DC application in determining whether the criteria in paragraph 52.59(a) or 52.59(b) are met.

3.4 Alternative 4: Removal of Duration of DCs and Renewal Requirements through Rulemaking

3.4.1 Description of Alternative 4

Under this alternative, the NRC would remove the 15-year duration for DCs established in Section 52.55 and DC renewal requirements in Sections 52.57, 52.59 and 52.61, “Duration of renewal,” and Part 52 DC appendices. This would result in DCs that never expire and, therefore, do not need to be renewed every 15 years.

3.4.2 Assessment of Alternative 4

This alternative would result in DC rules that do not need to be renewed. Therefore, the vendors would not need to apply for renewal of the DC rule, nor would the NRC assess the application to determine whether it meets the criteria in paragraph 52.59(a). The Commission could rely on paragraph 52.63(a)(1) for any changes to a DC rule. The criterion in paragraph 52.63(a)(1)(i) is similar to the requirement in paragraph 52.59(a) that states, in part, that the Commission shall issue a rule granting the renewal if the design complies with the Commission’s regulations in effect at the time the certification was issued. In addition, the Commission may modify, rescind, or impose new requirements on the certification information in accordance with paragraph 52.63(a)(1). The criteria in paragraphs 52.63(a)(1)(i), (ii), and (vi) are similar to the DC renewal criteria in paragraph 52.59(b) for the NRC to impose other requirements on a DC rule. The NRC, in making a determination under paragraph 52.63(a)(1), would consider information of the same type (i.e., bulletins, generic letters, operating experience) described for making a determination that a renewal applicant has met the paragraph 52.57(a) update requirement. Thus, the NRC retains the flexibility to address significant issues in a manner similar to the processes provided by the DC renewal regulations.

In addition, design vendors could amend the certification per paragraph 52.59(c) to address new information and incorporate voluntary changes to support future COL applications. This would maintain the benefits of certification, and the timing of any amendments would probably reflect the vendor’s specific situation better than the fixed 15-year renewal period. However, design vendors might not elect to amend the DC to address new information and incorporate voluntary changes to support future COL applications. In such cases, COL applicants might voluntarily change the design to address new information, to incorporate technological innovations, or for other reasons. Because these choices would be made on an application-by-application basis, there would be a reduction in standardization.

The potential review inefficiencies that could result from COL applicants taking different design approaches in addressing design scope issues can be avoided either by Commission action through rulemaking under paragraph 52.63(a)(1) or by design vendors voluntarily amending the design to support future COL applications. In addition, they can be mitigated by COL applicants voluntarily implementing the same design departures implemented by previous license applicants referencing the certified design. The NRC is also considering other items associated with standardization as discussed in Appendix H.2, “Change Process,” of this regulatory basis.

3.5 Alternative 5: Delayed DC Renewal

3.5.1 Description of Alternative 5

Under this alternative, the NRC would add a provision to the regulations to allow vendors to submit late-filed applications for renewals (i.e., after expiration of 15-year period). The duration of certifications established in Section 52.55 as well as the current renewal requirements would be retained.

3.5.2 Assessment of Alternative 5

Because the 15-year period for DC would be maintained, COL applications submitted after the 15-year period could not reference the original design. However, a new provision would be added to Section 52.57 and conforming changes would be made to Part 52 DC appendices to allow for a delayed renewal of the design. The vendor could submit a late-filed application for renewal (i.e., after expiration of the 15-year period). In addition, amendments to the design could also be sought after the 15-year period to support a future renewal application. This provision would allow a COL application to reference a late-filed renewal application. The late-filed renewal applications would be subject to the current requirements for DC renewals. However, the DC vendor would not realize the benefits of timely renewal provided in paragraph 52.57(b) because the 15-year period has expired. Similar to the current regulations, under this alternative a COL could not be issued until the DC is renewed and effective. This would result in renewing the design closer to COL issuance, thereby allowing the design to reflect the latest technological innovations. This approach is consistent with Part 52's aim for standardization and efficiency and would allow for granting a DC that meets NRC requirements for renewal at the most desirable time. However, the requirements in paragraph 52.57(a) would also still apply. Without the clarifications to paragraph 52.57(a) described in Alternative 2, Alternative 5 would present inefficiencies due to lack of clarity of the requirements in paragraph 52.57(a).

3.6 Alternative 6: Delayed DC Renewal and Clarification of Paragraph 52.57(a) Requirements through Guidance

3.6.1 Description of Alternative 6

This alternative combines Alternatives 2 and 5. Under this alternative, the NRC would allow for a delayed DC renewal application as described in Alternative 5. In addition, the NRC would implement Alternative 2 to clarify the paragraph 52.57(a) requirements.

3.6.2 Assessment of Alternative 6

This alternative would result in a renewal regulation that provides the flexibility for the design to be renewed closer to when it would be referenced by potential COL applicants, so the design could reflect the latest technological innovations as discussed in Alternative 5. Combining it with Alternative 2 would address the issue identified in Alternative 5 pertaining to inefficiencies due to the lack of clarity in paragraph 52.57(a) requirements.

4.0 REGULATORY SCOPE

Alternative 2 would clarify the existing paragraph 52.57(a) requirements pertaining to DC renewals. Alternative 3 would remove the updating requirements in paragraph 52.57(a).

Alternative 4 would eliminate the duration of DCs in Section 52.55 and the DC renewal requirements specified in Sections 52.57, 52.59, and 52.61. Alternative 5 would add a provision to Section 52.57 to allow for late-filed DC renewal applications. Alternative 6 would add a provision to Section 52.57 to allow for late-filed DC renewal applications and clarify the existing paragraph 52.57(a) requirements pertaining to DC renewals through guidance.

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

5.1 Alternative 1: No-Action

The “no-action” alternative represents the status quo and hence, no guidance or policy issues are associated with this alternative. However, it would continue the implementation issues given the lack of clarity in the requirements in paragraph 52.57(a).

5.2 Alternative 2: Clarification of Paragraph 52.57(a) through Guidance

This alternative would clarify current requirements, so it would not result in policy or implementation issues.

5.3 Alternative 3: Removal of Paragraph 52.57(a) Update Requirements

This alternative would shift the responsibility for updating the information in the DC to the NRC and hence, implementation of the alternative would necessitate the development of guidance and processes for the NRC to identify and assess new and applicable information for the design that is being reviewed for renewal. This alternative also presents a policy change in that it puts the burden solely on the NRC for the identification and assessment of information that may affect the design.

5.4 Alternative 4: Removal of Duration of DCs and Renewal Requirements through Rulemaking

This alternative would result in DCs that never expire, thereby changing the Commission’s policy established in the 1989 Part 52 rule that established the duration of DCs at 15 years and the requirement to have DC renewals to maintain the certification past the expiration date. Because each COL application may differ on how it changes the design to address a particular issue, this variation may affect design standardization as the design is implemented differently by each COL applicant.

5.5 Alternative 5: Delayed Renewal

This alternative does not present policy issues because it supports design standardization by requiring the design to be updated during DC renewal. However, it presents implementation issues due to the existing lack of guidance associated with paragraph 52.57(a).

5.6 Alternative 6: Delayed DC Renewal and Clarification of Paragraph 52.57(a) Requirements through Guidance

This alternative is a combination of Alternatives 2 and 5, and thus, will allow for late-filed renewals and development of guidance associated with the update requirements in

paragraph 52.57(a). Therefore, consistent with Alternatives 2 and 5, Alternative 6 does not present policy or implementation issues.

6.0 IMPACTS

As stated in Section 2.0, “Regulatory Issues,” the application submitted by GE Hitachi to renew the ABWR DC rule represents the only such application that has undergone review. Therefore, most of the benefit and cost data used in this section is based on the review of this application.

6.1 Alternative 1: No-Action

6.1.1 Impacts on Public Health, Safety, and Security

This alternative would maintain the status quo. Therefore, it does not represent any impacts on public health, safety, and security.

6.1.2 Impacts on Design Certification Vendors and COL Applicants

Because this alternative does not clarify current requirements associated with DC renewals, this alternative would result in continued inefficiencies for DC renewal applicants in satisfying the requirements in paragraph 52.57(a) because of its lack of clarity. This lack of clarity would result in potentially different interpretations by vendors and the NRC of what constitutes information needed to satisfy the update requirement in paragraph 52.57(a). In addition, it would not eliminate resource expenditures for renewing and implementing design changes for a design that may not be used by a COL applicant.

6.1.3 Impacts on the NRC

Similar to the impacts on DC vendors and COL applicants described above, this alternative would result in continued inefficiencies in NRC reviews as described in Section 6.1.2, “Impacts on Design Certification Vendors and COL Applicants,” to support the NRC’s determination in support of the paragraph 52.57(a) requirement due to its lack of clarity. In addition, it would not eliminate the potential inefficient use of resources to review a DC renewal application for a design that may not be used by a COL applicant.

6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 Alternative 2: Clarification of Paragraph 52.57(a) through Guidance

6.2.1 Impacts on Public Health, Safety, and Security

This alternative would clarify the updating DC information requirements in paragraph 52.57(a). Therefore, it does not represent any impacts on public health, safety, and security.

6.2.2 *Impacts on Design Certification Vendors and COL Applicants*

This alternative would result in savings to DC renewal applicants by addressing inefficiencies caused by the lack of clarity in the paragraph 52.57(a) requirements. The cost savings would largely be attributed to less time to develop the DC renewal application and less time to respond to NRC questions. This is estimated to save approximately \$1.2 million to a DC renewal applicant, in addition to the savings of approximately \$1.2 million to the NRC described in Section 6.2.3, "Impacts on the NRC." There would be no direct impact on COL applicants because this requirement only applies to DC renewal applicants. This averted cost is estimated using an aggregate renewal date of all 5 DCs, based on their current renewal dates, and assuming 3 DCs will be renewed as a best estimate, for two renewal periods. This results in the first renewal for the aggregate 3 DCs occurring in 2032, and then a second renewal 15 years after that, in 2047.

The averted costs in Alternative 2 would be approximately \$1.99 million (7 percent net present value [NPV]) and \$3.99 million (3 percent NPV), as shown in Table H.1-1.

Table H.1-1 DC Renewal Averted Costs to Industry, Alternative 2

Year	Activity	Number of Actions	Cost		
			Undiscounted	7% NPV	3% NPV
2032	Increased Efficiencies in DC renewal process	3	\$3,650,000	\$1,514,620	\$2,485,472
2049	Increased Efficiencies in DC renewal process	3	\$3,650,000	\$479,490	\$1,503,752
Total:			\$7,300,000	\$1,994,110	\$3,989,224

6.2.3 *Impacts on the NRC*

This alternative would result in a one-time cost to the NRC to develop guidance to address the lack of clarity of the paragraph 52.57(a) requirements. The clarification would address inefficiencies in NRC reviews of DC renewal applications to meet these requirements. This alternative would also provide cost savings by reducing the number of hours required for NRC review of a DC application and associated requests for additional information (RAIs). The savings to the NRC (and passed on to the applicant) for each renewal period are estimated to be \$1.2 million. This estimate is based on the level of resources expended by the NRC in identifying and reaching agreement with GE Hitachi that resulted in the February 19, 2016 revised DC renewal application, as discussed above (GE Hitachi 2016-TN6283). Given that the generic guidance is expected to consist of converting the draft guidelines developed for the review of the ABWR DC renewal application review, the level of effort is estimated to produce and finalize it as generic guidance is estimated to be 0.5 full-time equivalent employee (FTE).

The averted costs to the NRC of Alternative 2 would be approximately \$1.95 million (7 percent NPV) and \$3.94 million (3 percent NPV), as shown in Table H.1-2.

Table H.1-2 NRC Costs and Benefits, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2032	Increased Efficiencies in DC renewal process	3			\$3,650,000	\$1,514,620	\$2,485,472
2049	Increased Efficiencies in DC renewal process	3			\$3,650,000	\$479,490	\$1,503,752
Total:					\$7,246,519	\$1,948,926	\$3,939,547

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 Summary of Benefits and Costs

The net averted costs to industry and the NRC, for a single DC renewal (therefore this averted cost increases when all DCs are considered) would be approximately \$3.94 million (7 percent NPV) and \$7.93 million (3 percent NPV).

6.3 Alternative 3: Removal of Paragraph 52.57(a) Update Requirements

6.3.1 Impacts on Public Health, Safety, and Security

This alternative would amend the NRC’s regulations to remove the requirement for DC vendors to update the design as a result of new and applicable information since the design was certified. However, the NRC would still be required to assess new information to determine whether changes in the design are necessary to comply with the regulations in effect at the time of the original certification. In addition, the NRC can impose additional requirements under the provisions of paragraph 52.59(b). Therefore, this would not result in any impacts on public health, safety, and security.

6.3.2 Impacts on Design Certification Vendors and COL Applicants

Under this alternative, DC renewal applicants would no longer have to consider new information since the design was last certified to determine whether changes are needed to the design. This would result in a reduction of burden to analyze new information such as operating experience that could affect the design and effect changes in the design. The savings to the DC applicants is estimated to be \$2 million for each renewal period, but the change would result in an increase in burden on the NRC, as discussed below. This requirement does not apply to COL applicants. The cost estimate for this alternative is calculated using the assumptions described in Section 6.2.2; “Impacts on Design Certification Vendors and COL Applicants.”

The averted costs in Alternative 3 would be approximately \$3.31 million (7 percent NPV) and \$6.62 million (3 percent NPV), as shown in Table H.1-3.

Table H.1-3 Licensee Averted Costs, Alternative 3

Year	Activity	Number of Actions	Cost		
			Undiscounted	7% NPV	3% NPV
2032	Averted industry DC renewal research costs	3	\$6,058,824	\$2,514,196	\$4,125,764
2049	Averted industry DC renewal research costs	3	\$6,058,824	\$795,930	\$2,496,155
Total:			\$12,117,647	\$3,310,127	\$6,621,919

6.3.3 Impacts on the NRC

This alternative would shift the burden from the DC vendor to the NRC to research and assess new information to determine whether the criteria in paragraph 52.59(b) are met, and hence would result in a required change in the design. This would result in a decrease in the burden on the DC applicant but an increase in the burden on the NRC to analyze new information such as operating experience to determine if it may impact the design and determine if changes are required to the design by justifying the criteria in paragraph 52.59(b) (similar to backfit criteria). The corresponding costs to the NRC are estimated to be \$2.5 million for each renewal review that would be passed along to the DC applicant. The burden calculation assumes that it would cost the NRC the same as the DC applicant to analyze the new information discussed in Section 6.2.2, Impacts on Design Certification Vendors and COL Applicants,” with an added cost of developing the regulatory analysis to determine whether changes are required under paragraph 52.59(b) (similar to backfit criteria).

In addition, the NRC would incur rulemaking costs under Alternative 3.

The costs to the NRC from Alternative 3 (per-DC renewal) would be approximately (\$4.38 million) using a 7 percent NPV and (\$8.58 million) using a 3 percent NPV, as shown in Table H.1-4. Because these costs are passed on to DC renewal applicants, these NRC costs more than cancel out the averted costs above, making Alternative 3 not cost beneficial.

Table H.1-4 NRC Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2032	NRC research costs	3			(\$7,625,000)	(\$3,164,104)	(\$5,192,254)
2049	NRC research costs	3			(\$7,625,000)	(\$1,001,674)	(\$3,141,399)
Total:					(\$15,520,836)	(\$4,377,257)	(\$8,576,578)

6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.3.5 *Summary of Benefits and Costs*

The net costs of Alternative 3 to the NRC and industry would be approximately (\$1.07 million) using a 7 percent NPV and (\$1.96 million) using a 3 percent NPV, making Alternative 3 not cost beneficial.

6.4 **Alternative 4: Removal of Duration of DCs and Renewal Requirements through Rulemaking**

6.4.1 *Impacts on Public Health, Safety, and Security*

This alternative would eliminate the expiration of DCs and thus, the need to perform reviews every 15 years to determine whether any changes are required. The practical effect is that any changes identified affecting the certified design would need to be addressed when a COL applicant references the design or when a design vendor seeks to amend the design. Therefore, there would be no impacts on public health, safety, and security.

6.4.2 *Impacts on Design Certification Vendors and COL Applicants*

Because this alternative would involve removing the requirement to renew the design certification every 15 years, this would eliminate periodic reviews and associated costs to the DC applicant. For DC applicants and the NRC, the averted costs are estimated to be \$15 million.³ each per renewal period. This is based on the estimated vendor and NRC costs associated with the review of the ABWR DC renewal (\$14.5 million) and the current NRC estimate for completing the associated rulemaking (3 FTEs or approximately \$500,000). Of these averted costs, the staff estimates approximately \$7 million would result from reduced costs to DC applicants, and the remaining \$7.5 million would be from reduced NRC costs. However, the costs for COL applicants may increase if there is a need to depart from the referenced design, and potential inefficiencies in NRC reviews may increase if COL applicants differ in their approach to making design changes that may have otherwise been identified and included in a DC renewal (potential reduction in design standardization). The staff did not estimate these minor potential increases in cost to COL applicants quantitatively.

This cost estimate is performed using the assumptions described in Alternative 2, with the exception that the estimate assumes COL applicants would reference the designs 8 years later, in 2040. Therefore, each design averts the approximately \$15 million in renewal costs one time, and then when the COL applicant assesses the DC in 2040 to determine if any departures are necessary, the associated costs are estimated to be higher than they would have been if the design had gone through the renewal process in the status quo. The staff estimated approximately 15 percent of the DC renewal cost can reasonably be counted as a benefit toward later reviews, and therefore this 15 percent value is listed as a cost in 2040 (of not having the DCs renewed).

The averted costs for Alternative 4 would be approximately \$8.58 million (7 percent NPV) and \$13.6 million (3 percent NPV), as shown in Table H.1-5.

³ The estimated cost of GE Hitachi's ABWR DC renewal application was discussed at a meeting with the Advisory Committee on Reactor Safeguards held on August 23, 2019 (NRC 2019-TN6341)

Table H.1-5 DC Renewal Averted Costs, Alternative 4

Year	Activity	Number of Actions	Cost		
			Undiscounted	7% NPV	3% NPV
2032	Averted industry DC renewal costs	3	\$22,645,178	\$9,396,944	\$15,420,264
2040	Cost to COL Applicant of not having DC renewed	3	(\$3,396,777)	(\$820,366)	(\$1,825,935)
Total:			\$19,248,401	\$8,576,578	\$13,594,330

6.4.3 Impacts on the NRC

Because this alternative would remove the requirement to renew the DC every 15 years, it would eliminate periodic reviews and associated costs to the NRC (passed on to the DC applicant). The corresponding review savings are estimated to be \$7.5 million. This is based on the estimated costs associated with the review of the ABWR DC renewal and the NRC’s estimate of 3 FTEs, or approximately \$500,000, for completing the associated rulemaking. However, whenever a COL applicant references the design, the NRC may have to perform reviews of particular items representing departures from the certified design that may have otherwise been addressed in a DC renewal. To the extent that the design as implemented by COL applicants becomes less standardized, there may be more specific review activities during each COL application review. These costs of standardization have not been quantified.

As with applicants, the NRC averted cost from the removal of the renewal requirement uses the same assumptions described in Section 6.4.2 regarding the 5 DCs, and assumes one averted renewal per DC (in an aggregate) after the issuance of the final rule, in 2032. Then, in 2040 the staff assumes that COL applicants would reference the DCs and the NRC conducts a review of departures from the certified designs, at an additional 15 percent of the cost to the NRC of a DC renewal (using the same logic as described in Section 6.4.2). The averted costs to the NRC for Alternative 4 would be \$9.02 million (7 percent NPV) and \$14.4 million (3 percent NPV), as shown in Table H.1-6.

Table H.1-6 NRC Costs and Averted Costs, Alternative 4

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2032	Averted NRC DC renewal costs	3			\$24,225,074	\$10,052,545	\$16,496,097
2040	Cost to NRC of not having DC renewed	3			(\$3,396,777)	(\$820,366)	(\$1,825,935)
Total:					\$20,557,461	\$9,020,700	\$14,427,237

6.4.4 Additional Considerations

Alternative 4 would have no incremental impacts on State, local, or Tribal governments.

6.4.5 Summary of Benefits and Costs

Alternative 4 would result in net averted costs to industry and the NRC of \$17.6 million (7 percent NPV) and \$28.0 million (3 percent NPV). This alternative uses the time value of

money between the current renewal date and the estimated review date to calculate part of the benefit. Therefore, if the review occurs earlier, or later, the alternative would be more, or less cost beneficial accordingly.

6.5 Alternative 5: Delayed DC Renewal

6.5.1 Impacts on Public Health, Safety, and Security

This alternative would add a provision to the regulations to allow for late-filed renewal applications but maintain current requirements for the information needed to be included in the application in order for the design to be renewed. Therefore, this would not result in any impacts on public health, safety, and security.

6.5.2 Impacts on Design Certification Vendors and COL Applicants

This alternative potentially reduces the burden to DC renewal applicants because it allows them to delay the renewal of the design until a COL applicant chooses to reference the design. This would eliminate the need to undergo renewal reviews driven solely by the 15-year duration for the certification. If the DC is never referenced by a COL applicant, this would result in estimated savings of \$15 million to DC renewal applicants for every 15-year period for which a renewal application review does not need to take place as discussed in Section 6.4.2, Impacts on Design Certification Vendors and COL Applicants.” For the purposes of this cost estimate, the NRC assumed that one renewal period would pass without the design being referenced, but then before the next renewal period would have passed, a COL applicant would reference the design. This means that the costs of the first renewal after the issuance of the final rule, described above, would be averted. At the time of the second renewal, because the model assumes a COL applicant would reference the design, the costs of the regulatory baseline would resume. The costs are estimated using the assumptions described in Alternatives 2, 3, and 4, with the exception that in 2040 when COL applicants reference the design, DC renewals occur. This means that the averted costs result from the time value of money of the delayed DC renewal, from 2032 to 2040, reflected by calculating the NPVs at these two dates, shown below. In addition to these averted costs, the estimated costs associated with the DC renewal review and rulemaking are incurred at the most efficient time because changes in the design would reflect the actual design that would be implemented by the COL. Therefore, it would also reduce the potential burden to COL applicants associated with departures from the certified design to address design scope issues. It should be noted that it may negatively affect COL applicants if the DC vendor elects to use the late-filed application provisions given that the COL would not be issued until the DC renewal is approved. This could be mitigated by COL applicants coordinating with the design vendor so that the late-filed renewal application would be submitted sufficiently in advance of the COL application to minimize the impact. Therefore, this impact is not considered for this alternative.

The averted industry costs for Alternative 5 would be approximately \$3.93 million (7 percent NPV) and \$3.25 million (3 percent NPV), as shown in Table H.1-7.

Table H.1-7 Per-DC Averted Costs, Alternative 5

Year	Activity	Number of Actions	Cost		
			Undiscounted	7% NPV	3% NPV
2032	Averted industry DC renewal costs	3	\$22,645,178	\$9,396,944	\$15,420,264
2040	Industry DC Renewal costs	3	(\$22,645,178)	(\$5,469,107)	(\$12,172,899)
Total:			\$0	\$3,927,837	\$3,247,365

6.5.3 Impacts on the NRC

Given that this provision allows for DC vendors to delay submitting renewal applications until a COL applicant decides to reference the design, it potentially eliminates unnecessary DC renewal reviews if the design is never referenced. This would result in savings to the NRC (passed on to DC applicants) estimated to be \$7.5 million, as discussed in Section 6.4.3, "Impacts on the NRC," for each renewal period during which the design is not renewed. As in that section, the averted costs in the NRC's cost estimate are calculated using the assumptions from Alternatives 2, 3, and 4, and one delayed renewal process for all DCs is assumed. If DC renewal applicants pursue the late-filed renewal option as described above, this would result in fewer rulemaking activities associated with DC renewals because it limits the review to when a COL applicant references the certified design. The cost to the NRC to perform a rulemaking to allow for delayed DC renewal applications is also included in the cost estimate for Alternative 5.

The averted costs to the NRC in Alternative 5 would be approximately \$3.99 million (7 percent NPV) and \$3.23 million (3 percent NPV), as shown in Table H.1-8.

Table H.1-8 NRC Costs and Averted Costs, Alternative 5

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2032	Averted NRC DC renewal costs	3			\$24,225,074	\$10,052,545	\$16,496,097
2040	NRC DC renewal costs	3			(\$24,225,074)	(\$5,850,672)	(\$13,022,171)
Total:					(\$270,836)	\$3,990,394	\$3,231,001

6.5.4 Additional Considerations

Alternative 5 would have no incremental impacts on State, local, or Tribal governments.

6.5.5 Summary of Benefits and Costs

Alternative 5 would result in net averted costs to industry and the NRC of approximately \$7.92 million (7 percent NPV) and \$6.48 million (3 percent NPV). This alternative uses the time value of money between the current renewal date and the estimated renewal date to calculate part of the benefit. Therefore, if the renewal occurs earlier, or later, the alternative would be more, or less cost beneficial accordingly.

6.6 Alternative 6: Delayed DC Renewal and Clarification of Paragraph 52.57(a) Requirements through Guidance and Rulemaking

6.6.1 Impacts on Public Health, Safety, and Security

This alternative would add a provision to the regulations to allow for late-filed renewal applications but would maintain current requirements for the information needed to be included in a renewal application in order for the design to be renewed as described in Alternative 5. In addition, it would clarify the update requirement in paragraph 52.57(a), as described in Alternative 2. Therefore, this would not result in any impacts on public health, safety, and security.

6.6.2 Impacts on Design Certification Vendors and COL Applicants

This alternative would potentially reduce the burden to DC renewal applicants because it would allow them to delay the renewal of the design until a COL application chooses to reference the design. This would eliminate the need to undergo renewal reviews driven solely by the 15-year duration for the certification rather than by when the design is being sought to be used by a COL applicant. If the DC is never referenced by a COL applicant, this would result in estimated savings of \$15 million to DC renewal applicants for each 15-year period for which a renewal application review does not need to take place, as discussed in Section 6.4.2, “Impacts on Design Certification Vendors and COL Applicants.” This cost estimate is calculated using the same assumptions in Alternative 5, which carry forward from Alternatives 2, 3, and 4. In addition to these averted costs, the estimated costs associated with the DC renewal review and rulemaking would be incurred at the most efficient time because changes in the design would reflect the actual design that would be implemented by the COL. Therefore, it would also reduce the potential burden on COL applicants associated with departures from the certified design to address design scope issues. It should be noted that it may negatively affect COL applicants if the DC vendor elects to use the late-filed application provisions given that the COL would not be issued until the DC renewal is approved. This could be mitigated by COL applicants coordinating with the design vendor so that the late-filed renewal application would be submitted sufficiently in advance of the COL application to minimize the impact. Therefore, this impact is not estimated quantitatively for this alternative.

In addition, this alternative would result in savings to DC renewal applicants by addressing inefficiencies caused by lack of clarity in the paragraph 52.57(a) requirements. The cost savings would largely be attributed to less time to develop the DC renewal application and less time to resolve NRC comments. This is estimated to save \$2.4 million for a DC renewal applicant and is occurs in 2040, using the assumption that the DCs are referenced at that time, similar to the previous alternatives. There would be no direct impact on COL applicants because this requirement only applies to DC renewal applicants.

The averted cost to industry of Alternative 6 would be approximately \$4.41 million (7 percent NPV) and \$4.75 million (3 percent NPV), as shown in Table H.1-9.

Table H.1-9 Per-DC Industry Averted Costs, Alternative 6

Year	Activity	Number of Actions	Cost		
			Undiscounted	7% NPV	3% NPV
2032	Averted industry DC renewal costs	3	\$22,645,178	\$9,396,944	\$15,420,264
2040	Industry DC Renewal costs	3	(\$22,645,178)	(\$5,469,107)	(\$12,172,899)
2040	Increased Efficiencies in DC renewal process	3	\$3,650,000	\$479,490	\$1,503,752
Total:			\$3,650,000	\$4,407,327	\$4,751,117

6.6.3 Impacts on the NRC

Given that this provision allows for DC vendors to delay submitting renewal applications until a COL applicant decides to reference the design, this alternative potentially eliminates unnecessary DC renewal reviews if the design is never referenced. This would result in savings to the NRC (passed on to DC applicants) estimated to be \$7.5 million, as discussed in Section 6.4.3, “Impacts on the NRC,” for each renewal period that design is not renewed. The cost estimate uses the same assumptions as referenced in Section 6.6.2, carried through all the alternatives as applicable.

In addition, this alternative would result in a one-time cost to the NRC to develop guidance to address the lack of clarity of paragraph 52.57(a) requirements. The clarification would result in addressing inefficiencies in NRC reviews of DC renewal applications to meet these requirements. This alternative would also provide cost savings by reducing the number of hours required for NRC review of a DC application and associated RAIs. The savings to the NRC (and passed on to the applicant) are estimated to be \$1.2 million, occurring in 2040 in this cost estimate. This effort is expected to consist of converting the draft guidelines developed for the ABWR DC renewal application review into generic guidance. The NRC estimates the level of effort to produce and finalize this generic guidance to be 0.5 FTE.

The averted costs to the NRC for Alternative 6 would be approximately \$4.87 million (7 percent NPV) and \$5.19 million (3 percent NPV), as shown in Table H.1-10.

Table H.1-10 NRC Costs and Averted Costs, Alternative 6

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2032	Averted NRC DC renewal costs	3			\$24,225,074	\$10,052,545	\$16,496,097
2040	NRC DC renewal costs	3			(\$24,225,074)	(\$5,850,672)	(\$13,022,171)
2040	Increased Efficiencies in DC renewal process	3			\$3,650,000	\$881,523	\$1,962,055
Total:					\$3,379,164	\$4,871,916	\$5,193,056

6.6.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.6.5 *Summary of Benefits and Costs*

The net averted costs per DC for Alternative 6 would be approximately \$9.28 million (7 percent NPV) and \$9.94 million (3 percent NPV). This alternative uses the time value of money between the current renewal date and the estimated renewal date to calculate part of the benefit. Therefore, if the renewal occurs earlier, or later, the alternative would be more, or less cost beneficial accordingly.

7.0 BACKFITTING AND ISSUE FINALITY CONSIDERATIONS

None of the six alternatives described in this section of Appendix H, if implemented by the NRC, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would not impose a change in requirements or NRC staff positions. The changes to NRC regulations and guidance in Alternatives 2 through 6 would affect future DC renewal applicants, and Section 50.109 does not apply to future DC renewal applicants. The Section 52.63 issue finality provisions and the process for changes and departures in the DC appendices would not apply to the changes described Alternatives 2 through 6.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). At that meeting, NEI made a presentation about its suggestions for this rulemaking (NRC 2019-TN6228). The NEI provided feedback pertaining to DC renewal and offered the following suggestions:

- Revise Part 52 to remove the 15-year DC duration and the DC application window.
- Clarify Section 52.57 regarding what it means to "bring up to date" the information and data contained in the previous application" in the context of the Section 52.59 requirement that renewals comply with regulations applicable and in effect at time of the original certification.
- Revise Part 52 to allow DC renewal applications to be submitted after a facility's construction and initial operation.

Alternatives 2, 4, 5, and 6 currently being considered by the NRC in this rulemaking are consistent with NEI's suggestions 1 and 2 above. NEI's third suggestion would allow for a DC renewal application to be deferred until a facility using the certified design has been constructed and operated. Alternatives 5 and 6 propose to allow for "late-filed" renewal applications that could be submitted closer to time at which COL applications are being reviewed.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). The purpose of the meeting was to receive the ACRS members' observations of the implementation of the Part 52 process based on their individual perspectives from their reviews of new reactor license applications. The discussions focused on SECY-19-0084, "Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing

(RIN 3150-AI66)” (NRC 2019-TN6210). The staff received views and comments from the ACRS as individual members. Although one member of the ACRS commented on this issue, the ACRS as a body did not address the issue of DC renewals. See page 52 of the ACRS transcript that can be found in the Agencywide Documents Access and Management System under Accession No. ML19294A009 (NRC 2019-TN6225).

8.3 Feedback from Applicants

The NRC discusses relevant experience with DC renewal applicants in Section 5.0 of Appendix H.2.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 4, “Removal of Duration of DCs and Renewal Requirements through Rulemaking,” after giving due consideration to the potential benefits of maintaining the requirement to renew DCs as it pertains to design standardization. The staff’s recommendation is based on the following factors:

- There is no health or safety benefit to requiring renewal at the specified time of 15 years, and therefore is a burden on both industry and staff with little corresponding benefit.
- Renewing DCs on a set renewal application period forces the NRC staff and DC vendors to expend resources in reviewing design changes that may need to be revisited during the reviews of COL applicants referencing the design.
- The Commission may modify, rescind, or impose new requirements on the certification information in accordance with paragraph 52.63(a)(1).
- Design certification vendors can voluntarily seek to amend the DCs to reflect the design that will be sought to be implemented by COL applicants referencing the DCs at the most efficient time (i.e., at the time a license applicant seeks to reference the certified design).
- If the DC is not amended to address design issues, COL applicants can take departures from the design to address any design issues.
- This alternative is the most cost beneficial of all the alternatives, with averted costs of approximately \$17.6 million using a 7 percent NPV.

APPENDIX H.2 – CHANGE PROCESS

The ensuing sections of this appendix consider revisions and updates to the language describing the U.S. Nuclear Regulatory Commission’s (NRC’s) policies regarding (1) the process of changing the content of documents related to nuclear reactor license applications, (2) the alignment of guidance describing whether a licensee can proceed to change its facility or procedures or conduct a test or experiment without prior NRC approval, (3) the processes for making Tier 1 conforming changes and formatting changes and Tier 2 changes to organization and section numbering, (4) the alignment of licensee guidance for making changes to their facilities as described in their respective final safety analysis reports, and (5) the requirements for how a licensee that references the design certification appendix in the regulation can change or depart from the information within the scope of the certified design. The NRC recognizes that there is an interdependence between the recommendations in the H.2 and H.3 sections that would affect the cost benefit analysis. The effects of this interdependence will be analyzed during the proposed rulemaking stage.

1.0 MOVE 10 CFR 50.59-LIKE PROCESS FROM 10 CFR PART 52 APPENDICES TO SUBPART B

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” (TN249), Section 50.59, “Changes, tests and experiments,” describes the process by which a Part 50 operating license (OL) holder, and a 10 CFR Part 52, “Licenses, Certifications, and Approvals for Nuclear Power Plants” (TN251) combined license (COL) holder in certain circumstances, determines whether it can proceed to make a change to its facility or procedures or conduct a test or experiment without prior NRC approval, or whether the change, test, or experiment requires prior NRC approval through a license amendment using the process set forth in Section 50.90, “Application for amendment of license, construction permit, or early site permit.” The current requirements to change the information within the scope of a certified design are contained within each design certification (DC) appendix in Part 52. Applicants and licensees that reference a certified design can use a process similar to Section 50.59 (50.59-like) to depart from the plant-specific design control document (PS-DCD) Tier 2 information.⁴ This 50.59-like process appears in Section VIII.B.5 of each of the Part 52 DC appendices. This regulatory language states how an applicant or licensee determines whether a prospective change to PS-DCD Tier 2 information requires prior NRC approval or, for a licensee, whether the licensee can proceed with the change without prior NRC approval. The current requirements stipulate that the 50.59-like process is to be applied in cases where the change to Tier 2 information does not also involve a change to Tier 1 information, Tier 2* information, technical specifications, or an exemption. In these cases, the 50.59-like process does not apply, and prior NRC approval is required. The NRC is considering whether it is preferable to maintain the 50.59-like change process used by applicants and licensees in each individual Part 52 DC appendices or move it into Section 52.63, “Finality of standard design certifications,” in Subpart B, “Standard Design

⁴ The terms Tier 1, Tier 2, and Tier 2*, where applicable, are defined in Section II of the Part 52 DC appendices. Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by the appendix. Tier 2 means the portion of the design-related information contained in the generic DCD that is approved but not certified by the appendix. Tier 2* means the portion of the Tier 2 information designated as such in the generic DCD, which is subject to the change process in Section VIII.B.6 of the appendix.

Certifications,” of Part 52. The reason the NRC is considering the change is to simplify the Part 52 change process for applicants and licensees referencing a certified design and more closely align this change process with the change process in Section 50.59.

1.1 Existing Regulatory Framework

Each of the Part 52 DC appendices contains a Section VIII, “Processes for Changes and Departures,” which addresses the processes for making changes to different types of information in a COL PS-DCD that references the respective DCD. Section VIII includes Section VIII.B.5, which describes the change processes for Tier 2 information used by applicants or licensees referencing the corresponding certified design. Across the six appendices for the six certified designs, the 50.59-like change process descriptions are highly consistent, albeit with some minor wording differences. The primary difference involves the language addressing changes affecting the impacts from severe accidents and aircraft impacts, which are not included in the two appendices for expired certifications (Appendices B and C) for the System 80+ and Advanced Passive (AP600) designs but do appear in the remaining DC appendices.

A reference to the change processes for licensees who reference certified designs also appears in Subpart B of Part 52. Specifically, paragraph 52.63(b)(2) references the change processes in the DC appendices, as follows:

Subject to § 50.59 of this chapter, a licensee who references a design certification rule may make departures from the design of the nuclear power facility, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design. The licensee shall maintain records of all departures from the facility and these records must be maintained and available for audit until the date of termination of the license.

Similarly, the change process for COL holders referencing a certified design is referenced in Subpart C, “Combined Licenses.” Specifically, paragraph 52.98(c) references the DC appendices, stating:

(c) If the combined license references a certified design, then—

(1) Changes to or departures from information within the scope of the referenced 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 design certification rule are subject to the applicable change processes in 10 CFR part 50, unless they also involve changes to or noncompliance with information within the scope of the referenced design certification rule. In these cases, the applicable provisions of this section and the design certification rule apply.

1.2 Regulatory Issues

Better organizing the change process requirements for applicants and holders of licenses that reference a certified design would improve regulatory clarity and efficiency. Because the same

process is described in each DC appendix, it would be more efficient to describe the change process a single time in Part 52 and include references to the process in each of the DC appendices. This would make it clear that the change process and criteria are the same regardless of the certified design used.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

This alternative would maintain the current requirements for the Tier 2 change process in each of the DC appendices to Part 52.

1.3.1.2 Assessment of Alternative 1

The “no-action” alternative would retain the current organization of the change process regulations in the design certification appendices of Part 52. Persons considering referencing a certified design and trying to understand whether the change processes are the same or different between certified designs would need to compare the individual sets of regulations. Future Part 52 appendices for DC rulemakings would either continue to repeat the same requirements, thereby creating new unnecessary regulations or would adopt different requirements, thereby creating inconsistencies between certified designs.

1.3.2 Alternative 2: Rulemaking Affecting Future Certified Designs

1.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to revise Section 52.63 in Subpart B of Part 52 to include the change process information currently stated in Section VIII.B.5.b of the Part 52 DC appendices. Under this alternative, future Part 52 DC appendices would contain information pointing to the new regulatory language in Section 52.63. The rulemaking under this alternative would also revise Section 52.98 in Subpart C of Part 52 to reference Section 52.63.

The changes being considered under this alternative would not include any change in regulatory requirements.⁵

1.3.2.2 Assessment of Alternative 2

Alternative 2 would revise the current regulations in Part 52 for future DCs but would not create any new regulatory requirements or eliminate any existing ones. However, it would have the benefit of eliminating unnecessary regulatory language in the future.

In evaluating this alternative, the NRC also considered taking no action at this time and making these regulatory changes in the future as part of the rulemaking for the next certified design.

⁵ There are other regulatory issues addressed in this regulatory basis related to the Part 52 50.59-like process that are separate from this item. Other issues involve addressing the differences between the 10 CFR 50.59 process and the Part 52 50.59-like process and applying the 10 CFR 50.59 and 50.59-like process to early site permits and limited work authorizations.

This would have the benefit of deferring to a future rulemaking the costs associated with this regulatory change. However, deferring this change to a future DC rulemaking would also shift the cost from the NRC to the applicant for the next certified design because the DC applicant covers the cost of the DC rulemaking. This would result in that applicant shouldering the cost for a generic rulemaking from which all future applicants would benefit. Additionally, for future certified design rules, the NRC may consider using the direct final rule process, which is an expedited rulemaking process appropriate for noncontroversial matters. The NRC determined that making changes to Section 52.63 and 52.98 as part of a future certified design rulemaking may introduce issues to the rulemaking sufficient to require the use of the traditional rulemaking process, thereby delaying and adding costs to that future DC rulemaking. Therefore, in summary, making the changes to Sections 52.63 and 52.98 now would impose the rulemaking costs on NRC rather than on a single applicant and would not affect use of the direct final rule process for a future certified design.

1.3.3 Alternative 3: Rulemaking Affecting Both Future and Existing Certified Designs

1.3.3.1 Description of Alternative 3

This alternative is similar to Alternative 2 in that the NRC would pursue rulemaking to revise Section 52.63 and 52.98 to include the requirements for the Tier 2 change process so that each future Part 52 DC appendix would contain a reference to the new regulatory language in Section 52.63 instead of the change process itself. However, Alternative 3 would also include revisions to Section VIII.B.5 of the existing Part 52 DC appendices so that the language about the Tier 2 change process would be removed and replaced with references to Sections 52.63 and 52.98.

The changes being considered under this alternative do not include any change in regulatory requirements, but rather would change the location of where the current requirements appear in the regulations.

1.3.3.2 Assessment of Alternative 3

Like Alternative 2, Alternative 3 would revise the current regulations in Part 52, would not create any new regulatory requirements or eliminate any existing ones, and would have the benefit of eliminating unnecessary regulatory language in the future. However, because this alternative would include the additional change of eliminating repetition of the existing Tier 2 change process language appearing in Section VIII.B.5 of the current Part 52 DC appendices, it would affect all COL holders subject to the existing Section VIII.B.5 change process regulations.

1.4 Regulatory Scope

Under Alternatives 2 and 3, Sections 52.63 and 52.98 would be changed. These two regulations currently reference the Part 52 DC appendices for the Tier 2 change process. These regulations would be revised by including in Section 52.63 the information currently residing in Section VIII.B.5 of the appendices and by referencing Section 52.63 in Section 52.98.

In addition, under Alternatives 2 and 3, future Part 52 DC appendices would reference the Section 52.63 change process instead of including the change process in Section VIII.B.5.

Finally, under Alternative 3, Section VIII.B.5 of the existing DC appendices would also be revised to remove the specific change process requirements for Tier 2 information and replace them with a reference to Section 52.63 so that the regulatory language would be similar to the language described above for future DC appendices.

1.5 NRC Guidance, Policy, and Implementation Issues

If the NRC conducts rulemaking, the NRC would revise existing guidance, Regulatory Guide 1.187, Revision 1, “Guidelines for Implementation of Section 50.59 ‘Changes, Tests, and Experiments,’” (NRC 2019-TN6258), which endorses the Nuclear Energy Institute (NEI) 96-07, Appendix C, “Guidelines for Implementation of Change Processes for New Nuclear Power Plants Licensed Under Part 52” (NEI 200-TN6268), for nuclear units licensed under Part 52. This item does not raise any policy issues because it does not include any new requirements or eliminate any existing ones and none of the alternatives for this item raise implementation issues.

1.6 Impacts

This section analyzes the three alternatives for moving the regulations for the 50.59-like process from the Part 52 DC appendices to Part 52 Subpart B.

1.6.1 Alternative 1: No-Action

Under this alternative, the NRC would maintain the current requirements for the Tier 2 change process in each of the DC appendices to Part 52.

1.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current requirements in any way, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants or licensees.

1.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 *Alternative 2: Rulemaking Affecting Future Certified Designs*

Under this alternative, the NRC would undertake a rulemaking to revise Section 52.63 for future DCs to include the Tier 2 change process requirements that currently appear in Section VIII.B.5 of the Part 52 design certification appendices. In addition, Section 52.98 would be revised to reference the change process in Section 52.63. Future DC appendices to Part 52 would also reference Section 52.63 rather than contain the change process requirements.

1.6.2.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not involve imposing any new requirements or eliminating any existing requirements, it would not result in any impacts on public health, safety, and security.

1.6.2.2 *Impacts on Applicants and Licensees*

Because this alternative would not impose any new requirements or eliminate any existing requirements, it would not result in any impacts on applicants or licensees.

1.6.2.3 *Impacts on the NRC*

This alternative would not impose any new requirements or change or eliminate any existing requirements. However, it would result in a modest burden reduction for each future DC rulemaking because the NRC staff would not include, and the Commission would not need to review, rule language describing the Tier 2 change process in every DC rule. The NRC did not estimate this burden reduction quantitatively. This alternative would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent net present value (NPV) and (\$121,000) using a 3 percent NPV, as shown in Table H.2-1.

Table H.2-1 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

1.6.2.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

This alternative would have the qualitative benefits of assuring consistency in the change process across all future certified designs.

1.6.2.5 *Summary of Costs and Benefits*

This alternative would result in no quantifiable impacts on public health, safety, and security, licensees, or other stakeholders. This alternative would result in qualitative benefits associated

with simplification of future design certification rules. The NRC would incur rulemaking costs of approximately (\$106,000) using a 7 percent NPV.

1.6.3 Alternative 3: Rulemaking Affecting Both Future and Existing Certified Designs

Under this alternative, the NRC would undertake a rulemaking to change the location of the Tier 2 change process requirements that currently appear in Section VIII.B.5 of the Part 52 DC appendices by moving them to Section 52.63. In addition, Section 52.98 would be revised to reference the change process in Section 52.63. Future DC appendices to Part 52 would also reference Section 52.63 rather than contain the change process requirements. The existing Part 52 DC appendices would also be revised to replace the Tier 2 change process description in Section VIII.B.5 with a reference to Section 52.63.

1.6.3.1 Impacts on Public Health, Safety, and Security

Because this alternative would not involve imposing any new requirements or eliminating any existing requirements, it would not result in any impacts on public health, safety, and security.

1.6.3.2 Impacts on Applicants and Licensees

This alternative would not impose any new requirements or eliminate any existing requirements. However, it may require COL holders referencing the existing Part 52 certified design appendices to revise their internal procedures for processing Tier 2 changes, and thereby experience the associated cost impacts. These procedural changes would be a burden on licensees, estimated to be approximately (\$24,000) using a 7 percent NPV and (\$20,000) using a 3 percent NPV, as shown in Table H.2-2. Because there would be no change in requirements, the existing activities that licensees perform to determine whether a license amendment is required for any particular PS-DCD change would not need to change and implementing the rulemaking alternative would not affect the number of license amendment requests (LARs) from licensees.

Table H.2-2 Licensee Costs, Alternative 3

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Licensees develop procedures to evaluate SAR changes	5	42	\$134	(\$27,977)	(\$19,947)	(\$24,133)
Total:					(\$27,977)	(\$19,947)	(\$24,133)

1.6.3.3 Impacts on the NRC

This alternative would not impose any new requirements or change or eliminate any existing requirements. However, it would result in a modest burden reduction for each design the NRC certifies because the NRC staff would not include, and the Commission would not need to review, rule language describing the Tier 2 change process in every DC rule. In addition, this option would have the added benefit of assuring consistency in the Tier 2 change process across all future and existing certified designs. There would be higher costs to the NRC than under Alternative 2. Specifically, the rulemaking costs would be higher because of the costs associated with revising the appendices for existing certified designs. The NRC estimates rulemaking costs to the NRC of approximately (\$211,000) using a 7 percent NPV and (\$243,000) using a 3 percent NPV, as shown in Table H.2-3.

Table H.2-3 NRC Rulemaking Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
Total:					(\$270,836)	(\$211,478)	(\$242,925)

1.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

This alternative would have the benefit of assuring consistency in the change process across all certified designs, both existing and future.

1.6.3.5 Summary of Costs and Benefits

Alternative 3 would result in net costs to licensees and the NRC of approximately (\$231,000) using a 7 percent NPV and (\$267,000) using a 3 percent NPV.

1.7 Backfitting and Issue Finality

None of the alternatives considered in this section of Appendix H.2, if implemented by the NRC, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. The regulatory changes made under Alternative 2 would apply only to applicants and licensees referencing a future certified design. Alternative 3 would not affect the issue finality of existing DCs and COL holders referencing the existing certified designs because it would not amend certification information of any design (e.g., Tier 1 and Tier 2 information and technical specifications). Instead, Alternative 3 would amend the description of the Tier 2 change process in Section VIII.B.5. The Commission explained in the 2007 Part 52 final rule (72 FR 49352, August 28, 2007; TN4796) that paragraph 52.63(a), which provides the criteria for making changes to certified designs, applies to changes to the certification information but does not apply to changes to the certified design rule language (e.g., Section VIII).

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 **Staff Recommendation**

The NRC staff recommends Alternative 2, “Rulemaking Affecting Future Certified Designs,” because this alternative provides an opportunity to simplify NRC regulations, resulting in rulemaking costs of approximately (\$106,000) using a 7 percent NPV. While Alternative 3 would also simplify regulations, it would also impose a cost on COL licensees referencing existing certified designs, without a significant offsetting benefit. Therefore, the staff prefers Alternative 2.

2.0 **PROCESSES FOR MAKING TIER 1 CONFORMING CHANGES AND FORMATTING CHANGES AND TIER 2 CHANGES TO ORGANIZATION AND SECTION NUMBERING**

The NRC’s regulations specify the processes for an applicant or licensee under Part 52 to depart from information in a certified design, including both Tier 1 and Tier 2 information. The Commission intended that Tier 1 information should include the top-level design features and performance characteristics that are most important to safety for a standard design but did not specify what information should be included in Tier 1. A COL holder must request a license amendment and an exemption to change Tier 1 information in its plant-specific Design Control Document (DCD) (or FSAR), even where there is minimal safety significance to the change. The NRC is considering changes to these regulations to provide flexibility and reduce the regulatory burden on COL holders and applicants in making changes to the generic DCD, including Tier 1 and Tier 2 information, that do not have an appreciable safety impact, under the following three circumstances (Sub-items A–C):

- A. Tier 1 changes to address format inconsistencies between a COL and the referenced DCD that currently require a license amendment request and an exemption request.
- B. Tier 2 changes to a COL holder’s licensing basis that require conforming changes in corresponding Tier 1 information. The COL holder is currently required to request both a license amendment and an exemption for such changes regardless of the safety significance of the changes.
- C. A COL applicant referencing a DCD must include as part of its application a PS-DCD⁶ containing the same type of information and using the same organization and numbering as the generic DCD. A COL applicant must receive an exemption from this regulatory requirement to deviate from the organization and numbering of the generic DCD.

In discussing Sub-items, A, B, and C, Sub-items A and B are related and have been grouped together because they both involve COL licensees and the change process for Tier 1 information. Sub-item C is discussed separately because it is distinct from Sub-items A and B in that it applies to applicants instead of licensees.

⁶ Under 10 CFR Part 52, the certified design portion of the final safety analysis report for a combined license referencing a certified design is referred to as a PS-DCD.

2.1 Existing Regulatory Framework

2.1.1 *Regulatory Framework for Tier 1 Information Change Process (Sub-items A and B)*

Regulatory requirements related to Tier 1 information in a certified design appear in Sections II and VIII of DC appendices of Part 52. Section II.D provides the definition of Tier 1 and is generally the same across the DC appendices. Appendix D for the Advanced Passive 1000 (AP1000) certified design provides the following definition in Section II.D:

Tier 1 means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;
2. Design descriptions;
3. Inspections, tests, analyses, and acceptance criteria (ITAAC);
4. Significant site parameters; and
5. Significant interface requirements.

Under Section VIII.B.5 of the Part 52 appendices, any plant-specific change to Tier 1 information requires both a license amendment and an exemption. The requirement for a license amendment and an exemption applies to any licensee-initiated change to Tier 1, regardless of whether the change affects safety, concerns a non-safety-related matter, is a conforming change resulting from a corresponding Tier 2 change, or simply involves changing the formatting of the information in Tier 1.

The requirements regarding a COL holder's plant-specific changes to Tier 1 information are found in Section VIII.A.4 of the Part 52 DC appendices. As an example, Section VIII.A.4 of Appendix D for the AP1000 design states:

Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

The other Part 52 appendices contain equivalent language.

Paragraph 52.63(b)(1) also addresses the process for a licensee making a plant-specific change to Tier 1 information. Paragraph 52.63(b)(1) states:

An applicant or licensee 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 § 52.7. In addition to the factors listed in § 52.7, the Commission shall consider whether the special circumstances that § 52.7 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 operating license or combined license hearing.

When the NRC issued COLs under the current licensing framework for Part 52, most Tier 1 information appearing in the PS-DCD was included in Appendix C of the license. Therefore, most Tier 1 information appears twice in a COL holder's licensing basis—once in the PS-DCD and a second time in the COL Appendix C. To keep the documents consistent, any change made in Tier 1 information in a PS-DCD would need to be accompanied by a corresponding change in COL Appendix C, which would require a license amendment and an exemption.

2.1.2 *Regulatory Framework for the Organization and Numbering of Information in a PS-DCD in a COL Application (Sub-item C)*

Section IV.A.2.a of each Part 52 DC appendix contains a similar requirement for a COL applicant to use a specific organization and numbering format in its PS-DCD. Section IV.A.2(a) requires that an applicant for a COL that wishes to reference a certified design must include as part of its application “a plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD” for the design being referenced.

The basis for the organization and numbering regulation appears in SECY-96-077, “Certification of Two Evolutionary Designs” (NRC 1996-TN6271), dated April 15, 1996, which discussed the first two applications for certification of reactor designs under Part 52, the ABWR and the System 80+. The NRC subsequently certified these designs as Appendices A and B of Part 52 (62 FR 25800, May 12, 1997; TN6272, and 62 FR 27840, May 21, 1997; TN6273, respectively), using the same regulatory language proposed in the SECY. When originally issued, the regulation read, “a plant-specific DCD containing the same information and using the same organization and numbering as the generic DCD....” Since the original regulation was issued, the NRC revised the regulatory language, inserting the words “type of” between “same” and “information.”

The basis for the “same organization and numbering” requirement, as explained in SECY-96-077, is as follows:

Paragraph (a)(2)(i) is intended to make clear that the initial application must include a plant-specific DCD. This assures, among other things, that the applicant commits to complying with both Tier 1 and Tier 2 of the DCD. This paragraph also requires the plant-specific DCD to use the same format as the generic DCD and to reflect the applicant's proposed departures and exemptions from the generic DCD as of the time of submission of the application. The Commission expects that the plant-specific DCD will become the basis for the plant's final safety analysis report (FSAR), by including within its pages, at the appropriate points, information such as site-specific information for the portions of the plant outside the scope of the referenced design, including related ITAAC, and other matters required to be included in an FSAR by 10 CFR 50.34. Integration of the plant-specific DCD and remaining information, as the plant's FSAR, will be easier to use and should minimize "duplicate documentation" and the attendant possibility for confusion. Paragraph (a)(2)(i) is also intended to make clear that the initial application must include the reports on departures and exemptions as of the time of submission of the application.

2.2 Regulatory Issues

2.2.1 Regulatory Issues for the Tier 1 Information Change Process (Sub-items A and B)

A process that would allow a COL licensee to change the Tier 1 information in its PS-DCD (or FSAR) without having to request a license amendment and an exemption in cases where there is no safety significance to the change may improve regulatory efficiency. Such a change might involve a change in the format of the DCD or a conforming change that aligns Tier 1 information with a non-safety-significant Tier 2 change (e.g., a Tier 2 change that would not otherwise require prior NRC approval because it does not meet any of the 50.59-like criteria in Section VIII of the Part 52 DC appendices).

Allowing such changes without NRC involvement would be contrary to how Tier 1 information is defined in the Part 52 regulations for each certified design as “the portion of the design-related information contained in the generic DCD that is approved and certified....” The DC rule includes specific provisions for change processes, including the processes for changing Tier 1 information. Therefore, NRC approval of any changes to Tier 1 would be required, regardless of their significance.

Allowing Tier 1 changes without NRC involvement would also raise a regulatory issue regarding the handling of Tier 1 information. As stated in the previous section, for any Part 52 COL licensee, most Tier 1 information is maintained in two locations: in Appendix C of the license, and in the PS-DCD. Any approach implemented under this rulemaking item would need to address the challenge of maintaining consistency between Tier 1 information in these two locations or propose a new process that eliminates the need for two locations for Tier 1 information.

2.2.2 Regulatory Issues for the Organization and Numbering of Information in a PS-DCD in a COL Application (Sub-item C)

A process that would allow a COL applicant referencing a certified design to include in its COL application a PS-DCD that has an organization and numbering that departs from the organization and numbering in the generic DCD that it is referencing, without the need for an exemption request, would improve regulatory efficiency. The NRC recognizes that the organization and numbering of a PS-DCD is an administrative requirement not related to safety that was established to facilitate the use and review of the PS-DCD (or FSAR). The current requirement in Section IV.A.2 (a) of the Part 52 DC appendices, while intended to facilitate the review by having information presented “at appropriate points” and make the FSAR “easier to use,” as discussed in SECY-96-077, may not provide sufficient flexibility to COL applicants because it requires the organization and numbering of FSAR sections to be “the same” as in the generic DCD.

For the 19 COL applications submitted to the NRC for review, 8 COL applicants referencing one certified design requested exemptions from the organization and numbering requirement, primarily to include information organized according to topics identified in the NRC Standard Review Plan (SRP) (NUREG-0800; [NRC 2007/2019-TN6221]), which the NRC uses to guide its review. This represents 14 of the 27 units for which the NRC received COL applications. Of the remaining 11 COL applications referencing 3 other designs, no exemptions from this regulatory requirement were requested.

2.3 Discussion of Alternatives

2.3.1 *Alternatives for the Tier 1 Information Change Process (Sub-items A and B)*

2.3.1.1 *Alternative 1: No-Action*

Description of Alternative 1

This alternative would maintain the current regulations and require COL holders referencing a certified design to obtain a license amendment and exemption for any change to Tier 1 information, regardless of whether there was any safety significance to the change.

Assessment of Alternative 1

Under this alternative, changes to Tier 1 formatting and Tier 1 conforming changes that correspond to Tier 2 changes that do not meet any of the 50.59-like criteria from the associated design certification rule would continue to require license amendments and exemptions. Such changes would continue to require prior NRC approval. This alternative would ensure that, as changes to Tier 1 are made, the NRC would continue to evaluate all changes to Tier 1 information. In addition, for the Tier 1 information that appears in two locations, in the licensee's PS-DCD and Appendix C of the COL, the information would continue to be updated at the same time to ensure that the information in the two locations remains the same.

Other activities being conducted in parallel with this rule are addressing issues associated with this item for future certified designs. SECY-19-0034, "Improving Design Certification Content" (NRC 2019-TN6257), discusses NRC efforts to refine the general principles for Tier 1 content, including avoiding unnecessary detail so that NRC approval will not be required for design changes of minimal safety significance. The NRC's new approach maintains standardization, but standardization restrictions will typically apply at a qualitative and functional, rather than at a numeric, level of detail.

2.3.1.2 *Alternative 2: Rulemaking*

Description of Alternative 2

This alternative includes a new regulation that would allow a COL holder to make certain changes to Tier 1 information without a license amendment or exemption, using the 50.59-like criteria, or some other similar criteria, to determine whether prior NRC approval is required. This alternative would also include a process that would ensure that the copy of Tier 1 information in Appendix C of the license would be updated when the COL holder makes allowable Tier 1 changes without prior NRC approval (e.g., through a notification).

Assessment of Alternative 2

Alternative 2 would result in regulations that would allow a COL holder to make certain changes to Tier 1 information without a license amendment or exemption. However, rulemaking on this issue would be complex because the NRC would have to restructure the entire tiered process for certifying designs given that, as the process stands today, Tier 1 information is "approved and certified," in each DC rulemaking. The Commission approved the two-tier structure in the staff requirements memorandum for SECY-90-377, "Requirements for Design Certification Under Part 52," (NRC 1990-TN6274), so a change of this nature would be a policy issue, as

discussed below in Section 2.5.2. In addition, a change that made it easier for licensees to revise Tier 1 information could contribute to the erosion of design standardization, which was one of the stated goals of Part 52.

2.3.2 *Alternatives for the Organization and Numbering of Information in the PS-DCD in a COL Application (Sub-item C)*

2.3.2.1 *Alternative 1: No-Action*

Description of Alternative 1

This alternative would maintain the current regulations and require COL applications to contain a plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD, with no deviations allowed.

Assessment of Alternative 1

Under the “no-action” alternative, COL applicants would continue to request an exemption to allow any difference in organization and numbering between their PS-DCD and the generic DCD they are referencing, even if the applicant’s section numbering was based on the SRP or provided more detail than included in the referenced generic DCD. The NRC would need to review and make determinations regarding these exemption requests.

2.3.2.2 *Alternative 2: Rulemaking*

Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to eliminate the organization and numbering requirement in Section IV.A.2 (a) in each of the existing Part 52 DC appendices, as well as any future such appendices. Under this alternative, a COL applicant could follow any organization and numbering scheme for the FSAR in their COL application without needing to request an exemption.

Assessment of Alternative 2

Alternative 2 would give applicants the flexibility to include a PS-DCD using any organization and number scheme without needing an exemption. Changing the organization and numbering scheme of a PS-DCD may affect the efficiency of the NRC review, but it would not affect the outcome of the safety decision. The applicant would still have strong incentives to follow the organization and numbering of the generic DCD because the organization and numbering of a generic DCD reflects the insights of its designer.

2.4 **Regulatory Scope**

2.4.1 *Regulatory Scope for the Tier 1 Information Change Process (Sub-items A and B)*

For this sub-item, the affected regulations involve the change process for Tier 1 information for a COL licensee, specifically paragraph 52.63(b) and Section VIII.A.4 of the Part 52 DC appendices.

2.4.2 *Regulatory Scope for Organization and Numbering of Information in PS-DCD in a COL Application (Sub-item C)*

For this sub-item, the affected regulation is Section IV.A.2(i) in each of the current Part 52 DC appendices, as well as in any future such appendices.

2.5 NRC Guidance, Policy, and Implementation Issues

2.5.1 *NRC Guidance*

2.5.1.1 *NRC Guidance for the Tier 1 Information Change Process (Sub-items A and B)*

For this sub-item, if the NRC conducts rulemaking, the NRC would develop new regulatory guidance to describe an acceptable approach for COL holders referencing a certified design to implement the new process for determining whether a change in Tier 1 information requires prior NRC approval.

2.5.1.2 *NRC Guidance for the Organization and Numbering of Information in PS-DCD in a COL Application (Sub-item C)*

For this sub-item, if the NRC conducts rulemaking, the NRC would revise current regulatory guidance to address the flexibility allowed by eliminating the requirement for FSAR organization and numbering. Regulatory Guide (RG) 1.206, “Applications for Nuclear Power Plants” (NRC 2018-TN6192), would be an appropriate guidance document where the revised regulation could be addressed. The existing requirement for organization and numbering is discussed on pages 53, 54, and 74 of RG 1.206. As revised, this guidance would reference the statement of considerations accompanying the revised regulation and would address the past NRC experience where COL applicants followed or deviated from the organization and numbering of the referenced certified design. The NRC staff would make the draft regulatory guidance available for public comment when it issues the proposed rule.

2.5.2 *Policy Issues*

2.5.2.1 *Tier 1 Information Change Process (Sub-items A and B)*

The policy issue associated with rulemaking for this item is that it would change the requirements supporting the tiered structure of DC information that the NRC established in SECY-92-287, “Form and Content for a Design Certification Rule” (NRC 1992-TN6346) and has implemented since that time. Information reiterating the tiered structure was discussed more recently in SECY-19-0034, “Improving Design Certification Content.” Tier 1 information is the portion of the design-related information contained in the generic DCD that is approved and certified by the design certification rule (DCR). As discussed in SECY-92-287, change processes for Tier 1 information are limited to rulemaking, plant-specific orders, or exemptions, reflecting the status of Tier 1 information as being certified by NRC. This item would change the process COL holders are required to follow to make changes in Tier 1 information in their PS-DCDs. The relevant aspects of the process considered under this item, which include the need for a license amendment and exemption and which appear in paragraph 52.63(b)(2), have not changed since this issue was considered by the Commission in the early 1990s, as discussed in Section 2.3.2. To implement rulemaking for the Tier 1 change process, the Commission would need to change the current policy for the process.

As implemented under Part 52, after a plant has been licensed, Part 52 imposes an additional burden on the licensee to depart from Tier 1 design information, compared to a Part 50 licensee. For example, when comparing a Part 50 licensee and a Part 52 licensee that have similar information in their FSARs, the Part 50 licensee would be able to make certain changes without a license amendment or exemption using the Section 50.59 process, while the Part 52 licensee making the same changes would—if the information was specified as Tier 1 information—be required to obtain a license amendment and exemption. Current NRC policy supports this difference based on the benefits of standardization, but this policy did not consider the burden associated with making Tier 1 changes that have low safety significance, as was experienced during recent AP1000 plant construction.

2.5.2.2 Organization and Numbering of Information in PS-DCD in a COL Application (Sub-item C)

Changing the requirement for organization and numbering of information in the PS-DCD in a COL application (Sub-item C) is related to the policy issue of standardization, but it is not a policy issue by itself, and rulemaking would not require a new or revised Commission policy. There would be no potential conflict between different policies that would need to be resolved before initiating a proposed rule, and there would be no unresolved policy issue that would affect initiation or completion of this rulemaking.

2.5.3 Implementation Issues

2.5.3.1 Tier 1 Information Change Process (Sub-items A and B)

For these two sub-items, none of the alternatives raises implementation issues.

2.5.3.2 Organization and Numbering of Information in PS-DCD in a COL Application (Sub-item C)

For this sub-item, none of the alternatives raises implementation issues.

2.6 Impacts

2.6.1 Alternatives for the Tier 1 Information Change Process (Sub-items A and B)

This section analyzes the two alternatives addressing the requirement for COL holders to obtain both a license amendment and an exemption for any change to Tier 1 information in the PS-DCD, regardless of whether the change is limited to changing format or is the result of a Tier 2 change that does not meet any of the 50.59-like criteria in the associated DCR.

2.6.1.1 Alternative 1: No-Action

This alternative would maintain the current regulations and require COL holders to obtain a license amendment and exemption for any change to Tier 1 information, regardless of whether there was any safety significance to the change. Under this alternative, a COL holder making a change to Tier 1 information formatting and or making a Tier 1 conforming change that resulted from a Tier 2 change that did not meet any of the 50.59-like criteria would continue to be required to obtain a license amendment and exemption for the change.

Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

Impacts on Applicants and Licensees

This alternative would have no incremental impacts on licensees.

Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.1.2 Alternative 2: Rulemaking

This alternative would allow a COL licensee to make certain changes to Tier 1 information in its PS-DCD without either a license amendment or an exemption. If this alternative is implemented, the NRC would allow the COL holder to have noncompliances with its COL and with applicable NRC regulations justified by a 50.59-like process.

Impacts on Public Health, Safety, and Security

Because this alternative would involve only administrative requirements associated with making changes to licensing basis information, it would result in no impacts on public health, safety, and security.

Impacts on Applicants and Licensees

This alternative could result in cost savings to COL holders referencing one of the current certified designs or a future certified design by allowing them to make certain changes to Tier 1 information without having to obtain a license amendment and exemption. For the COL holder, the cost of preparing a license amendment request and exemption request for submittal to the NRC would be replaced by the presumably smaller cost for evaluating and internally processing the change. The COL holder would also experience the costs of developing and implementing new procedures for evaluating and processing Tier 1 changes under the new requirements. Whether actual cost savings would result is speculative because the number of avoided licensing actions is difficult to estimate. Experience to date for Tier 1 changes initiated by a COL holder is limited to licensees or former licensees having plants under construction for the same certified design. Based on this available information, the staff's estimate assumes two affected COL holders, each of which would see a reduction in 4 LARs submitted during the construction period, with an average level of effort of 267 hours per LAR. This analysis assumes one COL holder potentially averting 2 LARs in 2025 and 2 more in 2026, and the

same for a second COL holder in 2027 and 2028. This results in averted costs to licensees of approximately \$173,000 (7 percent NPV) and \$230,000 (3 percent NPV).

Table H.2-4 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2025	Averted license amendment request from licensee	2	267	\$134	\$71,621	\$47,724	\$59,982
2026	Averted license amendment request from licensee	2	267	\$134	\$71,621	\$44,602	\$58,235
2027	Averted license amendment request from licensee	2	267	\$134	\$71,621	\$41,684	\$56,538
2028	Averted license amendment request from licensee	2	267	\$134	\$71,621	\$38,957	\$54,892
Total:					\$286,484	\$172,967	\$229,646

Impacts on the NRC

In addition to rulemaking costs, the other impacts on the NRC, if any, associated with this alternative could result from a smaller number of LARs and exemption requests submitted by COL holders by allowing COL holders to make Tier 1 change determinations on their own without requesting a license amendment and exemption. Any changes to Tier 1 information processed by a COL holder without needing NRC review and approval would result in reduced cost for the NRC. This alternative would affect controls for Tier 1 and Tier 2* changes, which are fundamental aspects of the Part 52 regulatory regime. In addition, it puts the burden on NRC inspectors to determine the acceptability of the unreviewed changes to Tier 1 information.

If any such changes to Tier 1 information in the PS-DCD were implemented by COL holders under the less burdensome change process, the NRC would experience cost savings associated with any avoided requests for license amendments and exemptions. The NRC would experience costs needed to implement a yet-to-be-determined process by which the NRC would update the corresponding copy of Tier 1 information in Appendix C. The staff estimates the averted review of the LARs in the previous section would save the NRC approximately 133 hours of labor for each LAR.

The costs associated with Alternative 2 are estimated to be approximately (\$192,000) using a 7 percent NPV and (\$205,000) using a 3 percent NPV, as shown in Table H.2-5.

Table H.2-5 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	469	\$131	(\$61,453)	(\$53,675)	(\$57,925)
2022	Develop Proposed Rule	1	469	\$131	(\$61,453)	(\$50,164)	(\$56,238)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	469	\$131	(\$61,453)	(\$46,882)	(\$54,600)
2024	Develop/Issue Final Rule	1	469	\$131	(\$61,453)	(\$43,815)	(\$53,010)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2025	Averted license amendment request review	2	133	\$131	\$34,933	\$23,278	\$29,256
2026	Averted license amendment request review	2	133	\$131	\$34,933	\$21,755	\$28,404
2027	Averted license amendment request review	2	133	\$131	\$34,933	\$20,332	\$27,577
2028	Averted license amendment request review	2	133	\$131	\$34,933	\$19,001	\$26,773
Total:					(\$213,040)	(\$191,959)	(\$204,839)

Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

Summary of Benefits and Costs

Alternative 2 would result in costs to industry and the NRC of approximately (\$19,000) using a 7 percent NPV and averted costs of approximately \$25,000 using a 3 percent NPV.

2.6.2 Alternatives for the Organization and Numbering of Information in PS-DCD in a COL Application (Sub-item C)

This section analyzes two alternatives for addressing the COL application requirement for a PS-DCD to have the same organization and numbering as the generic DCD.

2.6.2.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing new reactor licensing process as described in the current regulation in Section VI.2.A.i of the Part 52 DC appendices and guidance, specifically RG 1.206. The NRC would not pursue any changes to the current process.

Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants or licensees.

Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

Summary of Benefits and Costs

This alternative would result in no impacts on public health, safety, and security, licensees, the NRC, or other stakeholders.

2.6.2.2 Alternative 2: Rulemaking

Under this alternative, the NRC would undertake a rulemaking to eliminate the organization and numbering requirement that appears in Section VI.2.A.i of the Part 52 DC appendices.

Impacts on Public Health, Safety, and Security

Because this alternative involves only administrative requirements that do not affect safety, it would result in no impacts on public health, safety, and security.

Impacts on Applicants and Licensees

Overall, this alternative could result in cost savings to future COL applicants referencing either an existing or a future certified design. Existing COL holders would not be affected. For any future COL applicant referencing a certified design, the applicant could include in its application a PS-DCD that has organization and numbering different from that of the generic DCD without having to request an exemption.

Impacts on the NRC

By changing the organization and numbering requirement for COL applicant PS-DCDs, the NRC could reduce the number of exemption requests included in a COL application. This could result in a more efficient process and potentially save the NRC time and resources. The NRC would incur rulemaking costs in Alternative 2 of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table H.2-6.

Table H.2-6 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

Allowing the change in structure and numbering of the plant-specific DCD would result in some increased time for NRC to perform reviews or to compare design features between COL applications. Depending on the level of change, COL holders may need to prepare a crosswalk to map the location of information between the generic and plant-specific DCD.

Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

Summary of Benefits and Costs

The NRC would incur rulemaking costs of approximately (\$106,000) using a 7 percent NPV, in Alternative 2.

2.7 Backfitting and Issue Finality

None of the alternatives in this section of Appendix H.2, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of any approval issued under Part 52.

The “no-action” alternatives would maintain the status quo regarding Tier 1 change processes for COL holders and the required organization and section numbering of a PS-DCD submitted by future COL applicants, thereby imposing no change in requirements or NRC staff positions.

Therefore, there would be no backfitting or issue finality concern associated with the “no-action” alternatives.

For the rulemaking alternative affecting the Tier 1 change process (Sub-items A and B), there would be no backfitting or issue finality concern because COL holders would be voluntarily changing their Tier 1 information. In addition, the rulemaking alternative would provide an approved alternate process, which would permit but no longer require prior NRC approval for some changes to Tier 1 information.

For the rulemaking and guidance alternative related to providing flexibility to any future COL applicant for the organization and numbering of the PS-DCD included in its COL application without needing to request a departure and exemption (Sub-item C), there is no concern about backfitting or issue finality. This alternative would apply only to future COL applicants referencing a certified design. It would not affect the issue finality of existing DCs and COL holders referencing the existing certified designs because it would not amend certification information of any design (e.g., Tier 1 and Tier 2 information and technical specifications). Instead, this alternative would only amend Section IV.A.2(a) in each of the existing Part 52 DC appendices. The Commission explained in the 2007 Part 52 final rule (72 FR 49352, August 28, 2007) that paragraph 52.63(a), which provides the criteria for making changes to certified designs, applies to changes to the certification information but does not apply to changes to the certified design rule language (e.g., Section IV).

2.8 Stakeholder Feedback

2.8.1 *Feedback from the Public Meeting for Comment*

The sub-items involving change processes for certain Tier 1 changes in a plant-specific DCD were addressed at NRC’s Category 3 public meeting held on January 15, 2019. At that meeting, the NEI made a presentation about its suggestions for this rulemaking, including the following information:

Need to provide for a more flexible change process for Tier 1 changes that do not decrease the level of safety, e.g., include a provision to allow administrative departures from Tier 1 without a LAR/Exemption. Note that DCR Appendi[x] Section III.C dictates that if there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls. Many of the administrative changes processed are to reconcile conflicts between Tier 2 and Tier 1 information where the Tier 2 information was correct. Note: [For] Vogtle Units 3&4 – [there have been] 4 example LARs [where a more flexible change process would have provided benefit:] 3 approved and 1 under review by NRC.

This topic is discussed on page 36 of the transcript for the January 15, 2019 public meeting (NRC 2019-TN6235).

For a rulemaking involving the Tier 1 change processes, some options involve the challenge of maintaining two copies of Tier 1 information—one version controlled by the licensee in the PS-DCD and a second version controlled by the NRC in Appendix C of the COL. NEI also identified this challenge as a concern in their presentation at the January 15, 2019 public meeting, and the discussion of that topic begins on page 48 of the public meeting transcript, as follows:

Comment/Basis: At the time of COL issuance, NRC elected to duplicate Tier 1 information into COL Appendix C ITAAC. The benefit of maintaining both Tier 1 and the COL Appendix C is not understood.

Recommendation: It would seem that all the info in Tier 1 could be issued with the COL as Appendix C with a full exemption from the need to maintain Tier 1 information. This would reduce the burden of multiple exemptions (which aren't being reflected in the COL), and also the burden of maintaining two documents with essentially the same requirements. Further, an acceptable 103(g) finding could simultaneously void the portions of the COL Appendix C which would no longer be applicable and authorize their removal. This would again reduce the burden of another license amendment to do the same action.

The issue of the sub-item involving departures in the COL application PS-DCD from the organization and numbering in the generic DCD, was not discussed in the NRC's Category 3 public meeting held on January 15, 2019.

2.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

For the sub-items involving change processes for certain Tier 1 changes in a PS-DCD (Sub-items A and B), the staff recommends Alternative 1, "No-Action." A rulemaking in this area would involve changing a longstanding NRC policy regarding standardization. In addition, a change in this policy would involve multiple complicating issues, including determining the criteria for what sort of changes would qualify for the new change process and a new process for maintaining consistency between the two copies of Tier 1 information in the PS-DCD and Appendix C of the COL. In addition, because the Tier 1 change issues have, to date, involved only a single certified design, it is not clear that the issues that gave rise to the problems in Tier 1 information exist for any other certified designs. Recent and ongoing DC submittals also may not experience this issue, because lessons learned from previous reviews are being applied to those designs. Finally, lessons learned about improving and correcting Tier 1 information could be addressed generically through a future renewal of a certified design.

For the sub-item involving departures in the COL application PS-DCD from the organization and numbering in the generic DCD (Sub-item C), the NRC staff recommends Alternative 2, "Rulemaking." This would provide flexibility and relief to COL applicants relative to applying the requirement in Section VI.2.A.i of the Part 52 DC appendices that a COL applicant's PS-DCD have the same organization and numbering as the referenced generic DCD. This alternative would have the potential to eliminate or reduce the number of future exemption requests related to FSAR organization and numbering that have no impact on safety.

3.0 10 CFR PART 52 APPENDIX A-E SECTIONS VIII.5.B.A AND VIII.5.B.B

Licensees of Part 50 commercial power reactors that propose to make changes to their facilities as described in their respective FSARs face different requirements than licensees of

commercial power reactors licensed under Part 52 regarding when they are allowed to begin making those physical changes to their facilities. For changes requiring NRC approval, licensees subject to change processes in Section 50.59 are allowed to begin making physical changes to the facility before the NRC approves the changes. However, for similar changes proposed by a licensee referencing a certified design and subject to the change processes in Section VIII.B.5 of the applicable Part 52 DC appendix, the licensee is allowed to begin making physical changes to the facility only after the NRC approves the change.

3.1 Existing Regulatory Framework

Section VIII.B.5 of each of the Part 52 DC appendices specifies requirements for how a licensee referencing that certified design can change or depart from the information within the scope of the certified design. For changes to Tier 2 information in the PS-DCD requiring NRC approval, these licensees are required to obtain NRC approval in the form of a license amendment before making certain changes to their facilities.

In each Part 52 DC appendix, paragraph VIII.B.5 states:

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the TS [technical specification], or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

5.b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

- (1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;
- (2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;
- (3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;
- (4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;
- (5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;
- (6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

Alternatively, Section 50.59 describes the process by which a Part 50 licensee and a Part 52 licensee in certain cases determines whether either it can proceed to make a change to the facility described in its FSAR without prior NRC approval or the change requires prior NRC approval through a license amendment using the process set forth in Section 50.90. Paragraph 50.59(c)(2) states:

A licensee shall obtain a license amendment pursuant to § 50.90 prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the final safety analysis report (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the final safety analysis report (as updated);

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the final safety analysis report (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the final safety analysis report (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report (as updated);

(vii) Result in a design basis limit for a fission product barrier as described in the FSAR (as updated) being exceeded or altered; or

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses.

The statement of considerations in the Section 50.59 rulemaking (“Changes, Tests, and Experiments; Final Rule” [64 FR 53582, October 4, 1999; TN6262]) discussed the timing of “implementation” of a change to the facility vis-à-vis the issuance of an amendment authorizing the proposed change. The Commission stated that a holder of an OL may install and test a change requiring an amendment under paragraph 50.59(c)(2) before the amendment is granted, provided that such installation and testing of the change does not violate a technical specification (TS) or otherwise meet one of the paragraph 50.59(c)(2) criteria for prior approval. The Commission stated that it did not consider the design change “implemented” until the

licensee used the redesigned SSC in facility operations, and that the licensee could do this only if the NRC had already granted an amendment authorizing use of the SSC as redesigned. In addition, the Commission clarified that such installation and testing of a change before receiving NRC approval is at the licensee's own risk. This means that if the Commission did not grant the requested amendment, the licensee must modify the facility to conform to the description in the FSAR, as updated, before resuming operation of the SSC. Thus, a licensee may design, plan, install and test a modification prior to receiving the license amendment to the extent that these preliminary activities do not themselves require prior NRC approval.

When paragraph 50.59(c) was issued in 1999, the Commission decided to defer consideration of conforming changes to Part 52, stating, "The Commission anticipates other rule changes for 10 CFR Part 52 arising from an ongoing lessons-learned review.... [T]he Commission will consider these proposed changes in an integrated manner later."

When the NRC updated Part 52 in 2007, some provisions of the paragraph 50.59(c)(2) language (e.g., the "more than minimal" provisions) were adopted in change process language in Section VIII.B.5 of the Part 52 appendices. However, the implementation requirements in paragraph 50.59(c)(2) were not addressed.

To address this situation, in part, the NRC developed Interim Staff Guidance (ISG) 025, "Interim Staff Guidance on Changes during Construction under 10 CFR Part 52" (NRC 2015-TN6269). COL-ISG-025 describes the preliminary amendment request (PAR) process. The PAR process preserves the design configuration control mechanisms while avoiding unnecessary construction delays by creating a process whereby a licensee can opt to submit a request to the NRC seeking a determination on whether the NRC objects to the licensee proceeding with construction changes, subject to conditions, before the NRC's review of the LAR is complete. If the NRC determines it has no objection to the licensee's request, the licensee may proceed with the construction change, but the licensee is required to return the facility to its current licensing basis if the related LAR is withdrawn or denied.

In addition, on April 28, 2020, the NRC issued draft regulatory guide (DG)-1321, "Guidance for Changes During Construction for New Nuclear Power Plants Licensed Under 10 CFR Part 52" (NRC 2020-TN6270), which describes a process that the NRC considers acceptable for implementation of changes to the design of SSCs of a facility being constructed under a COL to which paragraph 52.98(b) or (c) apply. Paragraph 52.98(b) covers COLs that do not reference a certified standard design or a manufacturing license (ML) and would apply to a COL that references a standard design approval, and paragraph 52.98(c) covers COLs that reference a certified standard design. Specifically, this DG addresses the timing of a proposed change to the design of facility SSCs during construction, as the facility design is described in the FSAR, and for which a license amendment is required by an applicable change process of Part 50 or 52. The DG explains that if the applicable change process requires a license amendment, then a COL holder may construct an SSC in accordance with a change to the facility described in the FSAR for a COL covered by paragraph 52.98(b) or 52.98(c)(2) or a departure from Tier 2 of the PS-DCD for a COL covered by paragraph 52.98(c)(1), without first obtaining a license amendment. A licensee must submit the request for a license amendment required to authorize the change within 45 days after the licensee begins construction of the SSCs subject to the change or departure. Submission of a LAR on this schedule would allow for sufficient time to process it so that the ITAAC findings under paragraph 52.103(g) and fuel load would not be delayed.

3.2 Regulatory Issues

At the time of the 2007 Part 52 rule, the NRC had not issued any COLs. Since then, through the issuance of COLs and the review of subsequent LARs, the NRC has gained experience with the COL change processes and has identified the additional requirements for changes made using the Section VIII.B.5 process and the ISG-025 guidance as an issue. In particular, requiring licensees subject to the Section VIII.B.5 process to obtain NRC approval before making certain physical changes while allowing other licensees to proceed with the physical changes prior to requesting NRC approval imposes an unnecessary burden on those licensees subject to the Section VIII.B.5 process.

3.3 Discussion of Alternatives

3.3.1 Alternative 1: No-Action

3.3.1.1 Description of Alternative 1

This alternative would maintain the current regulations regarding Part 52 departures and Part 50 changes to a facility or procedures or conduct of tests or experiments. The change process implementation provisions for Parts 50 and 52 licensees would remain different.

3.3.1.2 Assessment of Alternative 1

Under the “no-action” alternative, licensees subject to the Part 52 Section VIII.B.5 change process would not be allowed to begin making certain physical changes until the necessary LAR is approved by the NRC, unless the licensee sought to use the PAR process as described in DG-1321. This is unlike licensees who are subject to the Section 50.59 process. These licensees are allowed to make physical changes prior to submitting a LAR and receiving the NRC’s approval.

3.3.2 Alternative 2: Rulemaking

3.3.2.1 Description of Alternative 2

This alternative would align the implementation provisions in the departure process in the Part 52 DC appendices with the implementation provision in the Section 50.59 process such that the various licensees subject to these different regulations would be subject to similar requirements for when a licensee can implement a change proposed in a LAR.

Under this alternative, the NRC would pursue rulemaking to modify Section VIII.B.5 of each Part 52 DC rule appendix to replace the existing language that states “[a] proposed departure from Tier 2...” with the “prior to implementing a proposed change” language in Section 50.59(c)(2). For plants under construction, the NRC would also add language requiring the licensee to submit the LAR required to authorize the change to the facility or departure from Tier 2 of the PS-DCD within a specified time frame, which would be consistent with what the NRC proposes in DG-1321 (i.e., 45 days), after the licensee begins construction of the SSCs subject to the change or departure. Those modifications would give the licensee the option to continue construction and avoid construction delays. Any changes implemented by the licensee prior to receiving NRC approval would continue to be at the licensee’s own risk, and if the requested change was not approved by the NRC, the licensee would still be required to return the facility to its approved licensing basis prior to completing construction.

The NRC would also update existing guidance to reflect the revised regulations. These revisions would largely involve changes to citations of the text in the DC rules.

3.3.2.2 Assessment of Alternative 2

Alternative 2 would adopt regulatory language, similar to the language in paragraph 50.59(c)(2), regarding the timing of when a COL holder referencing a certified design can make physical changes to its facility under a proposed change submitted for NRC approval. This would eliminate any confusion on the part of licensees or other external stakeholders about any distinctions between the Parts 50 and 52 change processes with respect to the timing of physical changes to the facility.

This change would align requirements between Parts 50 and 52 for when licensees proposing to make changes to their facilities can, at their own risk, begin making physical changes and would impose a requirement on the timing of submittal of the related LAR within 45 days after beginning construction. This time frame would give the NRC sufficient time to process the LAR without delaying the Commission's ITAAC finding under paragraph 52.103(g) and fuel load. This alternative would give more flexibility to the licensee than it currently has regarding when it needs to submit a LAR.

3.4 Regulatory Scope

The regulatory changes for this item would need to be coordinated with other change process rulemaking items being considered in Appendix H of this regulatory basis. The affected regulations would be Section VIII.B.5 of the Part 52 appendices.

3.5 NRC Guidance, Policy, and Implementation Issues

3.5.1 NRC Guidance

If the NRC conducts rulemaking, then the NRC would update RG 1.187, Revision 1, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments.'" Regarding Part 52 licensees, draft regulatory guidance (DG-1321) was developed to describe an acceptable approach to implementing Tier 2 changes for COL holders referencing a certified design that are considering changes to their licensing basis during construction.

3.5.2 Policy Issues

The rulemaking alternative does not raise any new policy issues even if it would result in a change in requirements. As noted above in Section 3.1, in the 1999 Section 50.59 final rule, the Commission decided to defer consideration of conforming changes to Part 52 related to the Section 50.59 change process. The Commission anticipated rule changes for Part 52 arising from ongoing lessons learned and indicated that it would consider such changes in the future.

3.5.3 Implementation Issues

None of the alternatives for this item raise implementation issues.

3.6 **Impacts**

This section analyzes two alternatives regarding the implementation provisions for change processes to be submitted for NRC approval.

3.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing implementation provisions for the Tier 2 change process as described in the Part 52 appendices, Section VIII.B.5. The NRC would not pursue any changes to the current process.

3.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process for determining the need for a license amendment, there would be no increase or reduction in public health, safety, and security.

3.6.1.2 Impacts on Applicant and Licensees

This alternative would have no incremental impacts on applicants or licensees.

3.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

3.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

3.6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would undertake a rulemaking to revise the implementation provisions for when Tier 2 changes need to be approved by the NRC in a PS-DCD in the Part 52 appendices, Section VIII.B.5.

3.6.2.1 Impacts on Public Health, Safety, and Security

Because the licensee is still required to submit changes that must be reviewed and accepted by the NRC prior to the startup of the plant, there would be no impact to public health and safety. This alternative would involve changes in the implementation provisions for a facility during construction, as the facility is described in the FSAR, but not involve any changes in actual technical safety requirements (e.g., safety standards in Part 50).

3.6.2.2 Impacts on Applicants and Licensees

Overall, this alternative would result in ongoing cost savings or additional costs to licensees subject to the Section VIII.B.5 change process, including both plants under construction and operating plants.

Qualitative benefits resulting from allowing plants to proceed with construction prior to requesting NRC approval or a “no objection” letter (to a PAR) for a LAR are that licensees would have more flexibility in implementing changes, and the potential for delays while awaiting NRC approval would be lower. The NRC did not estimate the benefits associated with the increased flexibility and reduced potential for impacting construction because these benefits are difficult to quantify.

There would be no impacts on applicants.

3.6.2.3 Impacts on the NRC

Implementing this alternative would not quantifiably impact NRC staff time and resources expended for review of LARs because the NRC would perform the same review, but it would occur at a different time. A qualitative benefit is that NRC would experience greater schedule flexibility to review the LARs. The NRC has already issued a DG. The NRC would incur rulemaking costs under Alternative 2, estimated to be approximately (\$209,000) using a 7 percent NPV and (\$240,000) using a 3 percent NPV, as shown in Table H.2-7.

Table H.2-7 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	307	\$131	(\$40,250)	(\$35,156)	(\$37,939)
2022	Develop Proposed Rule	1	307	\$131	(\$40,250)	(\$32,856)	(\$36,834)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	307	\$131	(\$40,250)	(\$30,706)	(\$35,762)
2024	Develop/Issue Final Rule	1	307	\$131	(\$40,250)	(\$28,698)	(\$34,720)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
Total:					(\$267,961)	(\$209,203)	(\$240,331)

3.6.2.4 Additional Considerations

This alternative would have no incremental impact on State, local, or Tribal governments.

3.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in rulemaking costs to the NRC of approximately (\$209,000) using a 7 percent NPV.

3.7 Backfitting and Issue Finality

None of the alternatives considered for this item in this section of Appendix H, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would only amend Section VIII.B.5 of the DC appendices in Part 52. The Commission explained in the 2007 Part 52 final

rule that paragraph 52.63(a), which provides the criteria for making changes to certified designs, applies to changes to the “certification information” (i.e., the information in the generic DCD incorporated by reference in a certified design appendix in Part 52) but does not apply to changes in the certified design rule language (e.g., Section VIII).

3.8 Stakeholder Feedback

3.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, the NEI made a presentation about its suggestions for this rulemaking and identified this item on page 1 of its presentation handout, as follows:

Comment / Basis: Changes during construction and construction to licensing basis challenges are created by NRC's position that as soon as the COL is issued there is an approved licensing basis and the licensee, therefore, needs to be in compliance with its licensing basis at all times regardless of whether there is any impact to the health and safety of the public.

ITAAC verification and construction oversight via licensee programs (e.g., quality control), as well as implementation of operational programs, ensure that the facility has been constructed and will operate in accordance with its license.

Restrictions should be removed thus allowing temporary deviation from the approved licensing basis during construction where configuration control, corrective measures or license amendments are implemented that restore conformance of the plant with its licensing basis. 10 CFR 52 when created was intended to ensure better control over standardization. The unintended consequence of hindering construction was not fully understood at that time.

Recommendation: Modify NRC interpretation to allow at risk construction pending approval of a LAR or the processing of a 50.59-like change.

This interpretation would acknowledge the potential for LARs to be denied. Changes at risk would need to be subject to configuration control to ensure that if the LAR is not approved or the licensee does not or cannot process a 50.59-like change, the change at risk will be reversed in the field.

3.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the ACRS. The purpose of the meeting was to receive the ACRS members' observations of the implementation of the Part 52 process based on their individual perspectives from their reviews of new reactor license applications. The discussions focused on SECY-19-0084, “Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66) (NRC 2019-TN6210).” This topic was discussed during that meeting, and the ACRS member's feedback and concern was related to having an accumulation of the LARs at the end of the construction period but prior to the 52.103(g) finding. Consistent with that comment, the NRC staff recommends adding the specified time frame requirement to the rule.

3.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking,” to address this issue about the change in the implementation provisions of proposed changes to a facility during construction in the Part 52 change processes. This alternative is the only option that would resolve the issues associated with the item and will allow for greater flexibility for licensees while maintaining public health and safety.

4.0 INCLUDE 10 CFR 50.59(C) APPLICABILITY PROVISIONS IN 10 CFR PART 52, 10 CFR 50.59-LIKE PROCESS

Section VIII.B.5 in each of the Part 52 DC appendices specifies requirements for how a licensee that references the appendix can change or depart from the information within the scope of the certified design. For changes to Tier 2 information in the PS-DCD of an applicant or licensee subject to the Section VIII change processes, the NRC is considering modifications to Part 52 to include applicability provisions like those found in paragraph 50.59(c). The NRC is considering the change because the current requirements in Section VIII apply to “departures” from the PS-DCD, while the Section 50.59 change process applies to certain changes to a licensee’s facility and procedures as described in its FSAR and the licensee’s conduct of certain tests and experiments not described in its FSAR. In addition, Section 50.59 does not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes (see paragraph 50.59(c)(4)). The Part 52 regulations do not include a similar provision. Having different change process applicability requirements for FSARs and PS-DCDs in Parts 50 and 52, respectively, may be unnecessary and could lead to confusion.

4.1 Existing Regulatory Framework

Section 50.59 describes the process by which an OL holder, and a COL holder in certain circumstances, determines whether it can proceed to make a change to its facility or procedures or conduct a test or experiment without prior NRC approval. Paragraph 50.59(c)(1) describes the scope of changes, tests, and experiments that are subject to the requirements of the section:

A licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 only if:

- (i) A change to the technical specifications incorporated in the license is not required, and
- (ii) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

Paragraph 50.59(c)(2) provides eight evaluation criteria used by OL and COL holders to determine whether a license amendment is required for certain prospective changes, tests, or experiments. These criteria are referred to as the “more than minimal” criteria because several of the criteria involve determining whether a change, test, or experiment would result in more

than a minimal increase in the frequency, likelihood, or consequences of an accident or malfunction. For licensees referencing a certified design, similar criteria appear in Section VIII.B.5.b of the Part 52 appendices.

The requirements in Section VIII.B.5.a of the Part 52 DC appendices describe the applicability of the 50.59-like process appearing in subsection VIII.B.5. The 50.59-like process specifies the circumstances under which a COL holder who has referenced a particular certified design is required to obtain prior NRC approval through a license amendment before implementing a change to certain Tier 2 information:

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the TS [technical specification], or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

This process is referred to in the Part 52 regulations for DCs and COLs in paragraphs 52.63(b) and 52.98(c), respectively, and is described in Section 2.1 “Existing Regulatory Framework,” of this appendix.

The difference between paragraph 50.59(c)(1) and the Part 52 50.59-like provisions is that, paragraph 50.59(c)(1) refers to changes to the facility and procedures, tests, and experiments, and the 50.59-like process in Part 52 refers to “departures” from the PS-DCD. Whether there is a practical difference between these terms that would result in a LAR under Section 50.59 but not result in a LAR under the 50.59-like regulations is not discussed in existing guidance. However, Section 1.4.2.1, “COL UFSAR [Updated Final Safety Analysis Report] Changes Subject to 10 CFR 50.59,” of NEI guidance NEI 96-07, Appendix C, Revision 0 – Corrected, “Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52” (NEI 2014-TN6259), recognizes the two processes as being distinct. This NEI guidance is endorsed by the NRC in RG 1.187, Revision 1. Section 1.4.2.1 of NEI 96-07 states:

Changes to facilities or procedures described in the COL UFSAR and conduct of tests or experiments not described in the COL UFSAR, that are outside the scope of a referenced design certification rule are controlled under 10 CFR 50.59. Licensees should screen and evaluate, as appropriate, such changes using Sections 4.2 and 4.3 of the main body of NEI 96-07, Revision 1, except as updated to reflect new NRC requirements and/or regulatory guidance (e.g., dose limits identified in Section 4.4.2.2 of this appendix). Some changes may affect information within the scope of the design certification rule as well as information outside the scope of the design certification rule; in those cases, the applicable provisions of both change processes apply.

Paragraph 50.59(c)(4) also contains a provision not accounted for in the regulations for the Part 52 50.59-like process:

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.

This provision prohibits licensees from using the Section 50.59 process to make certain changes for which other, more specific change processes exist (e.g., Section 50.46 for emergency core cooling systems). Because this provision is not included in Part 52, a COL licensee using the 50.59-like process is not prohibited from using the 50.59-like change process even in cases where regulations governing Part 50 licensees require the use of other, more specific change processes. Section 4.1.1 of NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation, Revision 1" (NEI 2000-TN6260), endorsed by the NRC in RG 1.187 (NRC 2000-TN6261), identifies several other change control requirements that meet the intent of paragraph 50.59(c)(4) and may take precedence over Section 50.59 for control of specific changes.

When paragraph 50.59(c)(4) was issued ("Changes, Tests, and Experiments; Final Rule" [64 FR 53582, October 4, 1999]), the Commission identified the reasoning behind the requirement was to prevent the duplication of reviews. The Commission decided to defer consideration of conforming changes to Part 52, stating, "The Commission anticipates other rule changes for 10 CFR Part 52 arising from an ongoing lessons-learned review.... [T]he Commission will consider these proposed changes in an integrated manner later."

When the NRC updated Part 52 in 2007 ("Licenses, Certifications, and Approvals for Nuclear Power Plants" [72 FR 49352, August 28, 2007]), some provisions of the 50.59-like language in the Part 52 appendices were updated to conform to the provisions of Section 50.59. For example, the "more than minimal" provisions from paragraph 50.59(c)(2) were adopted into change process language in Section VIII.B.5 of the Part 52 appendices. However, the applicability requirements in paragraphs 50.59(c)(1) and (4) were not addressed.

4.2 Regulatory Issues

At the time of the issuance of the 2007 Part 52 final rule, the NRC had not issued any COLs. Since then, through the issuance of COLs and the review of LARs and other actions involving issued COLs, the NRC has gained experience with the COL change processes and has identified the regulatory language differences in the Section 50.59 and 50.59-like change processes as being an issue. In particular, having distinctly different regulatory language for the applicability aspects of the two processes that are nominally similar can result in confusion and lead to questions about why those aspects of the two processes are not the same.

4.3 Discussion of Alternatives

4.3.1 *Alternative 1: No-Action*

4.3.1.1 *Description of Alternative 1*

This alternative would maintain the current regulations regarding departures under Part 52 and changes to a facility or procedures or the conduct of certain tests or experiments under Part 50. The provisions related to change processes for Parts 50 and 52 licensees would remain different.

4.3.1.2 *Assessment of Alternative 1*

The "no-action" alternative would not eliminate the differences between the Part 50 change process regulations and those in the Part 52 DC appendices. Future Part 52 appendices for DC rulemakings would continue to repeat the same regulatory language as in the existing DC

appendices, thereby continuing the regulatory uncertainty about the differences between the requirements. The NRC-endorsed NEI guidance discussing application of each set of regulations would still be available.

4.3.2 Alternative 2: Rulemaking Affecting Future Certified Designs

4.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to include in Section VIII.B.5 of future Part 52 DC appendices provisions similar to the paragraphs 50.59(c)(1) and (c)(4) applicability provisions. The provisions would apply to Part 52 licensees referencing future certified designs. This alternative would include updating guidance addressing the revised regulations.

Under this alternative, the NRC would pursue rulemaking to incorporate the paragraph 50.59(c)(1) and (c)(4) applicability provisions into Part 52 change process regulations for future DCs. Because the change process regulations for COLs referencing a DC currently appear in Section VIII.B.5 of the Part 52 DC appendices (and therefore these regulations do not yet exist for future DCs), this alternative is linked to the rulemaking item addressed in Section 1.0, "Move 10 CFR 50.59-Like Process from 10 CFR Part 52 Appendices to Subpart B," in this appendix, which would change the location of the change process regulations, moving them from Section VIII.B.5 of the Part 52 DC appendices to Section 52.63. Presuming that rulemaking is implemented for that item, this alternative would revise Section 52.63 to add the paragraph 50.59(c)(1) and (c)(4) applicability provisions. If no action is implemented for Section 1.0 of this appendix, then this alternative would not involve rulemaking to revise Section 52.63, and the decision about whether to incorporate the paragraph 50.59(c)(1) and (c)(4) applicability provisions into Part 52 would be deferred until a future design is certified.

This alternative would not affect certain applicability provisions that appear in Section VIII.B.5 of the Part 52 DC appendices. In particular, the provisions regarding severe accident issues and aircraft impact assessments would not be affected and would continue to apply as is to Part 52 applicants and licensees.

4.3.2.2 Assessment of Alternative 2

Rulemaking under Alternative 2 would simplify the regulations and eliminate confusion about differences between the Parts 50 and 52 change processes and about why they are different. Guidance issued with the rule would clarify how similar applicability provisions apply to Part 50 licensees and certain Part 52 licensees.

4.3.3 Alternative 3: Rulemaking Affecting Both Future and Existing Certified Designs

4.3.3.1 Description of Alternative 3

This alternative is similar to Alternative 2 because rulemaking under Section 1.0 in this appendix would affect which regulations would be revised. If rulemaking is implemented for Section 1.0, then this Alternative 3 would revise Section 52.63 to include the paragraph 50.59(c)(1) and (4) applicability provisions for the Tier 2 change process and Section VIII.B.5 in the existing Part 52 DC appendices would be revised to reference Section 52.63. In future Part 52 DC appendices, Section VIII.B.5 would reference Section 52.63 using the same language as would be added to the existing appendices.

If rulemaking were not implemented for Section 1.0 of this appendix, then this Alternative 3 would revise Section VIII.B.5 in the existing Part 52 DC appendices to include the paragraph 50.59(c)(1) and (4) applicability provisions for the Tier 2 change process, and future Part 52 DC appendices, when issued, would contain the new regulatory language in Section VIII.B.5.

In either case, this alternative would include updating guidance addressing the revised regulations.

4.3.3.2 Assessment of Alternative 3

Like Alternative 2, Alternative 3 would revise the current regulations in Part 52, would not create any new regulatory requirements or eliminate any existing ones, and would have the benefit of eliminating unnecessary regulatory language in the future. However, because this alternative would revise the existing change process language in each Section VIII.B.5 of the current Part 52 DC appendices, it would affect all COL holders subject to the existing Section VIII.B.5 change process regulations. As a result, both existing and future COL holders would be subject to the same change process regulations.

4.4 Regulatory Scope

Under Alternatives 2 and 3, if rulemaking is implemented for the item addressed in Section 1.0 of this appendix, then the NRC would amend Section 52.63 and Section VIII.B.5 of future Part 52 DC appendices to either contain change process applicability language similar to that in Section 50.59 or to reference new change process applicability language that would be added to Section 52.63. In addition, Alternative 3 would revise Section VIII.B.5 of the existing Part 52 DC appendices to either contain or reference new language about change process applicability.

4.5 NRC Guidance, Policy, and Implementation Issues

4.5.1 NRC Guidance

If the NRC conducts rulemaking, the NRC would revise existing guidance RG 1.187, which endorses NEI 96-07, Appendix C, "Guidelines for Implementation of Change Processes for New Nuclear Power Plants Licensed Under 10 CFR Part 52," for nuclear units licensed under Part 52.

4.5.2 NRC Policy

This item does not raise any new policy issues even if it would result in a change in requirements. As noted above in Section 4.1, "Existing Regulatory Framework," in the 1999 Section 50.59 final rule, the Commission deferred issuing regulations related to the applicability of the 50.59-like process, and the applicability provisions were not among those addressed in the 2007 Part 52 final rule. The Commission anticipated rule changes for Part 52 arising from ongoing lessons learned and indicated that it would consider such changes in the future.

4.5.3 Implementation Issues

Under Alternative 2, because the recommended regulatory changes would affect only future certified designs, only future certified designs would benefit, and existing certified designs would remain under the existing change process regulations which appear in the individual design

certification appendices. Therefore, new and existing certified designs would be subject to different requirements. As a practical matter, the NRC did not see this as a significant concern because the new regulations would not impose significant burden or provide significant relief to either group of COL holders and the distinction could be addressed in guidance.

4.6 Impacts

This section analyzes the three alternatives regarding the applicability provisions for Tier 2 change processes.

4.6.1 Alternative 1: No-Action

Under this alternative, the NRC would continue with the existing applicability provisions for the Tier 2 change process as described in the Part 52 appendices, Section VIII.B.5. The NRC would not pursue any changes to the current process.

4.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process for determining the need for a license amendment, there would be no increase or reduction in public health, safety, and security.

4.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on licensees.

4.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

4.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

4.6.2 Alternative 2: Rulemaking Affecting Future Certified Designs

Under this alternative, the NRC would undertake a rulemaking to revise the applicability provisions for PS-DCD Tier 2 changes in future DCs by revising Section VIII.B.5 in Part 52 appendices for future DCs or, if rulemaking is implemented for the item addressed in Section 1.0 of this appendix, revising Section 52.63.

4.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would involve changes in the applicability of the Tier 2 change processes for COL licensees that reference certified designs but would not involve any changes to actual technical safety requirements (e.g., safety standards in Part 50), it would have no impacts on public health, safety, and security.

4.6.2.2 Impacts on Applicants and Licensees

This alternative is unlikely to result in any change in the number of required licensing actions. Therefore, there would be no impacts on applicants and licensees resulting from this alternative.

In addition, this rulemaking alternative would provide a qualitative benefit for future certified designs and licensees referencing them by enhancing the clarity and predictability of the new reactor licensing process by stating certain applicability provisions in the regulations. For future certified designs and licensees referencing them, it would eliminate the uncertainty regarding the difference between the applicability provisions in Parts 50 and 52.

The impacts of this rulemaking item would change depending on whether rulemaking for the item in Section 1.0 in this appendix is implemented. This is because, for future DC rules, the NRC may consider using the direct final rule process, which is an expedited rulemaking process appropriate for noncontroversial matters. If rulemaking were implemented for the item in Section 1.0 and this item, then the NRC’s ability to use the direct final rule process for future DC rules would not be affected. However, if rulemaking were not implemented for the item in Section 1.0 and this item, then the regulatory changes made under this item would be deferred and would occur as part of each future certified design rulemaking. Making the regulatory changes at that time may introduce issues into the rulemaking sufficient to require the use of the traditional rulemaking process, thereby delaying and adding costs to that future DC rulemaking. In addition, including this provision in future DC rulemakings would spread the cost across all future DC applicants because the DC vendor pays the costs for NRC review of the DC application. If these changes are implemented as part of a generic rulemaking, the NRC costs are shared by all NRC licensees.

4.6.2.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC resulting from an increase or decrease in the number of licensing actions requiring NRC review. If rulemaking was implemented for this item, then the NRC would incur rulemaking costs of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table H.2-8.

Table H.2-8 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

As noted above in Sections 4.3.2.1 and 4.6.2.2, rulemaking for the item addressed in Section 1.0 of this appendix would affect when the rulemaking costs for this item would be incurred because it would result in those costs occurring as part of this rulemaking rather than as part of

a future design certification rulemaking.⁷ As explained in Section 4.6.2.2, it would likely be more efficient and less burdensome to future DC applicants to implement this change as part of the larger rulemaking, separate from DC rulemakings. Therefore, in this regulatory basis the NRC assumed rulemaking on this Alternative 2 would occur as part of the larger rulemaking effort.

4.6.2.4 Additional Considerations

This alternative would have the long-term benefit of reducing regulatory uncertainty surrounding the applicability provisions of the Tier 2 change processes for licensees referencing future certified designs.

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.2.5 Summary of Benefits and Costs

While this alternative would not result in a direct cost or benefit to applicants, licensees, or the NRC, it would enhance the clarity and predictability of the new reactor licensing process by having the same applicability provisions for both Parts 50 and 52 change processes for future certified designs and those licensees referencing them. It would eliminate the uncertainty regarding the difference between the two sets of requirements. If rulemaking is implemented for the item addressed in Section 1.0 of this appendix, then Alternative 2 for this item would result in net costs to the NRC of (\$106,000) using a 7 percent NPV.

4.6.3 Alternative 3: Rulemaking Affecting Both Future and Existing Certified Designs

Under this alternative, the NRC would undertake a rulemaking to revise the applicability provisions for PS-DCD Tier 2 changes in future DCs by revising Section VIII.B.5 of the existing Part 52 DC appendices and, if rulemaking is implemented for the item addressed in Section 1.0, of this appendix, revising Section 52.63. Section VIII.B.5 in Part 52 appendices for future DCs would also contain similar language.

4.6.3.1 Impacts on Public Health, Safety, and Security

Because this alternative would involve changes to the applicability of the Tier 2 change processes for COL licensees that reference certified designs but would not involve any changes to actual technical safety requirements (e.g., safety standards in Part 50), there would be no impacts on public health, safety, and security.

4.6.3.2 Impacts on Applicants and Licensees

This alternative would not result in any change in the number of required licensing actions. However, it may require COL holders referencing the existing Part 52 certified design appendices to revise their internal procedures for processing Tier 2 changes, and thereby experience the associated cost impacts. These impacts are expected to be minor and speculative and were not estimated quantitatively.

⁷ The NRC staff did not quantitatively evaluate how various combinations of rulemaking recommendations would affect projected impacts for each individual regulatory change.

In addition, this rulemaking alternative would provide a qualitative benefit for certified designs and licensees referencing them by enhancing the clarity and predictability of the new reactor licensing process by stating certain applicability provisions in the regulations. For certified designs and licensees referencing them, including licensees referencing either an existing or a future certified design, it would eliminate the uncertainty regarding the difference between the applicability provisions in Parts 50 and 52.

4.6.3.3 Impacts on the NRC

This alternative would have the long-term benefit of reducing regulatory uncertainty surrounding the applicability provisions of the Tier 2 change processes for licensees referencing future certified designs. The NRC would incur rulemaking costs of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table H.2-9.

Table H.2-9 NRC Rulemaking Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

4.6.3.4 Additional Considerations

This alternative would have the long-term benefit of reducing regulatory uncertainty surrounding the applicability provisions of the Tier 2 change processes for licensees referencing an existing or future certified design.

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.3.5 Summary of Benefits and Costs

This alternative would result in no impacts on public health, safety, and security, the NRC, or other stakeholders.

This alternative could affect COL holders referencing the existing certified designs because it may require them to revise their internal procedures for processing Tier 2 changes.

This alternative would result in qualitative benefits associated with simplification of existing and future DC rules. Alternative 2 would result in net costs to the NRC of (\$106,000) using a 7 percent NPV.

4.7 Backfitting and Issue Finality

None of the alternatives considered in this section of Appendix H.2, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. The regulatory changes made under Alternative 2

would apply only to applicants and licensees referencing a future certified design. Alternative 3 would not affect the issue finality of existing DCs and COL holders referencing those existing certified designs because it would not amend certification information of any design (e.g., Tier 1 and Tier 2 information and TSs). Instead, Alternative 3 would only amend Section VIII.B.5. The Commission explained in the 2007 Part 52 final rule (72 FR 49352, August 28, 2007) that Paragraph 52.63(a), which provides the criteria for making changes to certified designs, applies to changes in the certification information but does not apply to changes to the certified design rule language (e.g., Section VIII).

4.8 Stakeholder Feedback

4.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, the NEI made a presentation about its suggestions for this rulemaking, and identified one item, located on page 3 of the NEI presentation, as follows:

Comment / Basis: The 50.59 process and departure process are similar in regulation but have been interpreted somewhat differently.

Recommendation: Directly use the 10 CFR 50.59 process for 10 CFR Part 52 regulatory changes.

This issue was also identified in a post-meeting NEI document that summarized NEI comments (NEI 2019-TN6265) to be included in the public meeting summary, as follows:

Comment / Basis: Section VIII currently does not provide for “Applicability” similar to 50.59(c)(4) for changes within the scope of the plant-specific DCD.

Note that operational program descriptions in the FSAR are governed by 50.59, including applicability determinations. Refer to NEI 96-07, Appendix C Section 1.2.

Recommendation: In Section VIII, consider whether to provide for “Applicability” similar to 50.59(c)(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.”

Note that all departures from the plant-specific DCD may need to be identified in Section X Departure reports, regardless of the change process used to evaluate them.

4.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies of the ACRS. No members of the ACRS provided feedback on this topic during or following the public meeting.

4.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking Affecting Future Certified Designs,” for this item. This alternative provides an opportunity to simplify NRC regulations. While Alternative 3 would also simplify regulations, it would also impose a cost on COL licensees referencing existing certified designs, without a significant offsetting benefit. Therefore, the staff prefers Alternative 2, which does result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent NPV.

The regulatory changes for this item will need to be coordinated with other change process rulemaking items being considered in Appendix H.2 of this regulatory basis. As noted in Sections 4.3.2.1, “Description of Alternative 2” and 4.6.2.2, “Impacts on Applicants and Licensees,” rulemaking for the item addressed in Section 1.0 in this appendix would influence which regulations are affected under rulemaking for this item and when they would be changed. If rulemaking is implemented, then for all designs certified after this rulemaking, the NRC might consider certifying the designs using the more expedient direct final rule process. Otherwise, the NRC would need to use the traditional rulemaking process for the first design certified after the conclusion of this rulemaking to implement the changes recommended in this section.

5.0 CHANGE PROCESS FOR ESP SSARS AND LWA SARS

The regulations of paragraph 52.39(e), “Early site permit amendment,” state that the holder of an early site permit (ESP) may not make changes to the ESP, including the site safety analysis report (SSAR), without Commission approval (i.e., license amendment). Under this regulation, an ESP holder would be required to obtain an ESP amendment to make changes having a limited safety nexus. This imposes a burden on both the ESP holder and the NRC and is not consistent with how FSAR changes with a similar safety nexus are made by holders of OLs and COLs that apply the change process in Section 50.59, or a 50.59-like process described in each DC rule, as appropriate. These processes allow a licensee to evaluate an FSAR change and, if certain criteria are met, proceed to make the change without obtaining prior NRC approval through a license amendment. To eliminate unnecessary burden for ESP holders and make the regulatory change approaches consistent, the NRC is considering establishing a 50.59-like change process for ESP SSARs. A similar approach is also being considered for holders of limited work authorizations (LWAs) issued under Section 50.10, “License required; limited work authorization,” that desire to change their safety analysis report (SAR).

5.1 Existing Regulatory Framework

The requirements for an ESP holder that desires to change its SSAR are specified in paragraph 52.39(e):

The holder of an early site permit may not make changes to the early site permit, including 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 meet the requirements of 10 CFR 50.90 and 50.92.

The approach specified under paragraph 52.39(e) differs from the graded approach for changes to OL and COL FSARs. For an OL or COL holder, some changes (e.g., changes in information meeting the applicable 10 CFR 50.59 or 50.59-like evaluation criteria) may be made without prior NRC approval.

The discussions in the 2006 proposed (71 FR 12781, March 13, 2006) and 2007 final Part 52 rules regarding changes to an ESP address options for change processes. In the 2007 final rule statement of considerations, the Commission stated:

The Commission does not believe that either subpart A of part 52 or an ESP with the contemplated approved updating procedures and criteria should contain a “change process” akin to § 50.59, allowing the ESP holder to make changes to the approved updating procedures and criteria without NRC review and approval. Any change (other than typographic and administrative corrections) should require an amendment to the ESP.

The Commission addressed the need for a process to make changes to an ESP through the addition of provisions allowing such changes through the license amendment process. The final rule also notes that:

[a change process allowing] for voluntary changes to an ESP by an ESP holder through the license amendment process ... will provide ESP holders with additional flexibility to resolve issues that were not addressed in the original ESP review and to achieve finality on new information.

The required information to appear in an ESP SSAR is similar to that for a COL FSAR but limited in scope to issues of site safety. Both have a similar organization, with the content generally aligning with applicable portions of NUREG-0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition” (SRP). The required content of an ESP SSAR is specified in paragraphs 52.17(a)(1)(i) through (xii) and aligns with corresponding items listed among the required content of a COL FSAR, which is specified in paragraph 52.79(a)(1).

The LWA regulations in Section 50.10 do not include provisions for making changes to the LWA SAR.

5.2 Regulatory Issues

Currently, no regulatory mechanism allows an ESP holder to make changes to its SSAR that have a limited nexus to site safety without obtaining prior NRC approval through a license amendment, similar to the existing process for COL and OL holders, who are able to make certain changes to information in their FSARs without a license amendment or prior NRC approval when those changes meet preestablished criteria. The COL or OL holder evaluates the prospective change against the criteria listed in either Section 50.59 or the corresponding Part 52 design certification appendix, paragraph VIII.B.5.b, as appropriate, to determine whether a license amendment is required. OL holders also use Section 50.59 to evaluate prospective changes to their FSARs to determine whether a license amendment is required. This contrasts with the current process for an ESP holder to change its ESP SSAR, which requires a license amendment for a holder-initiated change, regardless of the safety significance of the change.

The NRC has issued ESPs for six sites, and COLs have been issued for facilities at two of these sites. Of the four remaining ESPs that have 20-year terms, two of the ESPs are valid until 2027, one is valid until 2036, and one is valid until 2039. Until an ESP expires or is renewed, the ESP holder may want to make changes to its SSAR, including changes not having a substantive safety nexus. An efficient process for making changes may be desirable because requiring

license amendments for non-safety-significant changes is unnecessarily burdensome and inefficient.

The primary regulations for LWAs are in Sections 50.10, 52.27, and 52.91. However, there is no provision in the regulations that provides a process for making changes to the LWA SAR.

There are currently no LWAs, either issued or under review, associated with an ongoing COL application review. Since the LWA rule was revised in 2007, the NRC has only issued an LWA for a single site.

Past industry and NRC experience with amending ESPs and LWAs is limited to the one ESP mentioned above, for which three license amendments were requested and issued in 2012. These amendments revised the SSAR to allow the use of backfill from locations not included in the list of borrow locations specified in the SSAR and changed the classification of backfill used on the slopes of excavations.

5.3 Discussion of Alternatives

5.3.1 Alternative 1: No-Action

5.3.1.1 Description of Alternative 1

This alternative would maintain the current regulations. An ESP holder would be required to obtain prior NRC approval through a license amendment to make a change to its SSAR, regardless of whether the change had a safety nexus. For an LWA holder, there would be no process for changing the SAR, regardless of whether the change had a safety nexus, other than submitting a new LWA application in accordance with Section 50.10.

5.3.1.2 Assessment of Alternative 1

The “no-action” alternative would retain the potential unnecessary burden of cost and time to make SSAR changes that have no safety nexus. This burden would apply to holders of the currently issued ESPs, holders of any future issued ESPs, and the NRC.

5.3.2 Alternative 2: Rulemaking

5.3.2.1 Description of Alternative 2

In this alternative, the NRC would pursue rulemaking to define a graded approach for making changes to ESP and LWA SARs⁸ under which the ESP holder or LWA holder would evaluate prospective changes to SAR information using an approach similar to the 50.59-like evaluation performed by COL holders referencing a certified design for prospective changes to Tier 2 FSAR information (described in Section VIII.B.5.b of the associated Part 52 appendix) or the Section 50.59 process for COL holders not referencing a certified design and OL holders who are considering prospective changes to their FSARs. The ESP or LWA holder’s evaluation would allow changes with limited safety nexus to be completed without prior NRC approval through a license amendment. Alternative 2 would revise the current regulations for making changes to ESP SSARs in Part 52, Subpart A, and, in particular, the license amendment

⁸ In the following discussion of this regulatory basis, ESP SSARs and LWA SARs are referred to collectively as SARs.

requirement in paragraph 52.39(e). The NRC would also consider revising current regulations for LWAs in Section 50.10, which do not address making changes to an LWA SAR to include or reference a 50.59-type of evaluation. Under this alternative, changes initiated by the ESP or LWA holder that affect the content of the actual ESP or LWA, both of which are NRC-controlled documents, would require a license amendment. In addition, recordkeeping and reporting of SAR changes, similar to what is required for FSAR changes for COL and OL holders, would be required. Guidance issued at the time of rulemaking would clarify any issues or questions about the new requirement.

5.3.2.2 Assessment of Alternative 2

This alternative would allow for a reduced burden on an ESP or LWA holder when the holder desires to make a change to their SAR that has a limited safety nexus. The ESP or LWA holder would be required to evaluate the change against specified criteria for when a license amendment is required and, for any change that does not meet any of the criteria, the ESP or LWA holder could implement the change without a license amendment or prior NRC approval. This approach is consistent with the requirements for COL and OL holders to make changes to their FSARs.

This approach is not consistent with the Commission's statement in the 2007 Part 52 final rule that an ESP holder must use the amendment process to make changes to an ESP. However, since issuance of that rule, experience from processing LARs (see Section 5.2 of this appendix) has led the NRC to revisit this position.

5.4 Regulatory Scope

Under Alternative 2, the rulemaking would affect the existing requirements in paragraphs 52.39(e) and 50.10 for requesting a license amendment for any voluntary change to an ESP SSAR or LWA SAR. The regulations would contain, or reference specified evaluation criteria, similar to the Section 50.59 criteria or the 50.59-like criteria in Section VIII.B.5.b of the Part 52 DC appendices, against which an ESP or LWA holder would evaluate a prospective SAR change, and the prospective change would require a license amendment only if the change did not meet the criteria. The regulations would also include recordkeeping and reporting requirements for SAR changes similar to the recordkeeping and reporting requirements for COL FSARs in Section X of the Part 52 DC appendices or for COL or OL FSARs in paragraph 50.59(d).

5.5 NRC Guidance, Policy, and Implementation Issues

5.5.1 NRC Guidance

If the NRC conducts rulemaking, the NRC would develop new regulatory guidance to describe an acceptable approach for ESP and LWA holders to implement the SAR change processes. The regulatory guidance document would use concepts drawn from existing guidance documents and may involve NRC endorsement of an industry guidance document (e.g., Regulatory Guide 1.187), with exceptions and clarifications as needed. The regulatory guidance would describe at least one acceptable way for facilities to implement the evaluation of prospective changes to ESP and LWA SARs. The NRC would make the draft regulatory guidance available for public comment when it issues the proposed rule. The guidance would explain the criteria against which an ESP or LWA holder would evaluate a prospective change.

5.5.2 *Policy Issues*

5.5.2.1 *Current Policy Requiring License Amendments*

As noted above in Section 2, in the 2007 Part 52 final rule, the Commission stated that the regulations should not include a change process akin to Section 50.59 that would allow an ESP holder to make changes to the approved updating procedures and criteria without NRC review and approval. Therefore, implementation of the rulemaking alternative to establish such a process would require a new or revised Commission policy. The current policy would need to be changed to implement a graded approach under which ESP and LWA holders would be able to make certain changes without prior NRC approval. As noted above, the development of the current policy may not have considered the need for an ESP or LWA holder to make SSAR changes having minimal safety impacts.

5.5.3 *Implementation Issues*

None of the alternatives for this item raise implementation issues.

5.6 **Impacts**

This section analyzes the two alternatives for addressing issues associated with the ESP and LWA processes for changing SARs.

5.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would continue with the existing new reactor licensing process as described in the current regulations and guidance, including requiring license amendments for all changes to an ESP SSAR, no matter the safety significance of the change. The NRC would not pursue any changes to the current process.

5.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not involve changes in how the facility would be constructed or operated, this alternative would not result in any increase or decrease in public health, safety, and security.

5.6.1.2 *Impacts on Applicants and Licensees*

Because this alternative would not change any requirements applicable to licensees, this alternative would not result in an impact on licensees. Holders of ESPs would still be required to submit license amendments for prospective changes to their SSARs, regardless of their safety significance, and there would be no process for an LWA holder to change their SAR.

There would be no impacts on applicants.

5.6.1.3 *Impacts on the NRC*

Because this alternative would not change any requirements applicable to licensees or require the NRC to develop or implement new guidance or regulations, this alternative would not result in an impact on the NRC. The NRC would continue to perform reviews of all requests to change ESP SSARs, regardless of whether the changes had any safety significance.

5.6.1.4 Additional Considerations

Because this alternative would not change any requirements applicable to licensees, this alternative would have no impacts on State, local, or Tribal governments.

5.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

5.6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would undertake a rulemaking to provide a process for an ESP holder or LWA holder to evaluate all prospective SAR changes to determine whether a LAR and prior NRC approval is required. The rule would allow ESP and LWA holders to implement some SAR changes that do not have a safety nexus without prior NRC review and approval. The rule would require ESP and LWA holders to periodically report changes to their SARs. This alternative involves changes to how an ESP or LWA holder processes changes to its SAR. The rule would not involve changes to how the ESP or LWA holder or licensee constructs or operates the facility.

5.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would not involve safety-significant changes to how the facility would be constructed or operated, this alternative would not result in significant impacts on public health, safety, and security.

5.6.2.2 Impacts on Applicants and Licensees

This alternative would result in possible future costs and future cost savings to ESP holders and LWA holders. Eliminating the need for license amendments for ESP SSAR changes that do not have a significant nexus to safety could possibly decrease the number of ESP LARs. This would result in potential cost savings to current and future ESP holders. To date, for the six issued ESPs, three ESP amendment requests have been received and reviewed by the NRC, all for one site where two units were under construction and subject to an issued LWA. The number of future SSAR changes considered by the ESP and LWA holders is difficult to predict. However, for issued ESPs that are not under construction by an LWA, the incentive to modify the SSAR is not apparent, especially for minor changes having minimal safety significance that would be affected by a rulemaking. Therefore, the NRC believes the number of future SSAR changes having minimal safety significance that would be avoided under this rulemaking is small.

Eliminating the need for some license amendments may give ESP holders an incentive to implement more SAR changes that do not have a safety nexus than they would have pursued under current regulations, because those changes could be implemented without a license amendment. This would result in potential (voluntary) additional costs to current and future ESP holders. Current and future ESP and LWA holders may incur additional costs because they would be required to develop procedures to evaluate prospective SAR changes to determine whether a LAR is required. In addition, there would be some increased business risk in revising an ESP or an LWA without first obtaining prior NRC approval. If the NRC did not agree that the change did not require prior NRC approval, then the issue would have to be resolved in the NRC's review of the COL application referencing the ESP.

For any current and future ESP or LWA holders that make changes to their SARs, they would also incur additional costs for periodic recordkeeping and reporting to the NRC of SAR changes. These costs would be minor and were not estimated quantitatively.

There would be no impacts on applicants.

The NRC estimated the costs and benefits of Alternative 2 through 2030, beyond that time the number of expected future reactor applicants becomes too uncertain for meaningful estimation. The NRC assumed one licensee per year would need to perform procedural changes as a result of Alternative 2, and one licensee in total would need to submit a LAR. The estimated averted cost to industry from Alternative 2 is approximately \$27,000 (7 percent NPV) and \$31,000 (3 percent NPV), as shown in Table H.2-10.

Table H.2-10 Costs and Averted Costs from Regulatory Changes, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024-2030	Licensees develop procedures to evaluate SAR changes	7	42	\$134	(\$39,168)	(\$21,500)	(\$30,071)
2025	Averted license amendment request from licensee				\$73,333	\$48,865	\$61,416
Total:					\$34,166	\$27,365	\$31,344

5.6.2.3 Impacts on the NRC

Overall, this alternative would result in one-time costs to the NRC associated with rulemaking, followed by possible ongoing future costs and cost savings. By revising regulations to include a process for evaluating prospective changes to determine whether a license amendment is required for an ESP SSAR change, the revised requirements would potentially reduce the number of future LARs to revise ESP SSARs. This would result in a savings of NRC time and resources. However, the number of future avoided amendment requests is difficult to estimate but is likely to be small, as discussed above.

Because the rule would include a provision for periodic reporting or notification of SAR changes, similar to reports from certain COL holders required under Section X.B.1 of the Part 52 appendices or reports from OL holders or certain COL holders under paragraph 50.59(d), if ESP and LWA holders did proceed to make changes to their SARs, the NRC would incur an administrative burden associated with processing and reviewing the reports. This potential cost was not estimated quantitatively.

The NRC would incur costs estimated to be approximately (\$187,000) using a 7 percent NPV and (\$212,000) using a 3 percent NPV in Alternative 2, as shown in Table H.2-11.

Table H.2-11 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$35,784)	(\$38,617)
2022	Develop Proposed Rule	1	313	\$131	(\$40,969)	(\$33,443)	(\$37,492)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$31,255)	(\$36,400)
2024	Develop/Issue Final Rule	1	313	\$131	(\$40,969)	(\$29,210)	(\$35,340)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
2025	Averted NRC review of license amendment request				\$36,667	\$24,433	\$30,708
Total:					(\$234,170)	(\$187,046)	(\$212,217)

5.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.2.5 Summary of Benefits and Costs

As shown above, the rulemaking alternative results in net costs to the NRC, and net averted costs to the licensees, due to rulemaking, averted LARs, and minor procedure changes. This alternative results in net costs of approximately (\$160,000) using a 7 percent NPV and (\$181,000) using a 3 percent NPV, primarily due to rulemaking costs to the NRC.

5.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this section of Appendix H.2, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would create a new process for ESP and LWA holders to evaluate prospective SAR changes and new requirements for corresponding recordkeeping and reporting. However, existing ESP and LWA holders under Part 52 would be subject to the new rule requirements under Alternative 2 only if they voluntarily chose to make changes to their SARs. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

5.8 Stakeholder Feedback

5.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, NEI made a presentation about its suggestions for this rulemaking, which included the following suggestion that corresponds to this item:

[10 CFR] 52.39(e) requires that a license amendment be submitted to change the SSAR. The experience of the first licensees under... [10 CFR Part] 52 demonstrates a need for a change process for ESPs and LWAs. NRC should establish a...[10 CFR] 50.59-like change process for ESPs and LWAs.

This topic was discussed at the meeting. The discussion identified the license amendments that were required for making changes to the Vogtle ESP SSAR in 2010.

5.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

5.9 Staff Recommendation

The NRC staff recommends Alternative 1, “No-Action,” for this item. As discussed in Section 5.5.2 of this appendix, rulemaking for this item would require changing Commission policy on the change processes for ESPs. It would require the NRC to create a new process for changing ESP and LWA SARs. In addition, as noted in Section 5.6.2 of this appendix, implementing rulemaking for this item would incur costs to both NRC and licensees. The future benefit, if any, would likely involve only a small number of avoided licensing actions and may not outweigh the costs.

APPENDIX H.3 – DESIGN SCOPE AND STANDARDIZATION

The ensuing sections of this appendix address the U.S. Nuclear Regulatory Commission's (NRC's) recommended revisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), to add definitions of Tier 1, Tier 2, and Tier 2* consistent with principles in SECY-19-0034, "Improving Design Certification Content" (NRC 2019-TN6257), to clarify the phrase "essentially complete design," to modify restrictions on changes to a design certification or combined license referencing a design certification for reasons of standardization, to clarify the terms "site parameters" and "site characteristics," and to relocate requirements from design certification appendices to better serve licensee and NRC needs. The NRC recognizes that there is an interdependence between the recommendations in the H.2 and the H.3 sections that would affect the cost benefit analysis. The effects of this interdependence will be analyzed during the proposed rulemaking stage.

1.0 MODIFY 10 CFR PART 52 TO ADD DEFINITIONS OF TIER 1, TIER 2, AND TIER 2* AND REQUIRE INFORMATION CONSISTENT WITH PRINCIPLES IN SECY-19-0034

The terms "Tier 1," "Tier 2," and "Tier 2*," where applicable, are defined in Section II, "Definitions," of each design certification (DC) appendix to Part 52. The NRC is considering adding the definitions of those terms to Section 52.1, "Definitions," and revising the definitions to be consistent with the principles in SECY-19-0034. These definitions would apply to only new DC applications. The NRC is also considering modifying paragraphs 52.47(a), 52.79(a), 52.137(a), and 52.157 to require that an applicant's final safety analysis report (FSAR) identifies Tier 1, Tier 2, and Tier 2* information.

1.1 Existing Regulatory Framework

Tier 1 information is the part of the design-related information contained in the generic design control document (DCD) that is approved and certified in each DC appendix. Tier 2 information is the part of the design-related information contained in the generic DCD that is approved but not certified in each DC appendix. Tier 2* information is the part of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process of Section VIII.B.6 of each design certification appendix.

The terms "Tier 1," "Tier 2," and "Tier 2*" are currently defined in Section II, "Definitions," of the design certification Appendices A through E to Part 52. Appendix F includes tier information definitions for "Tier 1" and "Tier 2" but not "Tier 2*." Section 52.1 contains definitions used throughout Part 52. When the NRC issued the first DC rule, it placed the tier definitions in the DC appendix because the NRC did not know whether the tiered approach would be used for subsequent DCs. The NRC has issued six DC rules to date, and each DC rule has included the tiered information and placed the tier definitions in a DC rule appendix.

Requirements for the contents of applications for a DC, combined license (COL), standard design approval (SDA), and manufacturing license (ML) are found in Sections 52.47, 52.79, 52.137, and 52.157, respectively. These sections, however, do not require applicants to identify Tier 1, Tier 2, and Tier 2* information in their FSARs.

In each of the six approved DCs, the applicant identified Tier 1, Tier 2, and Tier 2* information, regardless of the lack of a requirement to do so. For each of those DCs, the NRC issued an SDA based on the same design and application content, and thus those SDAs identified Tier 1, Tier 2, and Tier 2* information. The NRC has issued several COLs, each of which incorporated by reference a DC rule. The NRC has not issued an ML under Part 52, nor has it issued a COL that does not reference a DC.

1.2 Regulatory Issues

Placing identical tier definitions in each appendix is repetitive; the tiers should be defined once, and this definition should be consistent across future Part 52 appendices. With regard to the content of the individual tiers, when developing DCs, applicants weigh the costs and benefits of the often-competing objectives of “standardization” and “flexibility.” Deviations (i.e., departures) from Tier 1 and Tier 2* information require NRC approval, whereas some departures from Tier 2 information do not. Tier 1 and Tier 2* information should contain fundamental functional requirements, whereas Tier 2 information should contain detailed supporting technical information for Tier 1. Experience has shown that some applications have included more information in Tier 1 than necessary; therefore, licensees have had to request NRC approval for departures which, because of their minimal safety significance, would more appropriately have been handled under a procedure such as that in 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,”(TN249), Section 50.59, “Changes, tests and experiments.” As a result, deviations from the certified design of minimal safety significance that could have been made without NRC approval actually required NRC approval and the attendant time and effort of both the applicant and the NRC.

Currently, DC applicants are not required to include tiers in their applications. DC applicants can include no tiers, more than the three tiers defined in the Part 52 appendices, or tiers with definitions that are different than those in current Part 52 appendices. This can lead to inconsistencies and increased burden for DC and COL applicants in preparing applications and the NRC in reviewing applications.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

This alternative would maintain the format and wording in the definitions and contents of applications sections of Part 52 and Section II of each DC appendix.

1.3.1.2 Assessment of Alternative 1

Licensees would continue to request NRC approval for changes that could more appropriately be made under a process like that in Section 50.59. Definitions for information tiers in DC rules would continue to be developed for each DC proceeding.

1.3.2 *Alternative 2: Rulemaking*

1.3.2.1 *Description of Alternative 2*

Alternative 2 would involve rulemaking to revise Section 52.1 to put the definitions for the terms Tier 1, Tier 2, and Tier 2* for future DC applications in Section 52.1 and to modify those definitions to be consistent with the principles described in SECY-19-0034. The Tier 1 definition would include a statement that Tier 1 information referenced by an applicant would contain the type of information that could not be changed by licensees under the provisions of paragraph 50.59(c)(2). This rulemaking would also amend the requirements for the contents of applications for a DC, COL, SDA, and ML in Sections 52.47, 52.79, 52.137, and 52.157 to require each applicant to identify Tier 1, Tier 2, and Tier 2* information in their FSAR.

1.3.2.2 *Assessment of Alternative 2*

Rulemaking would provide consistent and updated definitions of the terms Tier 1, Tier 2, and Tier 2* information. Updating these definitions consistent with the principles in SECY-19-0034 would result in greater regulatory clarity regarding the type of information that may appropriately be changed without NRC approval. This greater clarity, in turn, is expected to result in fewer license amendment requests (LARs) throughout the construction phase and likely throughout the operational phase because fewer changes would require prior NRC approval. Furthermore, requiring applicants to specifically designate information as Tier 1, Tier 2, or Tier 2* would eliminate ambiguity and clarify what departures would and would not require prior NRC approval.

1.4 **Regulatory Scope**

Rulemaking would revise Section 52.1; the requirements for contents of applications under Sections 52.47, 52.79, 52.137, and 52.157; and Section II of each future DC appendix in Part 52. The definitions of the terms Tier 1, Tier 2, and Tier 2* information would be moved from Section II of the design certification appendices to Section 52.1 and they would be amended consistent with the principles of these terms in SECY-19-0034. In addition, Sections 52.47, 52.79, 52.137, and 52.157 would be amended to require DC, COL, SDA, and ML applicants to identify Tier 1, Tier 2, and Tier 2* information in their FSARs.

1.5 **NRC Guidance, Policy, and Implementation Issues**

1.5.1 *NRC Guidance*

The recommended change is not likely to affect any NRC guidance.

1.5.2 *Policy Issues*

The recommended rulemaking should not affect any policy issues.

1.6 **Impacts**

1.6.1 Alternative 1: No-Action

1.6.1.1 Impacts on Public Health, Safety, and Security

There would be no impacts on public health, safety, or security because there would be no changes to the regulations under this alternative.

1.6.1.2 Impacts on Applicants and Licensees

Licensees would continue to request approval for changes more appropriately made under a process similar to that described in Section 50.59.

1.6.1.3 Impacts on the NRC

The NRC would continue to review and approve changes that have minimal or no impacts on safety.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking

1.6.2.1 Impacts on Public Health, Safety, and Security

Rulemaking would require applicants to provide the tiered information that in the past was voluntarily included in DC applications. However, there would be no impacts on public health, safety, or security as a result of requiring the tiered information to be provided in an application, nor would there be any impacts due to the revised definitions.

1.6.2.2 Impacts on Applicants and Licensees

Under this alternative, there would be a reduced burden on licensees regarding changes during the construction phase of a nuclear power plant licensed under Part 52. The NRC estimates that, by revising the definitions of tiered information, the DC applicant appropriately selecting which DCD information goes in each tier, and the differing change processes for each tier, a COL licensee referencing the DC would be expected to need 10 fewer license amendments over the course of construction of the plant (a reduction in burden). The license amendments avoided would result from information being downgraded from Tier 1 or Tier 2* to Tier 2, for which licensees need not request a license amendment to make changes provided there is a commensurate level of safety. The NRC estimates the COL licensee would spend approximately 200 hours to prepare and submit each amendment.

As with other cost estimates in this regulatory basis, the NRC calculated the averted costs assuming one COL applicant in 2024, another in 2027, and third in 2030. The 10 averted LARs

would affect each COL licensee within the first 3 years of receiving the license. The averted costs to industry of Alternative 2 would be approximately \$469,000 (7 percent net present value [NPV]) and \$651,000 (3 percent NPV), as shown in Table H.3-1.

Table H.3-1 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted license amendment requests	4	213	\$134	\$109,819	\$78,299	\$94,731
2025	Averted license amendment requests	3	213	\$134	\$85,945	\$57,269	\$71,978
2026	Averted license amendment requests	3	213	\$134	\$85,945	\$53,522	\$69,881
2027	Averted license amendment requests	4	213	\$134	\$109,819	\$63,916	\$86,692
2028	Averted license amendment requests	3	213	\$134	\$85,945	\$46,749	\$65,870
2029	Averted license amendment requests	3	213	\$134	\$85,945	\$43,690	\$63,951
2030	Averted license amendment requests	4	213	\$134	\$109,819	\$52,174	\$79,336
2031	Averted license amendment requests	3	213	\$134	\$85,945	\$38,161	\$60,280
2032	Averted license amendment requests	3	213	\$134	\$85,945	\$35,664	\$58,525
Total:					\$845,129	\$469,445	\$651,244

1.6.2.3 Impacts on the NRC

Under this alternative, there would be a reduced burden on the NRC regarding the review of license amendments during the construction phase of a nuclear power plant licensed under Part 52. As described in Section 1.6.2.2, "Impacts on Applicants and Licensees," the NRC estimates that each COL licensee would prepare 10 fewer license amendments over the course of construction of the plant (a reduction in burden). The NRC estimates that each license amendment would require approximately 100 NRC staff hours to review and make a regulatory decision. The NRC used a similar assumption in Section 1.6.2.2, "Impacts on Applicants and Licensees," except that the NRC review time was estimated to be half of the preparation time for each LAR.

Further, for this alternative, the NRC would perform a rulemaking to amend the subject regulations. The averted costs to the NRC of Alternative 2 would be approximately \$123,000 (7 percent NPV) and \$196,000 (3 percent NPV), as shown in Table H.3-2.

Table H.3-2 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
2024	Averted license amendment request review	4	107	\$131	\$53,564	\$38,191	\$46,205
2025	Averted license amendment request review	3	107	\$131	\$41,920	\$27,933	\$35,107
2026	Averted license amendment request review	3	107	\$131	\$41,920	\$26,106	\$34,085
2027	Averted license amendment request review	4	107	\$131	\$53,564	\$31,175	\$42,284
2028	Averted license amendment request review	3	107	\$131	\$41,920	\$22,802	\$32,128
2029	Averted license amendment request review	3	107	\$131	\$41,920	\$21,310	\$31,192
2030	Averted license amendment request review	4	107	\$131	\$53,564	\$25,448	\$38,696
2031	Averted license amendment request review	3	107	\$131	\$41,920	\$18,613	\$29,402
2032	Averted license amendment request review	3	107	\$131	\$41,920	\$17,395	\$28,545
Total:					\$276,795	\$123,233	\$196,183

1.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in averted costs to industry and the NRC of approximately \$593,000 (7 percent NPV) and \$847,000 (3 percent NPV).

1.7 **Backfitting and Issue Finality**

Neither of the alternatives presented by the NRC in this section of Appendix H.3, if implemented, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of any approval issued under Part 52. Alternative 1 would result in no change to existing requirements or NRC staff positions. Alternative 2 would apply only to new DC applications, and existing Part 52 DC appendices would remain unchanged. This alternative would not constitute backfitting or affect issue finality because such changes would not impose a new or amended requirement or staff position on a Part 50 licensee or a Part 52 approval. Also, under Alternative 2, requiring a DC, COL, SDA, or ML applicant to identify the Tier 1, 2, and 2* information in their application would not constitute backfitting or affect issue finality because this change would only apply to future applicants.

1.8 **Stakeholder Feedback**

1.8.1 *Feedback from Public Meetings for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.8.3 *Feedback from Applicants*

The subject matter addressed in this section of Appendix H.3 (Section 1.0) has been discussed with prior Part 52 applicants and licensees. At various times during the construction of Vogtle Electric Generating Plant Units 3 and 4 (VEGP 3&4) the licensee has described the burden of the change processes for Tier 1 and Tier 2* information compared to that of the Tier 2 information change process (NRC 2020-TN6494; NRC 2020-TN6495). The staff recommendation addresses, in part, the burden resulting from maintaining Tier 1 and Tier 2* information.

1.9 Staff Recommendation

The staff recommends Alternative 2, “Rulemaking,” to put the definitions of Tier 1, Tier 2, and Tier 2* information for future applications in Section 52.1, revise those definitions consistent with SECY-19-0034, and require applicants to identify the tiered information in their applications.

2.0 10 CFR 52.41(C)(1) AND (2) CLARIFICATION OF THE PHRASE “ESSENTIALLY COMPLETE DESIGN”

The NRC’s regulations in paragraphs 52.41(b)(1) and 52.47(c)(1) and (2) refer to the phrase “essentially complete design” in the context of DCs for nuclear power plants. The NRC is considering rulemaking to reflect that the term “essentially complete design” refers to a design (1) with a scope that addresses the parts of a plant, except for its site-specific elements, that can affect safe operation of the plant, and (2) that contains sufficient information to resolve all technical issues using an approach graded based on safety significance. The rulemaking would add this clarification to Section 52.1, “Definitions.”

2.1 Existing Regulatory Framework

Definitions of terms used in Part 52 are set forth in Section 52.1. Section 52.47 contains requirements for the contents of applications for standard DCs, and specifies in paragraph 52.47(a) that “[t]he 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.” Under paragraph 52.41(b)(1), any person may seek a standard DC for “*an essentially complete nuclear power plant design* [emphasis added] which is an evolutionary change from [currently operating] light-water reactor designs.” Under paragraph 52.41(b)(2), “any person may also seek a standard DC for a nuclear power plant design which differs significantly from the light water reactor designs described in 10 CFR 52.41(b)(1) or uses simplified, inherent, passive, or other innovative means to accomplish its safety functions.” Notably absent in paragraph 52.41(b)(2) is the term “essentially complete.” When Part 52 was first issued in 1989, the NRC purposely worded paragraph 52.41(b)(2) to allow certification of a less than full-scope design for certain advanced reactor designs whose balance of plant cannot significantly affect the safe operation of the plant (“Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors; Final Rule” [54 FR 15372, April 18, 1989; TN6256]).

Regulatory Guide (RG) 1.206, Revision 1 (NRC 2018-TN6192) provides guidance regarding the information to be submitted in a COL application for a nuclear power plant. Section C of RG 1.206 contains regulatory positions on standard format and content, additional technical information, applications referencing standard designs, and other miscellaneous topics.

2.2 Regulatory Issues

The term “essentially complete nuclear power plant design” is mentioned in paragraphs 52.41(b)(1) and 52.47(c)(1) and (2), but the term is not defined in those sections or in Section 52.1 with other definitions of terms used in Part 52. In paragraphs 52.47(c)(1) and (2), the regulations state that paragraph 52.47(c) applies to applicants who “provide an essentially complete nuclear power reactor design except for site-specific elements such as service water intake structure and the ultimate heat sink.” However, the context of the use of the term in paragraph 52.47(c)(1) and (2) implies that a design cannot be considered “essentially complete”

if it omits any element that cannot specifically be identified as being site-specific. That is, the term implies that the scope of the application includes all SSCs that are not considered to be site-specific. This term is also discussed in the 1989 final rule issuing 10 CFR Part 52, which describes it as including “all of a plant which can affect safe operation of the plant except its site-specific elements.”

However, such a definition of “essentially complete design” may be considered to be overly restrictive. For example, during the review of the application for the DC for the Advanced Power Reactor 1400 (APR1400), the NRC and the applicant discussed whether the design of the turbine control and overspeed protection system, as presented in the DC application without many specifics, was consistent with the definition of an “essentially complete design.” The proposed APR1400 design did not specify a turbine, thus giving any future COL applicant the flexibility to choose any turbine that fit within the envelope of the NRC’s safety evaluation. Requiring a detailed turbine control and overspeed protection system at the DC stage would have put limitations on the turbine design that future COL applicants would be able to choose. The NRC determined that the functional description of the turbine control and overspeed system that the applicant provided was sufficient to allow for the resolution of all safety concerns. The choice of a turbine design is not necessarily site-specific so an interpretation of “essentially complete design” as requiring detailed information about design features other than those that can be shown to be dependent on physical site characteristics could have caused the applicant to do design work that would more appropriately be done at the COL stage.

The NRC experienced some occurrences where the scope of the application included some of the non-site-specific SSCs, and, the level of detail in the application was at an appropriate level to resolve all safety issues without limiting future design choices. If the term “essentially complete design” were defined, it could reduce potential ambiguity in future Part 52 applications.

2.3 Discussion of Alternatives

2.3.1 Alternative 1: No-Action

2.3.1.1 Description of Alternative 1

This alternative would maintain the existing regulations’ references to an “essentially complete design” in paragraphs 52.41(b)(1) and 52.47(c)(1) and (2) without providing a definition of that term.

2.3.1.2 Assessment of Alternative 1

Leaving the regulations as they are could result in extended discussions between the NRC and applicants about the interpretation of “essentially complete design.” It could also require applicants for standard DCs to do detailed design work at the DC stage that may be more appropriate to do at the COL stage. Requiring design information at the DC stage that is more appropriately performed at the COL stage could also limit the design flexibility afforded to COL applicants.

2.3.2 *Alternative 2: Rulemaking*

2.3.2.1 *Description of Alternative 2*

The NRC would pursue rulemaking and is considering modifying Section 52.1 to state that the term “essentially complete design” refers to a design that includes (1) the design elements of a plant, other than site-specific elements, that can affect its safe operation, and (2) sufficient design information to allow the NRC to resolve all technical issues using an approach graded on safety significance.

2.3.2.2 *Assessment of Alternative 2*

Alternative 2 would clarify the term “essentially complete design,” in the regulations so that applicants would better understand the scope and level of design detail required at the DC stage to avoid future confusion. This alternative would provide a clear, meaningful definition in the regulations instead of relying on guidance to define key terminology.

2.3.3 *Alternative 3: Guidance*

2.3.3.1 *Description of Alternative 3*

The NRC would revise the guidance in RG 1.206 to define the term “essentially complete design” as one that would describe a design with a scope that addresses all aspects of a plant that can affect safe operation of the plant except its site-specific elements, and provides sufficient design information to allow the NRC to resolve all technical issues using an approach graded on safety significance.

2.3.3.2 *Assessment of Alternative 3*

By clarifying the term “essentially complete design” in RG 1.206, applicants would better understand the scope and level of design detail that is required at the DC stage to avoid future confusion.

2.4 **Regulatory Scope**

Alternative 2 would amend Section 52.1 to provide a definition of the term “essentially complete design.” Alternative 3 would revise RG 1.206 to clarify the meaning of the term “essentially complete design.”

2.5 **NRC Guidance, Policy, and Implementation Issues**

2.5.1 *NRC Guidance*

Alternatives 1 (no-action) and 2 (rulemaking) would not affect any NRC guidance. Alternative 3 focuses on revising RG 1.206 separately from the other alternatives.

2.5.2 *Policy Issues*

Alternative 2 would not affect current policy, create, a conflict between policies, or create an unresolved policy issue.

2.6 **Impacts**

2.6.1 *Alternative 1: No-Action*

2.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative requires no changes to the regulations, there would be no impacts on public health, safety, or security.

2.6.1.2 Impacts on Applicants and Licensees

Because this alternative requires no changes to the regulations, DC applicants may choose to discuss with the NRC whether certain aspects of a proposed design, in terms of both the scope of the application and the level of detail, are considered “essentially complete.”

2.6.1.3 Impacts on the NRC

Because this alternative requires no changes to the regulations, the NRC would likely continue to have to discuss with applicants whether certain aspects of a proposed design, in terms of both the scope of the application and the level of detail, are considered “essentially complete.”

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 *Alternative 2: Rulemaking*

2.6.2.1 Impacts on Public Health, Safety, and Security

Because rulemaking would not affect the design of any SSC for a nuclear power plant licensed under Part 52, it would result in no impacts on public health, safety, or security.

2.6.2.2 Impacts on Applicants and Licensees

Under Alternative 2, applicants may be less likely than under Alternative 1 to have to discuss with the NRC whether the level of detail provided in a proposed design can be considered “essentially complete.” Amending the regulation to give sufficient direction regarding the scope and level of detail required could save a DC applicant 200 hours of work between the reduced level of effort required when initially developing the application and when responding to any level of detail-related requests for additional information (RAIs). It is reasonable to estimate that a question about whether a design is “essentially complete” will arise at least once during the review of each DC.

Assuming one DC application every three years through 2030, following the issuance of the final rule, Alternative 2 would result in averted costs to applicants of approximately \$51,000 (7 percent NPV) and \$68,000 (3 percent NPV), as shown in Table H.3-3.

Table H.3-3 Licensee Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted DC Application level of effort for licensees	1	213	\$134	\$28,648	\$20,426	\$24,712
2027	Averted DC Application level of effort for licensees	1	213	\$134	\$28,648	\$16,674	\$22,615
2030	Averted DC Application level of effort for licensees	1	213	\$134	\$28,648	\$13,611	\$20,696
Total:					\$85,945	\$50,710	\$68,024

2.6.2.3 Impacts on the NRC

Under Alternative 2, as opposed to Alternative 1, the DC applicant would be less likely to discuss with the NRC whether the level of detail in a proposed design qualifies as “essentially complete.” The NRC estimates that approximately 130 hours of NRC review time per DC application could be saved. The NRC would also incur a one-time cost to amend the regulation in this rulemaking. Using the assumptions above, Alternative 2 would result in costs to the NRC of approximately (\$35,000) using a 7 percent NPV and a 3 percent NPV, as shown in Table H.3-4.

Table H.3-4 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$11,831	\$14,314
2027	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$9,657	\$13,099
2030	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$7,883	\$11,987
Total:					(\$32,157)	(\$35,474)	(\$34,525)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Costs and Benefits

There would be a cost to the NRC due to the rulemaking effort. Both the NRC and applicants could realize a benefit from establishing the definition of “essentially complete design.” The net averted costs of Alternative 2 would be approximately \$15,000 using a 7 percent NPV and \$33,000 using a 3 percent NPV.

2.6.3 Alternative 3: Guidance

2.6.3.1 Impacts on Public Health, Safety, and Security

Because updating content of application guidance in RG 1.206 would not affect the design of any SSC for a nuclear power plant licensed under Part 52, it would result in no impacts on public health, safety, or security.

2.6.3.2 Impacts on Applicants and Licensees

Under Alternative 3, applicants may have less of a need than under Alternative 1 to discuss with the NRC their questions about the level of detail provided in a proposed design so that the design is considered “essentially complete.” The impacts on applicants and licensees would be similar to those of Alternative 2. Amending the guidance to provide sufficient direction regarding the scope and level of detail required could save a DC applicant 200 hours of work between the reduced level of effort required when initially developing the application and when responding to any level of detail-related RAIs. It is reasonable to estimate that a question about whether a design is “essentially complete” will arise at least once during the review of each DC.

As with Alternative 2, Alternative 3 would result in averted costs to applicants of approximately \$51,000 (7 percent NPV) and \$68,000 (3 percent NPV), as shown in Table H.3-3.

2.6.3.3 Impacts on the NRC

Under Alternative 3, as opposed to Alternative 1, the NRC would be less likely to have to discuss with applicants whether the scope or level of detail in a proposed design qualifies as “essentially complete,” particularly when the NRC is developing and reviewing responses to RAIs. The NRC estimates that approximately 130 hours of NRC review time per DC application could be saved. The NRC would also incur a one-time cost to revise RG 1.206. However, under Alternative 3, the NRC would not incur costs related to rulemaking.

Alternative 3 would result in costs to the NRC of approximately (\$16,000) using a 7 percent NPV and (\$10,000) using a 3 percent NPV, as shown in Table H.3-5.

Table H.3-5 NRC Costs and Averted Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2024	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$11,831	\$14,314
2027	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$9,657	\$13,099
2030	Averted DC Application level of effort for NRC	1	127	\$131	\$16,593	\$7,883	\$11,987
Total:					(\$3,701)	(\$15,813)	(\$10,277)

2.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.3.5 Summary of Costs and Benefits

There would be a cost to the NRC to update guidance. Both the NRC and applicants could realize a benefit from a reduced need for interaction on the subject of “essentially complete design.” The incremental cost savings to industry and the NRC due to Alternative 3 would be the sum of the values provided in Table H.3-3 and Table H.3-5 which yields approximately \$35,000 (7 percent NPV) and \$58,000 (3 percent NPV).

2.7 Backfitting and Issue Finality

None of the alternatives would constitute backfitting or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no change in requirements or NRC staff positions. Alternative 2 would not apply to any current licensees or other entities within the scope of the Part 50 backfitting provisions and would apply to only DC applications for which issue finality provisions do not yet apply. Alternative 3 would not impose a new or amended requirement or staff position on a licensee or applicant referencing an approval. Therefore, none of the alternatives would constitute backfitting or affect issue finality.

2.8 Stakeholder Feedback

2.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, the NEI made a presentation about its suggestions for this rulemaking. Multiple comments or suggestions related to the topic of “essentially complete design” were received.

2.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The staff recommends proceeding with the rulemaking as described under Alternative 2, “Rulemaking.” By defining the term “essentially complete design” in the regulations, applicants would better understand the scope and level of design detail that is required at the DC stage and future confusion could be avoided. Revising RG 1.206 in accordance with Alternative 3 would add clarity; however, the staff believes that “essentially complete design” is a fundamental concept and that defining the term clearly in the regulations would provide for clarity. Furthermore, the fact that this issue has caused both staff and applicants to spend significant time trying to interpret the policy leads the staff to conclude that a rule change is appropriate.

3.0 10 CFR 52.63 MODIFYING RESTRICTIONS ON CHANGES TO A DC OR COL REFERENCING A DC FOR REASONS OF STANDARDIZATION

Section 52.63 contains requirements regarding issue finality for DCs. Those requirements include consideration of maintaining standardization when making changes⁹ to DCs and to COLs referencing those DCs. Construction experience has shown that the standardization consideration has become an unnecessary burden to the licensee and the NRC.

⁹ For purposes of this section of the appendix, “changes” may be amendments, exemptions, or departures. The process for each is different, and these processes are described in 10 CFR Part 52.

The NRC is considering revising paragraphs 52.63(a)(1)(vii), 52.63(a)(4)(ii), and 52.63(b)(1) to remove reasons of standardization from the criteria for making changes to a standard design either through rulemaking, plant-specific orders, or applicant or licensee exemption requests. The NRC is also considering revising paragraphs 52.93(c) and 52.171(b)(2) because there are also implications for standardization with respect to COLs and MLs.

3.1 Existing Regulatory Framework

Paragraph 52.63(a)(1) provides a list of criteria of which any one criterion must be met before the Commission modifies, rescinds, or imposes new requirements on certified information by rulemaking. Paragraph 52.63(a)(1)(vii) contains the criterion that the Commission determines that the change “contributes to increased standardization of the certification information.”

Paragraph 52.63(a)(4) restricts the Commission from issuing a plant-specific order addressing any part of the design of a specific plant referencing the DC rule if that part was approved in the DC while a DC rule was in effect under Section 52.55 or 52.61, unless several criteria apply. One of those criteria, in paragraph 52.63(a)(4)(ii), requires the Commission to weigh the special circumstances required to be present under Section 52.7 against any decrease in safety that may result from the reduction in standardization caused by the plant-specific order.

Paragraph 52.63(b)(1) permits an applicant or licensee who references a DC rule to request an exemption from one or more elements of the certification information. The NRC’s considerations for issuing such an exemption include whether the special circumstances that Section 52.7 requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption.

Paragraph 52.93(c) permits an applicant for a COL that has filed an application referencing a nuclear power reactor manufactured under an ML to include in the application a request for a departure from one or more design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The Commission may grant a request only if it determines that the departure will comply with the requirements of Section 52.7, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure.

Paragraph 52.171(b)(2) permits an applicant or licensee who references or uses a nuclear power reactor manufactured under an ML to request 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 Section 52.7, and that the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the departure. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the construction permit or COL hearing.

3.2 Regulatory Issues

The NRC’s experience with LARs involves the submittal of exemption requests during construction of the VEGP 3&4 (which reference the Advanced Passive 1000 [AP1000] DC). Lessons learned from new reactor licensing activities indicate that the need for the submittal and a review of an evaluation of how standardization is maintained does not result in significant insights that support the implementation of the policy; rather, experience shows that the requirement for maintaining standardization as a criterion for allowing changes is often

burdensome to a licensee without significant benefit. Additionally, experience has shown that it is challenging to evaluate whether any one particular change proposed in a LAR will decrease safety solely as a result of a reduction in standardization. The NRC recognizes that standardization is a goal of Part 52, and any changes made to those requirements should strive to support maintaining that goal when there is an appropriate safety benefit to doing so.

3.3 Discussion of Alternatives

3.3.1 Alternative 1: No-Action

3.3.1.1 Description of Alternative 1

This alternative would preserve the current requirements in Sections 52.63, 52.93, and 52.171 with respect to maintaining standardization as one of the restrictions to allowing changes to an approved design for an ML or certified design.

3.3.1.2 Assessment of Alternative 1

While the goal of increased standardization in new reactor designs remains an important NRC policy, based on lessons learned from new reactor licensing activities, the NRC has concluded that the need for the submittal of and a review of an evaluation of how standardization is maintained as a criterion for the approval of licensing actions for new reactors does not result in any significant insights or data for the evaluation of those actions that support the implementation of the policy. The NRC considers the requirement for maintaining standardization to be a restriction when changes are deemed necessary. Allowing changes to an approved design for an ML or certified design could potentially be burdensome to a licensee referencing that design without having a corresponding benefit to the NRC that would justify that burden. Similarly, the requirement is burdensome to the NRC because when an applicant makes an argument regarding effects on standardization, the NRC must provide a written evaluation of that argument. The time and effort spent preparing and evaluating such arguments are often not commensurate with the intended benefits, such as maintenance of, or improvement in, the degree of standardization.

3.3.2 Alternative 2: Rulemaking

3.3.2.1 Description of Alternative 2

In this alternative, the NRC would pursue rulemaking to revise paragraphs 52.63(a)(1)(vii), 52.63(a)(4)(ii), 52.63(b)(1), 52.93(c), and 52.171(b)(2) to remove consideration of standardization from the criteria for making changes in the design. In particular, paragraph 52.63(a)(1)(vii) would be removed in its entirety, the second sentence in paragraph 52.63(a)(4)(ii) would be removed, and the third sentence in paragraph 52.63(b)(1) would be removed. Similarly, the NRC would remove standardization as a criterion from paragraphs 52.93(c) and 52.171(b)(2).

3.3.2.2 Assessment of Alternative 2

The NRC has observed that the nature of the changes in the vast majority of the LARs have no significant impact on design standardization for a fleet of power reactors. Alternative 2 could eliminate unnecessary burden on applicants and licensees seeking exemptions from elements of an approved design for an ML or certified design and on the NRC's considerations for

approving the change to the design. In particular, applicants and licensees would no longer need to justify requested changes to the design based on the changes' effects on standardization.

3.4 Regulatory Scope

The regulations under consideration for this item are paragraphs 52.63(a)(1)(vii), (a)(4)(ii), and (b)(1); 52.93(c); and 52.171(b)(2).

3.5 NRC Guidance, Policy, and Implementation Issues

3.5.1 NRC Guidance

Neither alternative is likely to affect any NRC guidance. Under Alternative 2, the change the regulation should be self-contained, and required changes to RG 1.206, Revision 1 are not likely.

3.5.2 Policy Issues

Alternative 2 would not affect the Commission's policy of standardization under Part 52. Removing considerations of standardization from the criteria for making a change to a DC would not detract from this policy. Maintaining consideration of standardization during the change process can unduly hinder a COL holder from making changes to the design with no corresponding safety benefit that would justify that burden.

3.6 Impacts

3.6.1 Alternative 1: No-Action

3.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative does not propose to change any requirements or guidance, there would be no impacts on public health, safety, or security.

3.6.1.2 Impacts on Applicants and Licensees

Because this alternative does not propose to change any requirements or guidance, the NRC would not modify what types of changes might be precluded because of their adverse impact on standardization, and the burden on applicants or licensees to justify changes would remain. However, because the regulations are not being changed, there would be no impacts on applicants and licensees.

3.6.1.3 Impacts on the NRC

Because this alternative does not propose to change any requirements or guidance, there would be no impacts on the NRC.

3.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

3.6.2 Alternative 2: Rulemaking

3.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, the rulemaking would result in no substantive change to the NRC’s regulations regarding a licensee’s ability to request exemptions from a certified design or for a DC applicant to propose generic changes to a certified design. As a result, there would be no impacts on public health, safety, or security.

3.6.2.2 Impacts on Applicants and Licensees

Under this alternative, there would be a reduced burden on licensees justifying changes in an approved design for an ML or certified design. In particular, applicants and licensees would not need to include a reason related to the effects on standardization in their evaluation of the acceptability of proposed changes. The burden reduction would result from not having to consider and justify any potential reduction in standardization when compared to the safety benefit of the proposed change. The NRC estimates that a licensee would save four hours of work on each license amendment or exemption application. A similar benefit would accrue for applicants requesting exemptions. There is currently one 2-unit plant under construction, and each unit annually (on average) requests 10 exemptions that currently require this standardization consideration. As a result, this alternative would save applicants and licensees approximately \$10,000 annually.

Under this alternative, there would be a reduced burden on anyone requesting to modify, rescind, or impose new requirements on DC information. There would no longer be a need to justify exemption requests from certified information on the basis of standardization. DC amendment requests occur rarely, in part, because of the level of effort and the cost and time to develop the amendment request, for the NRC to review the request and develop a safety evaluation, and for the NRC to complete the rulemaking proceeding to codify the DC amendment. The NRC has received only one such request to amend a certified design since the issuance of Part 52 and over the course of certifying six DCs. The NRC does not expect to receive any DC amendment requests through 2030. As a result, the NRC estimates no burden reduction for a DC applicant requesting to amend the certified design. Similarly, because the NRC has not issued an ML to date, the NRC estimates no burden reduction to industry for ML-related changes.

Alternative 2 would result in averted costs to licensees and applicants of approximately \$41,000 (7 percent NPV) and \$58,000 (3 percent NPV), as shown in Table H.3-6.

Table H.3-6 Industry Averted Costs, Alternative 2

Year	Activity	Years	Number of Exemptions	Hours	Weighted Hourly rate	Cost		
						Undiscounted	7% NPV	3% NPV
2024-2030	Reduced design change request burden on licensees	7	10	8	\$134	\$75,202	\$41,280	\$57,737
Total:						\$75,202	\$41,280	\$57,737

3.6.2.3 Impacts on the NRC

This alternative would reduce the burden on the NRC as a result of no longer having to consider standardization when developing a safety evaluation for an exemption request for a COL that references a DC. The NRC estimates that this alternative would reduce the NRC's level of effort by 2 hours per exemption request. There is currently one 2-unit plant under construction, and each plant annually (on average) requests 10 exemptions that currently require this standardization consideration. As a result, this alternative would save the NRC approximately \$5,000 annually. This averted cost would be passed on to the licensee.

Under this alternative, there would be no change in burden on the NRC reviewing amendments to a DC that would no longer have to consider increased standardization as a possible reason for amending the design. As described above, the NRC does not expect to receive any DC amendment requests in the near future. As a result, the NRC estimates no burden reduction to the NRC for a DC applicant requesting to amend the certified design. Similarly, because the NRC has not issued an ML under Part 52, the NRC estimates no burden reduction to the NRC for ML-related changes.

The NRC would be affected by this alternative because it would incur the cost of performing the rulemaking to amend its regulations under paragraph 52.63(a)(1)(vii) and make conforming changes to Sections 52.63, 52.93, and 52.171.

Alternative 2 would result in costs to the NRC of approximately (\$45,000) using a 7 percent NPV and (\$46,000) using a 3 percent NPV, as shown in Table H.3-7.

Table H.3-7 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Years	Number of Actions	Hours	Weighted Hourly rate	Cost		
						Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule		1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule		1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule		1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule		1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024-2030	Reduced design change review burden on NRC	7	10	4	\$131	\$36,680	\$20,135	\$28,161
Total:						(\$45,257)	(\$44,711)	(\$45,763)

3.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 Summary of Costs and Benefits

Licensees and the NRC would see a reduction in exemption requests as a result of Alternative 2, and the NRC would incur rulemaking costs. The net costs of Alternative 2 using a 7 percent NPV would be minor, approximately (\$3,000), and the averted costs would be approximately \$12,000 using a 3 percent NPV, making this alternative essentially breakeven.

3.7 Backfitting and Issue Finality

Neither alternative described in this section of Appendix H would constitute backfitting as defined in Section 50.109 or affect the issue finality of an approved design for an ML or certified design issued under Part 52. Alternative 1 would result in no change existing regulations,

requirements, or NRC staff positions. Alternative 2 would eliminate standardization considerations as a basis for making changes to a plant design within the approved or certified design on a plant-specific basis. Alternative 2 would not significantly change a DC applicant's ability to voluntarily request an amendment to a DC because there are other means for justifying the change under paragraph 52.63(a)(1).

3.8 Stakeholder Feedback

3.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

3.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The NRC recommends Alternative 2, "Rulemaking," which would amend the NRC's regulations to remove considerations of standardization in justifying a change to an approved design for an ML or certified design. These changes would improve the efficiency of the preparation and review of exemption requests.

4.0 REVISE SECTION IV.A.2.D OF APPENDICES A THROUGH D TO 10 CFR PART 52 TO CLARIFY THE TERMS "SITE PARAMETERS" AND "SITE CHARACTERISTICS"

Section 52.79 establishes the requirements for the contents of applications for COL. Paragraph 52.79(d) provides additional requirements specific to COL applicants that reference a standard DC. Section IV.A.2 of each DC rule appendix in Part 52 provides additional requirements for and restrictions on COL applicants who reference that specific DC appendix. The NRC is considering revising Section IV.A.2(d) of Appendices A through D of Part 52 to clarify that "site characteristics" must be bounded by "site parameters," and that interface requirements (i.e., the points where the COL design meets with the certified design) must be met.

4.1 Existing Regulatory Framework

Paragraph 52.79(d) provides specific requirements for COL applicants that reference a DC rule. Among these is the requirement in paragraph 52.79(d)(1) that the COL application provides "information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the design certification." Paragraph 52.79(d)(2) requires that the interface requirements established for the DC under Section 52.47 have been met.

Sections IV.A.2(d) of DC Appendices A through D of Part 52 require that COL applications include "information demonstrating compliance with the site parameters and interface requirements." Section IV.A.2(d) of DC Appendix E of Part 52 clarified this requirement when

that rule was issued in Appendix E (79 FR 61943, October 15, 2014), and similarly when Appendix F was issued (84 FR 23439, May 22, 2019; TN6255). Sections IV.A.2(d) of Part 52, Appendix E and F, states that applications include “information demonstrating that the site characteristics fall within the site parameters and that the interface requirements have been met.”

Section 52.1 defines the terms “site characteristics” and “site parameters.” In 10 CFR Part 51, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions” (TN250), paragraph 51.50(c)(2) provides requirements for the environmental report for a COL application that references a DC. If the COL environmental report references the environmental assessment prepared by the NRC for the referenced DC rule, then the COL environmental report must include “information to demonstrate that the site characteristics for the COL site fall within the site parameters in the design certification environmental assessment.” Similar wording is provided in paragraph 50.51(c)(3) for a COL application referencing an ML.

4.2 Regulatory Issues

Paragraph 51.50(c)(2) requires a COL applicant to include in its environmental report “information to demonstrate that the site characteristics for the combined license site fall within the site parameters in the design certification environmental assessment.” In Section IV.A.2(d) of Appendices A through D of Part 52, a COL applicant referencing the DC is required to include in its application “information demonstrating compliance with the site parameters and interface requirements.” During the issuance of Appendix E, the NRC recognized that the requirement, as written in Appendices A through D, described the use of site parameters and site characteristics slightly differently than in paragraph 51.50(c)(2). As a result, the NRC wrote Section IV.A.2(d) to be consistent with the language in paragraphs 51.50(c)(2) and 52.79(d) when it issued Appendices E and F. However, this conforming change was not made to Appendices A through D. Clarifying the regulatory language will ensure consistency across DC appendices for future applicants who might reference the affected designs.

4.3 Discussion of Alternatives

4.3.1 *Alternative 1: No-Action*

4.3.1.1 *Description of Alternative 1*

This alternative would make no changes to the wording of Section IV.A.2(d) each DC appendix.

4.3.1.2 *Assessment of Alternative 1*

While the existing difference in rule language among Part 52 appendices is not consistent and could be confusing to future DC applicants or COL applicants or licensees referencing these appendices, the NRC anticipates that there would be no impacts on any applicant or licensee.

4.3.2 *Alternative 2: Rulemaking*

4.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to revise Section IV.A.2(d) of Appendices A through D to Part 52 to conform those requirements with the Section IV.A.2(d) of

Part 52 Appendices E and F. This change would make the requirements in this section of these appendices consistent with other DC rule appendices and with the language in paragraph 51.50(c)(2).

4.3.2.2 Assessment of Alternative 2

This alternative would result in consistency among appendices and clarify the regulatory language to ensure consistency across DC appendices for future applicants who might reference the affected designs.

4.4 Regulatory Scope

The recommended rulemaking would revise Section IV.A.2(d) of Appendices A through D to Part 52. The regulations in Section IV.A.2(d) of DC Appendices A through D to Part 52 require that applicants referencing the specific certified design include, as a part of their application, information demonstrating compliance with the site parameters and interface requirements.

4.5 NRC Guidance, Policy, and Implementation Issues

4.5.1 NRC Guidance

The recommended change, Alternative 2, would not affect any NRC guidance nor would it necessitate developing any new guidance.

4.5.2 Policy Issues

Because the recommended rulemaking only clarifies the information required in a COL application referencing DCs in Appendices A through D to Part 52 consistent with other DCs, it would not affect a current policy, create a conflict between policies, or create an unresolved policy issue.

4.6 Impacts

4.6.1 Alternative 1: No-Action

4.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change any requirements or guidance, there would be no impacts on public health, safety, or security.

4.6.1.2 Impacts on Applicants and Licensees

Because this alternative would not change any requirements or guidance, there would be no impacts on applicants or licensees.

4.6.1.3 Impacts on the NRC

Because this alternative would not change any requirements or guidance, there would be no impacts on the NRC.

4.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

4.6.2 Alternative 2: Rulemaking

4.6.2.1 Impacts on Public Health, Safety, and Security

Because the recommended rulemaking under this alternative only clarifies the information required in a COL application referencing DCs in Appendices A through D to Part 52 consistent with other DCs, there would be no impacts on public health, safety, or security.

4.6.2.2 Impacts on Applicants and Licensees

In this alternative, there would be a more precise and consistent description of the relationship between “site characteristics” and “site parameters.” This alternative would clarify the purpose of the information, specifically that interface requirements shall be met, rather than stating that information demonstrating compliance with interface requirements shall be provided. However, it is difficult to quantify such a benefit, because a prospective applicant could refer to other relevant regulations or guidance in RG 1.206 to understand the requirement.

4.6.2.3 Impacts on the NRC

The NRC would bear the cost associated with the rulemaking effort. The NRC estimates that the rulemaking would cost approximately (\$65,000) using a 7 percent NPV and (\$74,000) using a 3 percent NPV, as shown in Table H.3-8.

Table H.3-8 NRC Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
Total:					(\$81,937)	(\$64,846)	(\$73,925)

4.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.2.5 Summary of Costs and Benefits

The net costs of Alternative 2 would be due to rulemaking, approximately (\$65,000) using a 7 percent NPV.

4.7 Backfitting and Issue Finality

Neither alternative would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no change to existing regulations, other requirements, or NRC staff positions. Alternative 2 would clarify the existing requirements consistent with other relevant requirements, which results in no substantive change to existing regulations. The Commission explained in the 2007 Part 52 final rule that paragraph 52.63(a), which provides the criteria for making changes to DCs, applies to changes to the “certification information” (i.e., the information in the generic DCD incorporated by reference in a DC appendix in Part 52) but does not apply to changes to the DC rule language (e.g., Section IV). Therefore, Alternative 2 would not constitute backfitting or affect issue finality.

4.8 Stakeholder Feedback

4.8.1 Feedback from Public Meetings for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no suggestions related to this matter.

4.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

4.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking” to amend the regulations in Appendices A through D of Part 52 to conform Section IV.A.2(d) to the language in that section of Appendix E of Part 52. This alternative would result in rulemaking costs to the NRC of (\$65,000). However, this alternative may be justified because it would improve the clarity and consistency of the language in the appendices. The NRC notes that, in Appendix H.3, Section 5.0, of this regulatory basis, “10 CFR 52.79(d) & DC Appendices Section IV Relocation of Requirements From DC Appendices Section IV To 52.79(d),” the NRC is considering relocating Section IV.A.2.d and other provisions of each DC appendix to paragraph 52.79(d).

5.0 10 CFR 52.79(D) & DC APPENDICES SECTION IV RELOCATION OF REQUIREMENTS FROM DC APPENDICES SECTION IV TO 52.79(D)

Paragraph 52.79(d) provides the requirements for the contents of applications for COLs that reference a standard DC. Section IV for each DC appendix to Part 52 provides additional requirements for and restrictions on COL applicants who incorporate by reference that specific DC appendix. The requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of each DC appendix are virtually identical. For clarity and consistency for current and future COL applicants, the NRC is considering relocating to paragraph 52.79(d) the generic DCD information currently described in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of each DC appendix.

5.1 Existing Regulatory Framework

Paragraph 52.79(d) provides specific requirements for COL applicants that reference a DC. Such applicants are required to provide information sufficient to demonstrate that the site characteristics fall within the site parameters specified in the design certification. They are further required to demonstrate that interface requirements established for the design have been met and that all applicable requirements and restrictions set forth in the referenced design are satisfied. They are also required to demonstrate, in the FSAR, that all requirements and restrictions set forth in the referenced DC will be satisfied at the time of issuance of the license.

Section IV of each DC appendix contains additional requirements for COL applicants who reference a DC rule. Section IV requires such an applicant to include, as a part of its application, a plant-specific (PS)-DCD, a report of departures from the standard design, plant-specific technical specifications, information demonstrating compliance with site parameters, information that addresses COL action items, safeguards information, and vendor qualification.

Regulatory Guide 1.206 provides guidance on COLs for nuclear power plants. Part III of RG 1.206 provides guidance on applications referencing certified designs and or ESPs. NUREG-0800 provides guidance to the NRC for performing safety reviews of construction permit and OL applications under Part 50 and reviews of ESP, DC, COL, SDA, and ML applications under Part 52.

5.2 Regulatory Issues

When the first DC rules were issued, it was not clear whether the requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of the DC appendices should be applicable to all DCs. Therefore, the NRC included them within each individual DC rule. The NRC has now issued six DC rules and each rule includes the same requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f. Continuing to issue DC rules with these same requirements would be an inefficient and unnecessarily repetitive method of regulating.

5.3 Discussion of Alternatives

5.3.1 Alternative 1: No-Action

5.3.1.1 Description of Alternative 1

This alternative would retain the existing requirements in paragraph 52.79(d) and Section IV of each Part 52 DC appendix.

5.3.1.2 Assessment of Alternative 1

Because this alternative does not add or remove requirements, there would be no impacts on an applicant or licensee. Future COL applicants interested in referencing a DC rule would need to look in the specific DC appendix to understand that there are additional requirements beyond Section 52.79 that would apply to the COL application.

5.3.2 *Alternative 2: Rulemaking*

5.3.2.1 *Description of Alternative 2*

The NRC would pursue rulemaking to relocate the requirements in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of each Part 52 DC appendix to paragraph 52.79(d).

5.3.2.2 *Assessment of Alternative 2*

This alternative would clarify the requirements for an application for a COL by consolidating all application content requirements into Section 52.79. This rule change would not substantively change any requirements for a COL referencing a DC rule.

5.4 **Regulatory Scope**

The recommended rulemaking would revise Sections IV.A.1 and IV.A.2.a through IV.A.2.f of each DC appendix to Part 52 and move those COL application requirements to paragraph 52.79(d).

5.5 **NRC Guidance, Policy, and Implementation Issues**

5.5.1 *NRC Guidance*

The rule change would likely require revisions to the guidance contained in RG 1.206 and NUREG-0800. Any descriptions of the contents of paragraph 52.79(d) in RG 1.206 and NUREG-0800 would have to be reviewed to ensure that they accurately reflect the contents of the amended regulations.

5.5.2 *Policy Issues*

Because the rulemaking would not add, remove, or substantively change any current requirements, it would not affect a current policy, create a conflict between policies, or create an unresolved policy issue.

5.6 **Impacts**

5.6.1 *Alternative 1: No-Action*

5.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not amend or add any requirements, there would be no impacts on public health, safety, or security.

5.6.1.2 *Impacts on Applicants and Licensees*

Because this alternative would not amend or add any requirements, there would be no impacts on applicants or licensees.

5.6.1.3 Impacts on the NRC

Because this alternative would not amend or add any requirements or guidance documents, there would be no impacts on the NRC.

5.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

5.6.2 Alternative 2: Rulemaking

5.6.2.1 Impacts on Public Health, Safety, and Security

This alternative would not substantively change any current requirements. As a result, there would be no impacts on public health, safety, or security.

5.6.2.2 Impacts on Applicants and Licensees

This alternative would not substantively change any current requirements for applicants and licensees. This change, however, would eliminate an inefficient and unnecessarily repetitive method of regulating and the NRC estimates that this benefit would have minimal cost impact. As a result, the NRC has not quantified the impacts on applicants or licensees.

5.6.2.3 Impacts on the NRC

Under this alternative, the NRC would bear the cost of the rulemaking and for making conforming changes to the applicable guidance to change the regulatory citations for the relocated requirements. Alternative 2 would result in costs to the NRC of approximately (\$147,000) using a 7 percent NPV and (\$169,000) using a 3 percent NPV, as shown in Table H.3-9.

Table H.3-9 NRC Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$53,481)	(\$43,656)	(\$48,942)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$53,481)	(\$38,131)	(\$46,133)
Total:					(\$188,899)	(\$146,633)	(\$169,000)

5.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.2.5 Summary of Costs and Benefits

There would be no incremental changes in costs or benefits to applicants or licensees. The cost of rulemaking to the NRC under this alternative would be approximately (\$147,000) using a 7 percent NPV.

5.7 Backfitting and Issue Finality

Neither of the alternatives described in this section of Appendix H would constitute backfitting as defined in Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would result in no change to existing regulations, other requirements, or NRC staff positions. Alternative 2 would result in no new regulations; rather, it would result in a relocation of existing requirements. It would not affect the issue finality of existing DCs and COL holders referencing the existing certified designs because it would not amend certification information of any design (e.g., Tier 1 and Tier 2 information and technical specifications). Instead, this alternative would only amend Section IV.A.1 and IV.A.2.a through IV.A.2.f in each of the Part 52 DC appendices. The Commission explained in the 2007 Part 52 final rule that paragraph 52.63(a), which provides the criteria for making changes to DCs, applies to changes to the certification information but does not apply to changes to the DC rule language (e.g., Section IV). Therefore, Alternative 2 would not constitute backfitting or affect issue finality.

5.8 Stakeholder Feedback

5.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no suggestions related to this matter.

5.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

5.9 Staff Recommendation

The NRC staff recommends Alternative 2, "Rulemaking," relocating to 10 CFR 52.79(d) the generic DCD information currently described in Sections IV.A.1 and IV.A.2.a through IV.A.2.f of each DC appendix in Part 52. This alternative results in rulemaking costs to the NRC of approximately (\$147,000) using a 7 percent NPV. By consolidating the requirements into Section 52.79, Alternative 2 would improve the efficiency, clarity and consistency of the regulations for current and future COL applicants.

6.0 DESIGN CERTIFICATION RULE SECTION IX ITAAC

Section IX, "Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)," of each of the DC Appendices A through D of Part 52 contains requirements regarding inspections, tests, analysis, and acceptance criteria (ITAAC) for COL applicants that reference the appendix. In the 2007 Part 52 rulemaking, the NRC amended Sections 52.99, "Inspection during construction; ITAAC schedules and notifications; NRC notices," and 52.103, "Operation under a combined license,"

to require the same information as is required in Section IX of Appendices A through D of Part 52. The NRC is considering removing Section IX of Appendices A through D of Part 52 because it is no longer necessary and does not conform to more recently issued DC appendices.

6.1 Existing Regulatory Framework

Section IX in Appendices A through D of Part 52 provides the same requirements with respect to successful ITAAC completion and NRC verification prior to loading fuel for COL applicants that reference that appendix. Together, paragraphs 52.99(b), 52.99(c), 52.99(d)(1), 52.99(e)(2), 52.103(g), and 52.103(h) contain the same substantive requirements as Section IX.

6.2 Regulatory Issues

In the final rule for the Economic Simplified Boiling-Water Reactor (ESBWR) DC (79 FR 61943, October 15, 2014), the NRC found that Section IX of that draft DC (i.e., Part 52, Appendix E) would be redundant to Sections 52.99 and 52.103 and did not include any substantive requirements in Section IX of that appendix. In that same rulemaking, the NRC stated its intent to remove Section IX from Appendices A through D of Part 52 in future amendments to the regulations, separate from the ESBWR rulemaking.

6.3 Discussion of Alternatives

6.3.1 Alternative 1: No-Action

6.3.1.1 Description of Alternative 1

This alternative would not amend the requirements in Section IX in Appendices A through D of Part 52.

6.3.1.2 Assessment of Alternative 1

This alternative would leave in place requirements in Appendices A through D of Part 52 that are redundant to other Part 52 regulations, which is inconsistent with regulatory clarity objectives under the NRC's Principles of Good Regulation (NRC 2014-TN6227). This alternative would also decline an opportunity to fulfill a Commission direction made in the 2014 ESBWR rulemaking to remove the redundancy.

6.3.2 Alternative 2: Rulemaking

6.3.2.1 Description of Alternative 2

The NRC would amend Section IX of Appendices A through D of Part 52 to remove all of its paragraphs and hold the section in reserve.

6.3.2.2 Assessment of Alternative 2

Because the requirements that would be removed from Appendices A through D of Part 52 are redundant to other requirements in Part 52, the amendment would not add, change, or remove any substantive requirements for any applicant or licensee referencing the designs in these

appendices. In addition, in the context of Section IX, Appendices A through D of Part 52 would be consistent with Appendices E and F of Part 52.

6.4 Regulatory Scope

The regulations applicable to Alternative 2 include Section IX in Appendices A through D of paragraphs 52.99(b), 52.99(c), 52.99(d)(1), 52.99(e)(2), 52.103(g), and 52.103(h). These regulations describe the requirements for COL licensees regarding successful ITAAC completion and NRC verification prior to loading fuel.

6.5 NRC Guidance, Policy, and Implementation Issues

6.5.1 NRC Guidance

Alternative 2 would not affect any regulatory guidance.

6.5.2 Policy Issues

Alternative 2 would not likely affect a current policy, create a conflict between policies, or create an unresolved policy issue.

6.6 Impacts

6.6.1 Alternative 1: No-Action

6.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would take no action and thus not amend the requirements in Section IX in Part 52 Appendices A through D, there would be no impacts on public health, safety, or security.

6.6.1.2 Impacts on Applicants and Licensees

Because this alternative would take no action and thus not remove the redundant requirements in Section IX in Part 52 Appendices A through D, this alternative would be contrary to regulatory clarity under the NRC's Principles of Good Regulation. In addition, this redundancy of requirements could create confusion for prospective applicants and licensees when they are developing an application.

6.6.1.3 Impacts on the NRC

This alternative would result in no impacts on the NRC.

6.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

6.6.2 Alternative 2: Rulemaking

6.6.2.1 Impacts on Public Health, Safety, and Security

This alternative would recommend that the NRC amend its regulations to remove redundant regulations in Part 52 Appendices A through D. The rulemaking would result in no substantive changes to any requirements. As a result, there would be no impacts on public health, safety, or security.

6.6.2.2 Impacts on Applicants and Licensees

This alternative would eliminate duplicate requirements from generally applicable sections in Part 52 in Appendices A through D, providing clear and efficient regulation and eliminating any potential ambiguity about applicability. Because this alternative would remove the redundant requirements in Section IX in Part 52 Appendices A through D, this alternative would support regulatory clarity under the NRC's Principles of Good Regulation.

6.6.2.3 Impacts on the NRC

This alternative would require the NRC to amend the applicable regulations through rulemaking, at cost of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table H.3-10.

Table H.3-10 NRC Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

6.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.6.2.5 Summary of Costs and Benefits

There would be no costs to applicants or licensees, and no quantitative benefits associated with this item, but in the 2014 ESBWR rulemaking, the NRC stated its intent to remove Section IX from Appendices A through D of Part 52 in future amendments to the regulations, and this change would be consistent with that intention. The cost of rulemaking is estimated to be (\$32,000) using a 7 percent NPV.

6.7 Backfitting and Issue Finality

Neither alternative would constitute backfitting or affect issue finality of an approval issued under Part 52. Alternative 1 would result in no change to existing regulations, requirements, or NRC staff positions. Alternative 2 would eliminate redundant regulatory requirements and impose no new requirements. It would not affect the issue finality of existing DCs and COL holders referencing the existing certified designs because it would not amend certification information of any design (e.g., Tier 1 and Tier 2 information and technical specifications).

Instead, this alternative would only remove Section IX in Appendices A through D of Part 52. The Commission explained in the 2007 Part 52 final rule that paragraph 52.63(a), which provides the criteria for making changes to DCs, applies to changes to the certification information but does not apply to changes to the DC rule language (e.g., Section IX). Therefore, Alternative 2 would not constitute backfitting or affect issue finality.

6.8 Stakeholder Feedback

6.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

6.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

6.8.3 Feedback from Applicants

The NRC has received no feedback from applicants about this topic.

6.9 Staff Recommendation

The NRC staff recommends Alternative 2, "Rulemaking," which would remove the redundant requirements from Section IX in the DC rules in Part 52, Appendices A through D and hold each of those sections in reserve. The requirements are already included in Sections 52.99 and 52.103. This alternative results in rulemaking costs of approximately (\$32,000) to the NRC. This change may be justified because the alternative would provide clarity and consistency among the DC appendices and associated requirements in Part 52 at relatively low cost.

APPENDIX H.4 – STANDARD DESIGN APPROVAL

This appendix addresses the U.S. Nuclear Regulatory Commission's (NRC's) consideration of amending its regulations to allow more than one standard design approval (SDA) to be referenced in design certifications (DCs), manufacturing licenses (MLs), and applications for construction permits (CPs) or combined licenses (COLs). An applicant for a CP, COL, or ML may reference an SDA in its application. However, the NRC's regulations do not specify whether more than one SDA may be referenced in that application. To enhance clarity and reduce uncertainty for both applicants and the NRC, the NRC is considering an amendment to the NRC's regulations to allow more than one SDA to be referenced in these applications.

1.0 EXISTING REGULATORY FRAMEWORK

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), Section 52.135, "Filing of applications," allows an applicant to submit for NRC review a proposed standard design for a nuclear power reactor described in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249), Section 50.22, "Class 103 licenses; for commercial and industrial facilities." The application submittal for an SDA may consist of either the final design for the entire facility or the final design of major portions thereof. Paragraphs 52.73(a), 52.133(a), and 52.153(b) apply to SDAs and their relationship to CP, COL, and ML applications. Specifically, paragraph 52.73(a) states that an application for a COL may, but need not, reference an SDA or ML issued under Part 52. Paragraph 52.133(a) states that an applicant for a CP or COL may reference an SDA, and paragraph 52.153(b) states that an ML applicant may reference an SDA in its application. None of these regulations, however, specify that more than one SDA may be referenced in those applications.

2.0 REGULATORY ISSUES

Some reactor designers have informed the NRC that they are considering submitting applications for SDAs and major portions of the design. The NRC's regulations do not specify whether only one or more than one SDA may be referenced in CP, COL, and ML applications, although it is implicit that more than one SDA could cover the final design of major portions of an entire facility. If more than one SDA exists for a particular design, and the scope of each of those SDAs covers only a major portion of the design as permitted under paragraph 52.135(a), then a CP, COL, or ML applicant may want to reference more than one SDA. The lack of clarity in the regulations on this matter could result in unnecessary expenditures of time and resources by both the NRC and applicants while trying to ascertain whether a CP, COL, and ML applicant can reference more than one SDA.

3.0 DISCUSSION OF ALTERNATIVES

3.1 Alternative 1: No-Action

3.1.1 *Description of Alternative 1*

This alternative would maintain the current regulations.

3.1.2 *Assessment of Alternative 1*

The “no-action” alternative would maintain the status quo as to whether more than one SDA may be referenced in CP, COL, and ML applications. This continuing lack of clarity could cause a burden on future NRC staff and applicants, because time and resources would continue to be used to determine whether the regulations allow the flexibility of referencing more than one SDA in CP, COL, and ML applications.

3.2 Alternative 2: Rulemaking

3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to amend its regulations so more than one SDA may be referenced in a CP, COL, or ML application if each referenced SDA represents a major portion of the same reactor design.

3.2.2 *Assessment of Alternative 2*

This alternative would eliminate any uncertainty for applicants referencing one or more SDAs by giving them two options: an applicant could reference one SDA for all or a major portion of that facility, or an applicant could reference more than one SDA if each of those referenced SDAs represents a major portion of the same design.

4.0 REGULATORY SCOPE

The NRC is considering amending the regulations in paragraphs 52.133(a), 52.73(a), and 52.153(b).

5.0 NRC GUIDANCE, POLICY, AND IMPLEMENTATION ISSUES

5.1 NRC Guidance

There is no written guidance on the number of SDAs that may be referenced in a CP, COL, or ML application if each referenced SDA represents a major portion of the same reactor design. A rule change that clears up any uncertainty about the number of SDAs that may be referenced in such cases would be preferable to and obviate the need for guidance.

5.2 Policy Issues

The issue of whether a CP, COL, or ML application can reference more than one SDA, the associated ambiguity in the NRC’s regulations, and the options to address the ambiguity through rulemaking would not require a new or revised Commission policy. There would be no potential conflict between different policies that need to be resolved.

6.0 IMPACTS

This section analyzes the alternatives for addressing issues associated with the lack of clarity in the NRC’s regulations whether more than one SDA may be referenced in CP, COL, and ML applications.

6.1 Alternative 1: No-Action

Under this alternative, the NRC's regulations would be unchanged and uncertainty regarding the number of SDAs that may be referenced in CP, COL, and ML applications would remain.

6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current regulations, guidance, or process, there would be no impacts on public health, safety, and security.

6.1.2 Impacts on Licensees

Because this alternative would not change the current regulations, guidance, or process, there would be no impacts on licensees or applicants.

6.1.3 Impacts on the NRC

Because this alternative would not change the current regulations, guidance, or process, there would be no impacts on the NRC.

6.1.4 Additional Considerations

Because this alternative would not change the current regulations, guidance, or process, there would be no impacts on State, local, or Tribal governments.

6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would undertake a rulemaking to clarify that more than one SDA may be referenced in DC, CP, and COL applications, as long as each of the referenced SDAs represents a major portion of the same design.

6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the design, construction, or operation of a nuclear power plant, there would be no impacts on public health, safety, and security.

6.2.2 Impacts on Licensees

This alternative would amend the regulations to allow CP, COL, or ML applicants the ability to reference more than one SDA in their applications. Under this alternative, the rule change would remove any uncertainty in the regulations by clarifying that more than one SDA may be referenced in any of the applications. Rule changes that clear up uncertainty could save applicants' resources they might spend trying to understand the scope and flexibility of a rule that might not otherwise be apparent. Although rulemaking would remove the current uncertainty in the rule, the NRC estimates this clarity would result in no substantive cost savings to those applicants referencing multiple SDAs.

6.2.3 Impacts on the NRC

This alternative would result in minimal one-time costs to the NRC. The NRC performing a rulemaking to clarify that more than one SDA may be referenced in CP, COL, and ML applications would cost approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table H.4-1.

Table H.4-1 NRC Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.2.5 Summary of Benefits and Costs

The NRC estimates there would be no substantive change in the burden on an applicant or the NRC by performing rulemaking to clarify that more than one SDA may be referenced in CP, COL, and ML applications.

There would be a one-time cost to the NRC to develop the rule. The NRC estimates the rulemaking cost to be approximately (\$32,000) using a 7 percent NPV.

7.0 BACKFITTING AND ISSUE FINALITY

Neither of the alternatives presented by the NRC in this section of Appendix H.4, if implemented, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would not impose new requirements or staff positions on any Part 50 or 52 applicants or licensees. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

8.0 STAKEHOLDER FEEDBACK

8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS).

No members of the ACRS provided feedback on this topic during or following the public meeting.

9.0 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, "Rulemaking." Under this approach, the NRC would pursue rulemaking to clarify that more than one SDA may be referenced in CP, COL, and ML applications. Alternative 2 would result in one-time cost to the NRC staff to perform the rulemaking. However, there is merit in assuring the NRC's regulations clearly reflect the different options available to an applicant referencing an SDA.

APPENDIX H.5 – CONTENT OF APPLICATIONS

The U.S. Nuclear Regulatory Commission's (NRC's) potential revisions to modify requirements for evaluating conformance of a standard design certification with the Standard Review Plan, aligning requirements for timely completion of construction requirements, and clarifying requirements for an applicant referencing an early site permit and a design certification or approval are addressed in the following sections of this appendix.

1.0 MODIFYING REQUIREMENTS TO EVALUATE CONFORMANCE WITH THE STANDARD REVIEW PLAN

The NRC's regulations require an applicant for license, certification, or approval under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249), and Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), to submit an evaluation of the standard plant design against the "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (NUREG-0800; NRC 2007/2019-TN6221) revision in effect 6 months before the date the application is docketed. When an application is different than the Standard Review Plan (SRP), the regulations require the applicant to include a discussion of how the proposed alternative in the application provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The NRC is considering amending the regulations to remove requirements for an evaluation against the SRP and provide a more flexible approach to demonstrating compliance with the underlying regulations referenced by the SRP.

1.1 Existing Regulatory Framework

For light water-cooled nuclear power plants, applications submitted under paragraphs 50.34(h), 52.17(a)(1)(xii), 52.47(a)(9), 52.79(a)(41), 52.137(a)(9), and 52.157(f)(30) require an evaluation of the facility against the SRP revision in effect 6 months before the docket date of the application. The regulations further require that this evaluation include identification and description of all differences in design features, analytical techniques, and procedural measures proposed for the design and those corresponding features, techniques, and measures given in the SRP acceptance criteria. Where a difference exists, the regulations require the evaluation to discuss how the proposed alternative in the application provides an acceptable method of complying with the Commission's regulations, or portions thereof, that underlie the corresponding SRP acceptance criteria. The regulations note that the SRP is not a substitute for the regulations and compliance with the SRP is not a requirement.

The purposes of the SRP are to ensure the quality and uniformity of the NRC's review and to improve understanding of the staff review process. The Commission originally codified the requirement to evaluate conformance with the SRP in Section 50.34, "Contents of applications; technical information," to assist the staff in identifying how the applicant's proposed alternatives to the SRP acceptance criteria comply with the regulations and, therefore, lead to improved efficiency and effectiveness of the NRC safety reviews ("Rule to Require Applicants to Evaluate Differences From the Standard Review Plan; Final Rule" ([47 FR 1651, March 18, 1982]; TN6237)).

1.2 Regulatory Issues

Recent experience with new reactor licensing highlighted the fact that applicants expend significant resources to evaluate the differences between their applications and the SRP. Such an extensive evaluation was not necessary because the information in the application described how the applicant's proposal met the regulations. An applicant is required to identify differences between the design features, analytical techniques, and procedural measures proposed for its facility and the SRP acceptance criteria and evaluate how the proposed alternatives to the SRP acceptance criteria provide an acceptable method of complying with the NRC regulations. However, unless the SRP is up to date and customized (or technology-inclusive) for the specific application, its use as a guide for reviewing some applications could impact the efficiency and effectiveness (including safety focus) of the licensing process for those applicants as well as the NRC. Although the change could have an adverse effect on the efficiency of the NRC acceptance review to assess the adequacy of the submittal before the application is docketed, there is no evidence that, overall, the NRC evaluations of the applications' conformance with the SRP provided a corresponding increase in staff efficiency sufficient to justify the burden expended by applicants to comply with this requirement.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

Alternative 1 would maintain the current requirements to submit an evaluation against the SRP revision in effect 6 months before the docket date of the application, including an evaluation of the differences between the application and the SRP acceptance criteria to demonstrate compliance with the regulations.

1.3.1.2 Assessment of Alternative 1

Under Alternative 1, an applicant would continue to provide a table identifying differences in its application with the SRP in addition to describing how it meets the regulations in the applicable sections of the application. The existing burden on applicants would remain without a commensurate benefit in NRC review efficiency. Although a roadmap documenting differences from the SRP could be helpful in efforts to identify some areas to focus on in NRC's review, the SRP guidance was developed based on the operating fleet of large light water reactors (LWRs), and the most recent applications have been for small modular reactors for which the NRC has had to develop additional staff review guidance beyond the SRP. Near-term prospective LWR applications are also expected to be for small modular reactors. Therefore, the benefit of a comparison to the SRP is expected to be even smaller for future LWR applications.

1.3.2 Alternative 2: Rulemaking to Remove the Requirement for an Evaluation against the SRP and Updating Guidance to Applicants

1.3.2.1 Description of Alternative 2

In Alternative 2, the NRC would pursue rulemaking to amend paragraphs 50.34(h)(2), 52.17(a)(1)(xii), 52.47(a)(9), 52.79(a)(41), 52.137(a)(9), and 52.157(f)(30) to remove the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application.

1.3.2.2 Assessment of Alternative 2

Alternative 2 would relieve applicants from expending resources to compare their applications with the SRP and show how differences from the SRP still meet the NRC's regulations. An additional benefit of this alternative stems from the fact that, unless the SRP is up to date and customized (or technology-inclusive) for the specific application, its use as a guide for reviewing some applications could impact the efficiency and effectiveness (including safety focus) of the licensing process for those applicants as well as the agency.

Currently, Regulatory Guide (RG) 1.206, "Applications for Nuclear Power Plants," Revision 1 (NRC 2018-TN6192), provides guidance to applicants on the format and content of applications for nuclear power plants. Alternative 2 would update RG 1.206 to correspond with the removal of the requirements for an evaluation against the SRP in effect 6 months prior to docketing of an application.

1.4 **Regulatory Scope**

The NRC is considering amending the regulations in paragraphs 50.34(h), 52.17(a)(1)(xii), 52.47(a)(9), 52.79(a)(41), 52.137(a)(9), and 52.157(f)(30) to remove the requirement for an applicant to evaluate its application against the applicable SRP.

1.5 **NRC Guidance, Policy, and Implementation Issues**

1.5.1 *NRC Guidance*

Under rulemaking Alternative 2, the NRC would update RG 1.206 to conform with the removal from the regulations of the requirement for an applicant to evaluate its application against the applicable SRP.

1.5.2 *Policy Issues*

The requirement to evaluate conformance with the SRP was originally put in place to promote the improved efficiency and effectiveness of NRC safety reviews. That requirement has not provided the intended improvements to a level sufficient to justify the increased burden on applicants. Removing the requirement would not raise new policy issues.

1.6 **Impacts**

1.6.1 *Alternative 1: No-Action*

Under Alternative 1, the NRC would not pursue any changes to the current process.

1.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 *Impacts on Applicants*

Under this alternative, there would be no change to the impacts on applicants. The applicant would still be required to evaluate its design against the SRP. The cost of any individual

applicant's actions to address the differences from the SRP is difficult to ascertain and would depend on the design and the extent to which the applicant documents differences from the SRP.

1.6.1.3 Impacts on the NRC

This alternative would have no impacts on the NRC. The NRC would continue to require unnecessary information in the application summarizing conformance with the SRP, and the information in the applicable sections of the application. The application would also continue to contain more detailed information than would be needed for NRC to make its safety determination. This is because a table summarizing the applicant's evaluation against the SRP is not necessary because the information in the individual sections of the application would describe how the applicant's proposal meets the regulations.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking to Remove the Requirement for an Evaluation Demonstrating Conformance with the SRP and Updating Guidance to Applicants

Under Alternative 2, the NRC would undertake a rulemaking to remove the requirement for an evaluation demonstrating conformance with the SRP and update its guidance to conform with the removal of this requirement from the regulations.

1.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no impacts on public health, safety, and security because the NRC would continue to receive sufficient information from the applicant to evaluate conformance with the regulations. This alternative would only eliminate a requirement to submit a summary of information about conformance to the SRP. This information can also be found in the individual sections of the application.

1.6.2.2 Impacts on Applicants and Licensees

New reactor applicants would likely see a reduction in cost because the burden of submitting an evaluation against the SRP in their application would be removed. The NRC considered the anticipated burden reduction for design certification (DC) applicants, early site permits (ESPs), manufacturing licenses (MLs), combined licenses (COLs), and operating licenses (OLs), and estimates an average reduction in burden of 2,000 hours per application. Using an estimate of one affected application every 3 years through 2030, beginning in the year of the expected issuance of the final rule, the cost estimate used sensitivity values around this mean estimate to calculate the averted costs. Based on these assumptions, Alternative 2 would result in averted costs to applicants of approximately \$456,000 (7 percent net present value [NPV]) and \$611,000 (3 percent NPV), as shown in Table H.5-1.

Table H.5-1 Industry Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted Application level of effort for licensee	1	1917	\$134	\$257,388	\$183,514	\$222,025
2027	Averted Application level of effort for licensee	1	1917	\$134	\$257,388	\$149,802	\$203,185
2030	Averted Application level of effort for licensee	1	1917	\$134	\$257,388	\$122,283	\$185,943
Total:					\$772,165	\$455,600	\$611,153

1.6.3 Impacts on the NRC

By removing the requirement to submit an evaluation demonstrating conformance with the SRP, the NRC would likely see a reduction in resources to review that portion of the application. However, the NRC would also see a corresponding increase in resources due to the added burden of having to discern whether the applicant followed the guidance in the SRP or met requirements in a different manner absent the applicant having addressed this issue in a consolidated manner in the application. For the purpose of this regulatory basis, the NRC is assuming the added and reduced burdens would essentially offset each other such that there would be no net impacts on the NRC. The NRC would incur rulemaking costs of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table H.5-2.

Table H.5-2 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

1.6.3.1 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.3.2 Summary of Costs and Benefits

Alternative 2 would result in a net averted cost to industry and the NRC of approximately \$350,000 (7 percent NPV) and \$490,000 (3 percent NPV).

1.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC in this section of Appendix H.5, if implemented, would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to requirements or NRC staff positions. Alternative 2 would remove a requirement and would not impose new requirements or staff interpretations.

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The NRC staff recommends Alternative 2 to pursue rulemaking to remove the requirement to demonstrate conformance with the SRP and to update guidance to applicants. This alternative appears to be cost-effective for industry and the NRC. The change would relieve applicants from expending resources to compare their applications with the SRP and show how differences from the SRP still meet the NRC's regulations. In addition, it could benefit the NRC because, unless the SRP is up to date and customized (or technology-inclusive) for the specific application, its use as a guide for reviewing some applications could impact the efficiency and effectiveness (including safety focus) of the licensing review for the agency.

2.0 ALIGNING REQUIREMENTS FOR TIMELY COMPLETION OF CONSTRUCTION REQUIREMENTS

The NRC's regulations do not require COLs under Part 52 to specify the earliest and latest date for completion of construction or modification of a facility, as is the requirement for Part 50 construction permits (CPs). Nevertheless, regulations that provide for the revocation, suspension, or modification, in whole or in part, of a COL could be read to imply that a COL is conditioned to state the earliest and latest dates for completion of the construction or modification and that the COL can be revoked, suspended, or modified if it fails to achieve timely completion of the proposed construction or modification of the facility.

The NRC is considering rulemaking to correct this inconsistency in the regulations.

2.1 Existing Regulatory Framework

Section 50.100, "Revocation, suspension, modification of licenses, permits, and approvals for cause," provides for the revocation, suspension, or modification, in whole or in part, of a COL for failure to construct or operate a facility in accordance with the terms of the license, but notes that failure to achieve timely completion of the proposed construction or alteration of a facility is governed by the provisions of paragraph 50.55(b). The introductory paragraph of Section 50.55, "Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses," reads, in relevant part, that while CPs are subject to all paragraphs

within Section 50.55 except paragraph (i), COLs are subject to only paragraphs (e), (f), and (i) of Section 50.55.

For CPs, paragraph 50.55(b) states that if the proposed construction or modification of the facility is not completed by the latest completion date, the CP will expire, and all rights will be forfeited.

2.2 Regulatory Issues

Section 50.100 can be read to imply that a COL could be revoked, suspended, or modified for failure to achieve timely completion of the licensee's proposed construction or alteration of the facility. This regulation is inconsistent with Section 50.55 that does not require conditioning the COL to state the earliest and latest dates for completion of the construction or modification of the facility. In addition, in the 2007 Part 52 final rule ("Licenses, Certifications, and Approvals for Nuclear Power Plant" [72 FR 49352, August 28, 2007; TN4796]), the Commission stated that COLs were being excluded from this requirement in light of the amendment to Section 185 of the Atomic Energy Act of 1954, as amended (42 U.S.C. § 2011 *et seq.*; TN663), that was made by Section 2801 of the Energy Policy Act of 1992 (Pub. L. No. 102-486, 106 Stat. 3120; TN6236). The Energy Policy Act established separate requirements for COLs, such that requirements for "stand-alone" CPs, including the need to specify the earliest and latest date for completion of construction, do not apply to the CP portion of a COL. Although there is a clear inconsistency between Section 50.100 and paragraph 50.55(b), there is no evidence that this inconsistency has caused any problems for COL applicants or holders. The requirements in paragraph 50.55(b) are the controlling requirements regarding the timely completion of the proposed construction or alteration of a facility and those requirements are clear about which sections apply to COLs. Nevertheless, the existing inconsistency could cause confusion about the Commission's intent.

2.3 Discussion of Alternatives

2.3.1 *Alternative 1: No-Action*

2.3.1.1 *Description of Alternative 1*

This alternative would maintain the current inconsistency in the requirements related to a COL that may be revoked, suspended, or modified upon failure to complete the proposed construction or alteration of the facility.

2.3.1.2 *Assessment of Alternative 1*

The "no-action" alternative would maintain the existing inconsistencies in the regulations.

2.3.2 *Alternative 2: Rulemaking to Remove the Provision Implying the Ability to Revoke, Suspend, or Modify a Combined License Failing to Make Timely Completion of the Proposed Construction or Alteration of a Facility*

2.3.2.1 *Description of Alternative 2*

In this alternative, the NRC would pursue rulemaking to amend Section 50.100 to remove the provision implying that the NRC has the ability to revoke, suspend, or modify, in whole or in part,

a COL upon failure to achieve timely completion of the proposed construction or alteration of the facility.

2.3.2.2 Assessment of Alternative 2

This alternative addresses the inconsistency related to revoking, suspending, or modifying a COL for failure to achieve timely completion of construction or alteration of a facility because the COL applicant is not required to provide, and the COL is not conditioned to state, the latest date for completion of construction. This alternative would also be consistent with the Commission's intent as expressed in the statement of considerations for the 2007 Part 52 rulemaking.

2.4 Regulatory Scope

The NRC is considering updating the regulations in Section 50.100 to remove the provision that implies that the NRC, under the provisions in paragraph 50.55(b), can revoke, suspend, or modify, in whole or in part, a COL if the licensee fails to achieve timely completion of the proposed construction or alteration of the facility.

2.5 NRC Guidance, Policy, and Implementation Issues

2.5.1 NRC Guidance

There is currently no regulatory guidance that addresses this regulation, and the NRC would not develop new regulatory guidance as part of the actions for resolving this issue.

2.5.2 Policy Issues

Under the rulemaking alternative discussed above, no policy issues would need to be brought to the Commission.

2.6 Impacts

2.6.1 Alternative 1: No-Action

Under this alternative, the NRC would not pursue any changes to the current regulations.

2.6.1.1 Impacts on Public Health, Safety, and Security

There would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Applicants and Licensees

Under this alternative, the inconsistencies in the regulations would remain, and could create confusion about the requirements for COL applicants and licensees.

2.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Rulemaking to Remove the Provision to Revoke, Suspend, or Modify a Combined License Failing to Make Timely Completion of the Proposed Construction or Alteration of a Facility

Under this alternative, the NRC would undertake a rulemaking to remove the provision in Section 50.100 that implies the ability to revoke, suspend, or modify, in whole or in part, a COL upon failure to achieve timely completion of the proposed construction or alteration of the facility.

2.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no impacts on public health, safety, and security.

2.6.2.2 Impacts on Applicants and Licensees

Under this alternative, COL applicants and licensees would have clarity on the requirements of the COL, and, therefore, would not have to seek clarification from the NRC.

2.6.2.3 Impacts on the NRC

By removing the inconsistent requirement, the NRC would benefit from consistent requirements for a COL and the elimination of the need to answer questions from applicants or licensees seeking clarification on this matter. The NRC would incur rulemaking costs of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table H.5-3.

Table H.5-3 NRC Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in rulemaking costs to the NRC of approximately (\$32,000) using a 7 percent NPV.

2.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this section of Appendix H.5 would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to Section 50.100, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would remove a procedural inconsistency in the regulations, thereby imposing on applicants and licensees no change in requirements or NRC staff positions.

2.8 Stakeholder Feedback

2.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

2.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Remove the Provision to Revoke, Suspend, or Modify a Combined License Failing to Make Timely Completion of the Proposed Construction or Alteration of a Facility” to correct the inconsistencies in the regulations by removing the provision implying the ability to revoke, suspend, or modify, in whole or in part, a COL upon failure to achieve timely completion of the proposed construction or alteration of the facility. This is consistent with the Commission’s intent and other parts of the regulations that do not require the COL applicant to state the earliest or latest date for completion of construction of the proposed facility.

3.0 CLARIFYING REQUIREMENTS FOR AN APPLICANT REFERENCING AN EARLY SITE PERMIT AND A DESIGN CERTIFICATION OR APPROVAL

The NRC has identified a potential need to clarify the requirements for a COL applicant who references both an ESP and either a standard design approval (SDA) or a DC. Although the regulations contain requirements for a COL applicant referencing an ESP, an SDA, or a DC, if a COL applicant references both an ESP and either an SDA or a DC, then the language of the current regulations may be unclear as to what is required.

3.1 Existing Regulatory Framework

The current regulations in paragraph 52.79(b)(1) require a COL applicant referencing an ESP to incorporate by reference the ESP and demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP. For a COL applicant

referencing an SDA, the regulations in paragraph 52.79(c)(1) require that the applicant incorporate by reference the SDA and demonstrate that the characteristics of the site fall within the site parameters specified in the SDA. Similarly, for a COL applicant referencing a standard DC, the regulations in paragraph 52.79(d)(1) require that the applicant incorporate by reference the certified design and demonstrate that the characteristics of the site fall within the site parameters specified in the DC.

Regulatory Guide 1.206, "Applications for Nuclear Power Plants," provides guidance on the format and content of applications for nuclear power plants submitted to the NRC under Part 52. Section C.2.6 of RG 1.206 is entitled "Combined License Application Referencing a Design Certification or Early Site Permit, or Both."

3.2 Regulatory Issues

There is currently no language in the regulations that explicitly addresses the case of a COL applicant that references both an ESP and either an SDA or a DC. By implication the COL applicant must comply with all applicable regulations, but clarification that, if a COL applicant chooses to reference both an ESP and either an SDA or DC, then the requirements of both paragraph 52.79(b)(1) and either paragraph 52.79(c)(1) or paragraph 52.79(d)(1) apply, may be beneficial. Moreover, one purpose of these paragraphs is that the COL applicant must demonstrate that application information resolved by the previous approval under the ESP, SDA, or DC bounds the specific circumstances being presented in the COL application. Clarifying what is needed for demonstrating what is bounded by a referenced ESP and either an SDA or DC may be beneficial for a COL applicant referencing such approvals. The NRC is considering rulemaking to clarify the applicability of the various demonstration requirements of an applicant referencing an SDA or a DC, and an ESP.

3.3 Discussion of Alternatives

3.3.1 *Alternative 1: No-Action*

3.3.1.1 *Description of Alternative 1*

This alternative would maintain the current requirements for a COL applicant referencing an ESP and either an SDA, or a DC.

3.3.1.2 *Assessment of Alternative 1*

The "no-action" alternative would maintain the lack of specific provisions in the regulations addressing the requirements for a COL applicant referencing both an ESP and either an SDA or a DC.

3.3.2 *Alternative 2: Rulemaking to Clarify the Requirements for a COL Applicant Referencing an ESP and Either an SDA or a DC*

3.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to amend Section 52.79 to clarify the requirements for a COL applicant referencing an ESP and either an SDA or DC. In addition, this alternative would revise the guidance in RG 1.206 related to preparation of a COL

application referencing an ESP and either a DC or an SDA in the same manner as described in Section 3.3.3.1 for Alternative 3, below.

3.3.2.2 *Assessment of Alternative 2*

This alternative would address the lack of explicit requirements for a COL applicant referencing both an ESP and an SDA, and a COL applicant referencing both an ESP and a DC, but would not change the requirements for such an applicant. These applicants would still be required to address all of the existing requirements for COL applicants referencing any combination of previous permits, approvals, or certifications. However, the requirements would be more explicitly stated than they are currently.

3.3.3 *Alternative 3: Guidance Revision to Clarify Implementation of the Requirements for a COL Applicant Referencing an ESP and Either an SDA or a DC*

3.3.3.1 *Description of Alternative 3*

This alternative would revise the guidance in RG 1.206 related to preparation of a COL application referencing an ESP and either a DC or an SDA. Although RG 1.206 already has a Section C.2.6 entitled “Combined License Application Referencing a Design Certification or Early Site Permit, or Both,” it does not have a great deal of guidance for a COL application referencing both. Additional guidance would be added to cover these types of applications as part of the update of RG 1.206 that would result from this rulemaking effort. The added guidance would include additional text devoted to COL applicants referencing both an ESP and either a DC or an SDA that would explain that the applicant must demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the ESP and that the characteristics of the site fall within the site parameters specified in the DC or SDA.

3.3.3.2 *Assessment of Alternative 3*

This alternative would clarify the applicability of the requirements in paragraphs 52.79(b)(1), 52.79(c)(1), and 52.79(d)(1) and the demonstration needed under these regulations for a COL applicant referencing both an ESP and either a DC or an SDA. Because a change to the existing requirements is not necessary to address this issue, the development of additional guidance in RG 1.206 could address the current lack of clarity on this matter by providing a separate section with explicit language for applicants that reference both an ESP and a DC or an SDA.

3.4 **Regulatory Scope**

The NRC is considering clarifying the applicability of requirements for a COL applicant referencing an ESP and an SDA or an ESP and a DC and the demonstration needed under the regulations in Section 52.79. This clarification could be provided either through revisions to Section 52.79 or revisions to the applicable guidance in RG 1.206.

3.5 **NRC Guidance, Policy, and Implementation Issues**

3.5.1 *NRC Guidance*

The NRC has guidance for the format and content of COL applications in RG 1.206. The NRC would update this guidance as part of the actions for addressing the lack of explicit regulations

for an applicant referencing both an ESP and either an SDA or a DC during the update of RG 1.206 that would result from this rulemaking effort.

3.5.2 *Policy Issues*

No change in policy is required to address this issue. Under both Alternatives 2 and 3, there would be no change to existing NRC requirements or NRC staff positions.

3.6 Impacts

This section analyzes the alternatives discussed above to address the requirements for a COL applicant referencing an ESP and either an SDA or a DC.

3.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would not pursue any changes to the current regulations.

3.6.1.1 *Impacts on Public Health, Safety, and Security*

There would be no increase or reduction in public health, safety, and security.

3.6.1.2 *Impacts on Applicants and Licensees*

Under this alternative, the ambiguity in the regulations would remain and could create confusion about the requirements of a COL applicant referencing an ESP and either an SDA, or a DC.

3.6.1.3 *Impacts on the NRC*

Under this alternative, the lack of specific provisions in the regulations would remain regarding the requirements of a COL applicant referencing an ESP and an SDA, or an ESP and a DC. Resources may need to be expended in the future to address the ambiguity resulting from the current lack of explicit requirements to address these situations. In addition, resources may need to be expended to support the review of applications not meeting requirements for a COL referencing an ESP, along with an SDA or DC, as appropriate.

3.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 *Summary of Costs and Benefits*

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

3.6.2 *Alternative 2: Rulemaking to Clarify the Requirements for an Applicant Referencing an ESP and Either an SDA or a DC*

Under this alternative, the NRC would undertake a rulemaking to amend Section 52.79 to clarify the requirements of a COL applicant referencing an ESP and either an SDA or a DC.

3.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no impacts on public health, safety, and security.

3.6.2.2 Impacts on Applicants and Licensees

Under this alternative, the applicant would have enhanced clarity about the requirements when referencing an ESP and either an SDA or a DC. This could allow the applicant to be more efficient and effective in the development of its application. It could also reduce the potential for additional work to correct an application that is submitted without appropriately addressing the requirements for referencing both of the previous NRC approvals. The NRC did not estimate these potential cost savings.

3.6.2.3 Impacts on the NRC

By removing the ambiguity in the requirements, the NRC could benefit from an application submitted consistent with requirements for an applicant referencing an ESP and an SDA, or an ESP and a DC, which was considered qualitatively. Alternative 2 would result in rulemaking costs to the NRC of approximately (\$69,000) using a 7 percent NPV and (\$79,000) using a 3 percent NPV, as shown in Table H.5-4.

Table H.5-4 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	20	\$131	(\$2,620)	(\$2,139)	(\$2,398)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	20	\$131	(\$2,620)	(\$1,868)	(\$2,260)
Total:					(\$87,177)	(\$68,852)	(\$78,582)

3.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 Summary of Costs and Benefits

This alternative would result in net costs to the NRC of approximately (\$69,000) using a 7 percent NPV.

3.6.3 *Alternative 3: Guidance Revision to Clarify Implementation of the Requirements for a COL Applicant Referencing an ESP and Either an SDA or a DC*

Under this alternative, the NRC would revise the guidance in RG 1.206 related to preparation of a COL application referencing an ESP and either a DC or an SDA, but would not pursue any changes to the current regulations. These revisions would take place during the update of RG 1.206 that would result from this rulemaking effort.

3.6.3.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no impacts on public health, safety, and security.

3.6.3.2 Impacts on Applicants and Licensees

Under this alternative, COL applicants would have enhanced guidance to clarify the requirements when referencing an ESP and an SDA or an ESP and a DC. This could allow an applicant to be more efficient and effective in the development of its application. It could also reduce the potential for additional work to correct an application that was submitted without appropriately addressing the requirements for referencing both of the previous NRC approvals. The NRC did not estimate these potential reductions in burden.

3.6.3.3 Impacts on the NRC

By addressing the ambiguity in the requirements through enhanced guidance, the NRC could benefit from an application submitted consistent with requirements for an applicant referencing an ESP and either an SDA or a DC. The change in the guidance would occur as part of the update of RG 1.206 that would result from this rulemaking effort. The costs to include this item would be small, approximately (\$4,400) using a 7 percent NPV and (\$4,900) using a 3 percent NPV, because the changes would be minor changes to a portion of the guidance that already addresses this subject area.

Table H.5-5 NRC Rulemaking Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	20	\$131	(\$2,620)	(\$2,288)	(\$2,470)
2022	Finalize/Issue Reg Guide independently	1	20	\$131	(\$2,620)	(\$2,139)	(\$2,398)
Total:					(\$5,240)	(\$4,427)	(\$4,867)

3.6.3.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.3.5 Summary of Costs and Benefits

Alternative 3 would not result in any changes in the current regulatory framework, and would result in minor costs to the NRC for guidance changes of approximately (\$4,400) using a 7 percent NPV.

3.7 Backfitting and Issue Finality

None of the alternatives presented by the NRC staff in this section of Appendix H.5 would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo of the current requirements for a COL applicant referencing an ESP and either an SDA or a DC, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would provide clarity about the NRC's requirements when a COL applicant references two approvals consistent with the current regulations, without imposing on applicants any new requirements or NRC staff positions. Alternative 3 would provide clarity about the existing requirements through updated guidance without imposing on applicants any new NRC staff positions.

3.8 Stakeholder Feedback

3.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

3.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The NRC staff recommends Alternative 3, “Guidance Revision to Clarify Implementation of the Requirements for a COL Applicant Referencing an ESP and Either an SDA or a DC,” to clarify the implementation of the requirements for a COL applicant referencing both an ESP and either an SDA or DC, because it addresses the ambiguity in the regulations for an applicant referencing two approvals without the increased resource expenditure that would be required for rulemaking. No change in the regulations would be needed to address this issue because an applicant referencing both an ESP and either an SDA or DC must meet all of the existing requirements for these types of applications.

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APPENDIX I – ENVIRONMENTAL TOPICS

The U.S. Nuclear Regulatory Commission's (NRC's) potential revision of the application requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2, "Agency Rules of Practice and Procedure" (TN6204), paragraph 2.101(a)(5), and change to clarify in 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions" (TN250), paragraph 51.50(a), that an applicant for a construction permit (CP) can reference an environmental assessment from a certified design are addressed in the following sections of this appendix.

1.0 REVISING THE APPLICATION REQUIREMENTS IN 10 CFR 2.101(A)(5)

An applicant for a CP under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249), or a combined license (COL) under 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251), is allowed under paragraph 2.101(a)(5) to submit its application in two parts: safety information and an environmental report. Either part can be submitted first as long as the second part is submitted within 6 months of the first submittal. Paragraph 2.101(a)(5) requires that the part that is submitted first must contain information about financial qualifications, emergency planning, and decommissioning funding assurance. Because this information is not used in the environmental report or environmental impact statement, the NRC is considering removing the requirement for an applicant to submit this information when the environmental report is submitted before the safety information under paragraph 2.101(a)(5).

1.1 Existing Regulatory Framework

Paragraph 2.101(a)(5) permits a CP or COL applicant to submit its application in two parts: the safety information and an environmental report. The second part must be submitted within 6 months of the first part. Whichever part is filed first must also include the information required by Section 50.33, "Contents of applications; general information." Paragraph 50.33(f) requires information regarding the applicant's financial qualifications to carry out the activities for which the permit or license is sought. Paragraph 50.33(g) requires information regarding radiological emergency planning. Paragraph 50.33(k) requires a report indicating how reasonable assurance would be provided that funds would be available to decommission the licensed facility.

1.2 Regulatory Issues

The NRC uses the information in the CP or COL applicant's environmental report to develop the agency's environmental impact statement. If the applicant submits the environmental report before the safety information, then, under Section 50.33, the applicant is required to submit information regarding financial qualifications, emergency planning, and decommissioning funding assurance. While this information is not used in the environmental impact statement, it is ultimately required for the safety review of the application. If an applicant submits the environmental report without submitting the information regarding financial qualification, emergency planning, or decommissioning funding assurance, then the applicant needs to request an exemption from the applicable provisions of Section 50.33.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

This alternative would maintain the current requirement for an applicant for a CP or a COL to include information regarding financial qualifications, emergency plans, and decommissioning funding assurance as part of the initial submittal under paragraph 2.101(a)(5).

1.3.1.2 Assessment of Alternative 1

This alternative would continue to require that an applicant submit financial qualification, emergency plan, and decommissioning funding assurance information even when the environmental report is submitted prior to the safety analysis report. This information may be used in the NRC's docketing evaluation; therefore, maintaining the submission requirements for it would continue to allow for timely and informed docketing decisions. Because both the safety and environmental parts must be submitted within 6 months of each other, it is reasonable that supporting financial qualification, emergency plan, and decommissioning funding assurance information would have been developed to support both of those parts for either a CP or COL application. As such, providing this information is not likely to be an undue burden for CP and COL applicants. Furthermore, based on recent legislation to shorten the duration of NRC reviews of applications to NRC, specifically, Fixing America's Surface Transportation Act (FAST-41; 42 U.S.C. § 4370m *et seq.*; TN6392), and Nuclear Energy Innovation and Modernization Act (NEIMA; Public Law 115-439, 132 Stat. 5565; TN6469), it is unlikely that CP and COL applicants would submit applications in multiple parts in the future. If desired, however, CP or COL applicants may submit a request for an exemption from paragraphs 50.33(f), 50.33(g), and 50.33(k).

1.3.2 Alternative 2: Rulemaking

1.3.2.1 Description of Alternative 2

The NRC would pursue rulemaking to remove the requirement for a CP or COL applicant to submit financial qualification and emergency plan information and decommissioning funding assurance with an environmental report when the environmental report is submitted before the safety information under paragraph 2.101(a)(5).

1.3.2.2 Assessment of Alternative 2

This alternative would alleviate the requirement for a CP or COL applicant to submit the financial qualification, emergency plan, and decommissioning funding assurance information with an environmental report when the environmental report is submitted first. Although the regulations permit the submission of CP and COL applications in parts, this option has been rarely used by applicants and has not resulted in notable application review efficiencies. As a result, the NRC estimates that there will be little or no burden reduction if this alternative is adopted. Delayed submittal of the financial information may also create difficulties for the NRC in making application docketing decisions, as the NRC may rely on financial qualification, emergency planning, and decommissioning funding assurance information in its docketing review. Also, based on recent legislation on shortening the duration of NRC reviews of

applications to NRC (e.g., FAST-41 and NEIMA), it is unlikely that CP and COL applicants would submit applications in multiple parts in the future.

1.4 Regulatory Scope

The regulation affected under Alternative 2 would be paragraph 2.101(a)(5) to specify that the information in paragraphs 50.33 (f), 50.33(g), and 50.33(k) is not required to be submitted if the environmental report is submitted first.

1.5 NRC Guidance, Policy, and Implementation Issues

No regulatory guides would be affected by Alternative 2. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP; NRC 2007/2019-TN6221), and NUREG-1555, "Standard Review Plans for Environmental Reviews for Nuclear Power Plants: Environmental Standard Review Plan" (ESRP; NRC 2013-TN3547) do not address this issue and no update to the SRP and ESRP would be needed. No policy issues would be associated with Alternative 2, which would not likely affect a current policy, create a conflict between policies, or create an unresolved policy issue.

1.6 Impacts

1.6.1 Alternative 1: No-Action

1.6.1.1 Impacts on Public Health, Safety, and Security

There would be no change to the current regulation. There would be no increase or reduction in public health, safety, and security.

1.6.1.2 Impacts on Licensees

There would be no reduction in the burden to submit information before it is necessary or an exemption from the requirement to submit the information.

1.6.1.3 Impacts on the NRC

The NRC would continue to review requests for exemptions.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 *Alternative 2: Rulemaking*

1.6.2.1 *Impacts on Public Health, Safety, and Security*

This alternative would remove a regulatory burden for the applicant to submit information regarding financial qualification, emergency planning and decommissioning funding assurance when it would not be needed by the NRC for its review of the licensee’s environmental report. There would be no increase or reduction in public health, safety, and security.

1.6.2.2 *Impacts on Licensees*

Applicants would still need to prepare and submit financial qualification, emergency planning, and decommissioning funding assurance information within 6 months after the environmental report is submitted. Applicants would no longer be required to apply for an exemption to this regulation in order to not submit the information with the environmental report when the environmental report is submitted first. Based on licensing experience, the NRC assumes, however, that applicants will choose not to submit applications in parts and that no exemption requests would be averted.

1.6.2.3 *Impacts on the NRC*

Alternative 2 could, but is unlikely to, result in an overall cost savings to the NRC. There would be a one-time cost to the NRC to undertake the rulemaking process to amend this regulation. There would be no further need for the NRC to review and approve exemption requests, but future exemption requests are unlikely. This would not result in an incremental cost savings to the NRC in time and resources. This alternative would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table I-1.

Table I-1 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

1.6.2.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 *Summary of Benefits and Costs*

Alternative 2 would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent NPV.

1.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this appendix section would constitute backfitting under Section 50.109, "Backfitting," or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to requirements or NRC staff positions. Alternative 2 would not apply to existing Part 50 licensees or holders of Part 52 approvals. Alternative 2 would affect applicants for a Part 50 CP or Part 52 COL. Applicants and potential applicants are not, with certain exceptions not applicable here, within the scope of the NRC's backfitting regulation in Section 50.109 or any issue finality provisions under Part 52.

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The NRC staff recommends Alternative 1, "No-Action," to keep the requirement for an applicant to submit financial qualifications, emergency planning information, and decommissioning funding assurance when submitting the environmental report before the safety information under paragraph 2.101(a)(5). This recommendation is based on the fact that the current regulations have not been a significant burden for past applicants, and future applications are not likely to be submitted in two parts. Because there is no discernable benefit to changing the rule, the rulemaking cost does not justify the low benefit of changing the rule.

2.0 CHANGE TO CLARIFY 10 CFR 51.50(A) THAT AN APPLICANT FOR A CONSTRUCTION PERMIT CAN REFERENCE AN ENVIRONMENTAL ASSESSMENT FROM A CERTIFIED DESIGN

A COL applicant that references a standard design certification (DC) is allowed, under paragraph 51.50(c)(2), to incorporate by reference the environmental assessment (EA) previously prepared by the NRC for the referenced DC. Paragraph 51.50(a) does not contain the same option for an applicant for a CP referencing a DC to incorporate by reference the EA prepared for the DC. Under the current regulatory framework, while a CP does not have this finality directly by way of a rule, the CP applicant could still base its Severe Accident Mitigation Design Alternatives analysis in the CP environmental report (ER) on what was done in the DC EA to show that the applicant fits the conditions for relying on the DC EA's results. However, because the regulations do not explicitly permit the CP applicant to directly reference the DC

EA, the CP applicant and the NRC would need to repeat the preparation of the EA done for the DC. The NRC staff recommends a change to paragraph 51.50(a) to clarify that a CP applicant can incorporate by reference the EA prepared for a DC.

2.1 Existing Regulatory Framework

Paragraph 52.80(b) requires a COL applicant to include an ER. Paragraph 51.50(c), the regulation describing the contents of a COL applicant's ER, permits the COL applicant referencing a DC to incorporate by reference the EA prepared for the DC.

Paragraph 50.30(f) requires a CP applicant to submit an ER. Paragraph 51.50(a), the regulation describing the contents of a CP applicant's ER, does not contain an option for a CP applicant referencing a DC to incorporate by reference the EA prepared for the DC.

2.2 Regulatory Issues

Paragraph 51.50(a) does not specify that a CP applicant can incorporate by reference the EA for a referenced certified design. This represents an inconsistency and lack of clarity in the regulations because paragraphs 51.50(c) and (c)(2) affirmatively state that COL applicants may reference in their ERs information contained in a final environmental document prepared by the NRC (e.g., an EA in the case of an application referencing a standard DC), while paragraph 51.50(a) does not specify whether a CP applicant may reference such a document. Although paragraph 51.50(a) does not explicitly forbid CP applicants from referencing final NRC environmental documents, the differing language raises the question of whether the NRC intended for different reference requirements to apply to CP and COL applicants.

2.3 Discussion of Alternatives

2.3.1 Alternative 1: No-Action

2.3.1.1 Description of Alternative 1

This alternative would not change the regulation.

2.3.1.2 Assessment of Alternative 1

The regulation would continue the current potentially divergent regulatory approach with respect to COL and CP applicants and their ability to reference an EA for a referenced DC. Although the current regulatory framework would allow the CP applicant to base its severe accident mitigation design alternative (SAMDA) analysis in the CP ER on what was done in the DC EA to show that the applicant fits the conditions for relying on the DC EA's results, because the regulations do not provide for the CP applicant to directly reference the DC EA, the CP applicant and the NRC would need to repeat the preparation of the EA done for the DC. This regulatory structure unnecessarily treats two classes of applicants differently, creating unnecessary burden and lack of clarity for CP applicants by not providing them with the ability to reference the analysis of an existing EA.

2.3.2 *Alternative 2: Rulemaking*

2.3.2.1 *Description of Alternative 2*

The NRC would pursue rulemaking to bring paragraph 51.50(a) into conformance with paragraph 51.50(c) to clarify that an applicant for a CP can incorporate by reference an EA for a certified design referenced in the CP.

2.3.2.2 *Assessment of Alternative 2*

By revising paragraph 51.51(a), NRC would explicitly give CP applicants the same regulatory option provided to COL applicants with respect to the ability to reference an EA for a referenced certified design. This alternative would clarify the regulations to allow CP applicants to incorporate by reference the EA previously prepared by the NRC for the referenced DC. If the DC EA is referenced, then similar to COL applicants who reference a DC EA, the CP applicant must include information in its environmental report to demonstrate that the site characteristics for the CP site fall within the site parameters in the DC EA. This would obviate the need for a CP applicant to perform a full SAMDA analysis.

2.3.3 *Alternative 3: Guidance Development*

2.3.3.1 *Description of Alternative 3*

This alternative would revise the guidance in Regulatory Guide (RG) 4.2, "Preparation of Environmental Reports for Nuclear Power Stations" (NRC 2018-TN6006), to clarify that an applicant for a CP can reference an EA for a certified design in its application. RG 4.2 has guidance for a COL application referencing an EA prepared for a certified design in Section A.6 entitled "COL Application Referencing Standard Design Certification." The RG does not have equivalent guidance for a CP application referencing a DC. This guidance could be added to RG 4.2 to clarify that a CP application could incorporate by reference an EA for a certified design similar to a COL application.

2.3.3.2 *Assessment of Alternative 3*

This alternative would clarify the applicability of the requirements in paragraph 51.50(a) to clarify that a CP applicant could incorporate by reference an EA for a certified design. Although a change to the existing regulation is not necessary to address this issue, the lack of consistency in the regulations between a COL application allowed to reference an EA and the CP application not specifically stating that an applicant can reference an EA is a lack of clarity that does not conform with the NRC Principles of Good Regulation (NRC 2014-TN6227).

2.4 **Regulatory Scope**

The regulation affected would be paragraph 51.50(a) to allow an applicant to incorporate by reference an EA for a referenced certified design.

2.5 **NRC Guidance, Policy, and Implementation Issues**

No regulatory guides would be affected by this change. No policy issues would be associated with this change. The change would not likely affect a current policy, create a conflict between policies, or create an unresolved policy issue.

2.6 **Impacts**

This section analyzes the two alternatives for making a conforming change to paragraph 51.50(a) to allow an applicant to incorporate by reference an EA for a referenced certified design.

2.6.1 Alternative 1: No-Action

2.6.1.1 Impacts on Public Health, Safety, and Security

Alternative 1 would result in no change to the current regulation. Therefore, there would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Applicants and Licensees

Applicants for a CP would continue to face a lack of clarity created by a regulatory structure that specifically allows an applicant for a COL to incorporate by reference an EA for a referenced certified design but does not specifically provide the same allowance for a CP applicant. Because the regulations do not permit the CP applicant to directly reference the DC EA, the CP applicant must prepare and submit a SAMDA analysis identical to that for the DC. This unnecessarily treats two classes of applicants differently, creating unnecessary burden and lack of clarity for CP applicants by not providing them with the ability to reference the analysis of an existing EA. This may result in a need for additional regulatory interactions with the NRC to understand the applicable requirements. Licensees would not be affected.

2.6.1.3 Impacts on the NRC

Because the regulations do not permit the CP applicant to directly reference the DC EA, the NRC would need to repeat the review of the SAMDA analysis done for the DC. The NRC may need to engage in case-specific regulatory interactions with applicants to provide guidance on whether it is acceptable for a CP applicant to reference a standard DC EA.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Rulemaking

2.6.2.1 Impacts on Public Health, Safety, and Security

Alternative 2 would result in no increase or reduction in public health, safety, and security.

2.6.2.2 Impacts on Applicants and Licensees

Applicants would no longer face uncertainty regarding why the regulations are different for CP and COL applicants referencing an EA for a certified design. Because a CP applicant would be able to incorporate by reference the DC EA, there would be a burden reduction of approximately

1,200 hours. Specifically, the CP applicant would no longer have to prepare and submit a SAMDA analysis identical to that presented in the DC EA. As with other sections of this regulatory basis, the staff assumes three future CP applicants in 2024, 2027, and 2030. This alternative results in averted costs to applicants of approximately \$287,000 (7 percent NPV) and \$385,000 (3 percent NPV), as shown in Table I-2 below.

Table I-2 Industry Averted Implementation Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$115,694	\$139,973
2027	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$94,441	\$128,095
2030	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$77,092	\$117,225
Total:					\$486,800	\$287,226	\$385,292

2.6.2.3 Impacts on the NRC

Because a CP applicant would be able to incorporate by reference the DC EA, there would be cost savings for the NRC. The NRC would no longer have to review SAMDA analysis in addition to that presented in the DC EA, which is estimated to save approximately 150 labor hours. Using the assumptions above regarding future applicants, the averted costs of these SAMDA reviews is included in Table I-3 below. The NRC would improve the clarity of its regulations, making clear that the NRC would not have to repeat preparation of the EA done for the DC. The NRC would incur costs of approximately (\$18,000) using a 7 percent NPV and (\$9,700) using a 3 percent NPV, as shown in Table I-3.

Table I-3 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	NRC Averted SAMDA Review	1	131	\$131	\$17,161	\$12,236	\$14,803
2027	NRC Averted SAMDA Review	1	250	\$131	\$32,685	\$19,023	\$25,801
2030	NRC Averted SAMDA Review	1	250	\$131	\$32,685	\$15,528	\$23,612
Total:					\$593	(\$18,059)	(\$9,708)

2.6.2.4 Summary of Benefits and Costs

Alternative 2 results in averted costs to industry and the NRC of approximately \$269,000 (7 percent NPV).

2.6.3 Alternative 3 – Guidance

2.6.3.1 Impacts on Public Health, Safety, and Security

Alternative 3 would result in no increase or reduction in public health, safety, and security.

2.6.3.2 Impacts on Applicants and Licensees

Applicants reading the regulations may still face uncertainty regarding why the regulations are different for CP and COL applicants referencing an EA for a certified design. The applicants would have to find the clarification in RG 4.2 to understand the clarification. Similar to Alternative 2, there would be the same cost savings to the applicant of \$287,000 (7 percent NPV) and \$385,000 (3 percent NPV), shown in Table I-4 below. Licensees would not be affected.

Table I-4 Industry Averted Implementation Costs, Alternative 3

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$115,694	\$139,973
2027	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$94,441	\$128,095
2030	Averted licensee SAMDA	1	1208	\$134	\$162,267	\$77,092	\$117,225
Total:					\$486,800	\$287,226	\$385,292

2.6.3.3 Impacts on the NRC

The NRC would improve the clarity of its regulations by updating guidance and not the regulations. This guidance-only alternative requires the NRC to prepare or update RG 4.2. Similar to Alternative 2, the NRC would benefit from averted SAMDA reviews, but would incur the cost of developing guidance. Alternative 3 results in averted costs to the NRC of \$31,800 (7 percent NPV) and \$53,800 (3 percent NPV), shown in Table I-5, below.

Table I-5 NRC Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Reg Guide independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Reg Guide independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2024	NRC Averted SAMDA Review	1	250	\$131	\$32,685	\$23,304	\$28,194
2027	NRC Averted SAMDA Review	1	500	\$131	\$65,500	\$38,122	\$51,706
2030	NRC Averted SAMDA Review	1	250	\$131	\$32,685	\$15,528	\$23,612
Total:					\$77,388	\$31,769	\$53,836

Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.3.4 Summary of Benefits and Costs

Alternative 3 results in averted costs to industry and the NRC of \$319,000 (7 percent NPV).

2.7 Backfitting and Issue Finality

None of the alternatives presented by the NRC in this appendix section would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to requirements or NRC staff positions. Alternative 2 would not apply to existing licensees and would affect only CP applicants under Part 50. Applicants and potential applicants are not, with

certain exceptions that are not applicable here, within the scope of the NRC's backfitting regulation in Section 50.109 or any issue finality provisions under Part 52.

2.8 Stakeholder Feedback

2.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

2.8.2 Feedback from Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 Staff Recommendation

The NRC staff recommends amending the regulations to conform paragraph 51.50(a) with paragraph 51.50(c) in order to clarify that an applicant for a CP can incorporate by reference the EA for a certified design (Alternative 2). Although this alternative is not the most cost beneficial, it nonetheless results in averted costs of \$270,000 (7 percent NPV) to applicants and the NRC and the recommended change would improve the clarity of the NRC's regulations, and therefore, justifies the costs of amending the regulations.

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APPENDIX J – APPLICABILITY OF OTHER PROCESSES TO THE 10 CFR PART 52 PROCESS

This appendix discusses the U.S. Nuclear Regulatory Commission's (NRC's) considerations related to amending its regulations governing licensing-related processes not addressed in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251) but nonetheless applicable to Part 52. These processes are the definition of "contested proceeding" in 10 CFR Part 2, "Agency Rules of Practice and Procedure" (TN6204); backfitting requirements in 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249); and the requirements in paragraph 50.71(e)(3)(iii) for a combined license (COL) applicant to maintain the final safety analysis report (FSAR) originally submitted as part of its COL application. Each distinct process is discussed as a separate item below.

1.0 DEFINITION OF CONTESTED PROCEEDING IN 10 CFR 2.4

The inspections, tests, analyses, and acceptance criteria (ITAAC) hearings included in paragraph 52.103(a) do not fit into the framework set forth in the current definition of "contested proceeding" in Section 2.4, "Definitions." However, the ITAAC hearings are treated like contested proceedings in other regulations. To avoid unnecessary ambiguity, the NRC is considering a revision to Section 2.4 to expand the definition of "contested proceeding" to include ITAAC hearings under paragraph 52.103(a).

1.1 Existing Regulatory Framework

The term "contested proceeding" is defined in Section 2.4 to refer to the following procedural postures in NRC proceedings: (1) there is a controversy between the NRC 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) 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/was an applicant for a standard design certification under Part 52; and (3) 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. But contrary to this definition, Section 2.340 is titled, in part, "Initial decision in certain contested proceedings," and paragraph 2.340(c), for example, refers to initial decisions on findings in ITAAC hearings under Section 52.103, "Operation under a combined license." Various other provisions in Section 2.340 also refer to matters and findings for ITAAC hearings.

The regulation in paragraph 52.103(a) provides, among other things, that the NRC must provide notice that any person whose interest may be affected by operation of the plant may 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 will not be granted for those ITAAC that the Commission found were met under paragraph 52.97(a)(2).

1.2 Regulatory Issues

The regulation in paragraph 52.103(a) requires the NRC to issue a notice of opportunity of a hearing on compliance with the acceptance criteria in a COL (i.e., an ITAAC hearing) not less than 180 days prior to the scheduled date of fuel load. Although an ITAAC hearing is treated as

a contested proceeding under some regulations (e.g., 10 CFR 2.340(c)), the definition of “contested proceeding” in Section 2.4 does not currently include ITAAC hearings within its scope. The inconsistency in regulatory language and ambiguity in the applicable hearing process could lead to disputes that would unnecessarily consume time and resources.

1.3 Discussion of Alternatives

1.3.1 Alternative 1: No-Action

1.3.1.1 Description of Alternative 1

Under this alternative, the NRC would not pursue amending the regulations and would retain the current language of Section 2.4.

1.3.1.2 Assessment of Alternative 1

Alternative 1 would not align the definition of “contested proceeding” in Section 2.4 with the treatment of ITAAC hearings in other parts of the regulations. Although the substantive hearing requirements would not change under this alternative, the continuing lack of alignment between Section 2.4 and other parts of the regulations under the “no-action” alternative may result in some confusion on the part of external stakeholders regarding whether Part 2 includes ITAAC hearings.

1.3.2 Alternative 2: Rulemaking to Amend 10 CFR 2.4

1.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue amending Section 2.4 to include ITAAC hearings in the definition of “contested proceeding.”

1.3.2.2 Assessment of Alternative 2

Alternative 2 would align the definition of “contested proceeding” with the ITAAC hearings in other parts of the regulations. This amendment would advance several regulatory interests. As part of the Principles of Good Regulation (NRC 2014-TN6227), the NRC commits to clarity and transparency in regulation; clarifying regulatory definitions when there is an opportunity to do so is consistent with this commitment. The clarification would advance stakeholders’ understanding of the ITAAC hearing process and, in doing so, minimize the potential for disputes on what the applicable hearing process is during the period when an opportunity for hearings on ITAAC closure occurs (e.g., filings to the Commission seeking clarification on procedures may be avoided, which would save time and resources).

1.4 Regulatory Scope

The NRC is considering amending Section 2.4 by adding language to include ITAAC hearings in the scope of the definition for “contested proceeding.”

1.5 NRC Guidance, Policy, and Implementation Issues

1.5.1 NRC Guidance

The Commission approved generic ITAAC hearing procedures (81 FR 43266, July 1, 2016; TN6222), which serve as guidance in ITAAC proceedings. The clarifying changes discussed in this section would not affect or require any changes in these procedures or the development of new regulatory guidance.

1.5.2 Policy Issues

The rulemaking alternative would not affect a current policy, create a conflict between policies, or create an unresolved policy issue.

1.6 Impacts

1.6.1 Alternative 1: No-Action

1.6.1.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 Impacts on Licensees

Alternative 1 would have limited potential impacts on licensees; however, in maintaining the status quo, there may be a potential for greater confusion among licensees related to the lack of alignment among regulations.

1.6.1.3 Impacts on the NRC

Under this alternative, there would be no incremental impacts on the NRC.

1.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking to Amend 10 CFR 2.4

1.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no increase or reduction in public health, safety, and security.

1.6.2.2 Impacts on Licensees

There would be a small improvement in regulatory clarity of a regulatory definition under Alternative 2, but there would be no changes to the ITAAC closure process, or the ITAAC hearing notification or scheduling processes, or in the treatment of the ITAAC hearing as a contested proceeding. The improvement in clarity may minimize the potential for unnecessary litigation filings, resulting in a potential savings of time and resources that the staff did not quantify.

1.6.2.3 Impacts on the NRC

Under this alternative, the NRC would ensure the clarity of its regulations consistent with the NRC's Principles of Good Regulation. In addition, limiting the potential for stakeholder confusion may promote efficiency in the ITAAC hearing process. The NRC would incur rulemaking costs estimated to be approximately (\$32,000) using a 7 percent net present value (NPV) and (\$37,000) using a 3 percent NPV, as shown in Table J-1.

Table J-1 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

1.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.2.5 Summary of Benefits and Costs

The benefits under Alternative 2 are the added clarity that would be achieved by aligning the definition in Section 2.4 with the hearing provided for by Section 52.103. In addition, assuring the clarity and correctness of regulations is an important aspect of the NRC's values because it pertains directly to clarity and transparency.

Under Alternative 2, the rulemaking costs are approximately (\$32,000) using a 7 percent NPV. Overall, this item is low in complexity and, therefore, should not require much commitment of resources.

1.7 **Backfitting and Issue Finality Considerations**

Neither of the alternatives presented by the NRC in this section, if implemented by the NRC, would constitute backfitting under Section 50.109, "Backfitting," or affect any issue finality under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would add clarity to the definition of "contested hearing" to include the ITAAC hearing process but would not change the requirements for the conduct of such hearings. Therefore, neither of these alternatives would constitute backfitting or affect issue finality.

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Amend 10 CFR 2.4,” to include ITAAC hearings in the definition of “contested hearing” in Section 2.4 to align the definition with the ITAAC hearing opportunity provided in other parts of the regulations. This alternative provides the benefit of clarifying a definition in the NRC regulations, where the importance of clarity is paramount, consistent with the NRC’s Principles of Good Regulation. This alternative may avoid stakeholder confusion and may, therefore, lead to greater efficiency and productiveness during ITAAC hearings. The incremental cost of making this change in the rulemaking is low.

2.0 MAINTENANCE OF RECORDS IN 10 CFR 50.71(E)(3)(III)

The requirements in Section 50.71, “Maintenance of records, making of reports,” specify that applicants for a COL must provide annual updates to the FSAR during the period from the docketing of the COL application until the Commission finds that the acceptance criteria in the COL are met under paragraph 52.103(g). The NRC is considering the applicability of this requirement to COL applicants that have requested the NRC to suspend its review of the application, and to COL holders that have notified the NRC that they are not pursuing construction.

2.1 Existing Regulatory Framework

The regulation in paragraph 50.71(e)(3)(iii) requires annual updates to the FSAR following the docketing of an application for a COL until the Commission finds that the acceptance criteria in the COL are met under paragraph 52.103(g).

2.2 Regulatory Issues

The applicability of requirements in Section 50.71 to a COL applicant that has requested the NRC to suspend its review of the application or to a COL holder that has notified the NRC that the COL holder is not pursuing construction may create an unnecessary burden on the COL applicant or holder. The regulation requires annual updates to the FSAR for new information or reevaluated conditions, but an applicant that has requested the NRC to suspend its review would not have new information or reevaluated conditions, so an update—even a submittal

explaining the lack of any updates—would be an unnecessary burden on the applicant. Similarly, a COL holder that is maintaining its COL, but has not notified the NRC that it is not undertaking, or plans to suspend, construction of the facility is subject to the same requirement and, therefore, the same burden.

2.3 Discussion of Alternatives

The NRC is considering two alternatives to address the applicability of the requirement for annual FSAR updates for a COL applicant that has requested suspension of its application and for a COL holder not pursuing construction.

2.3.1 Alternative 1: No-Action

2.3.1.1 Description of Alternative 1

Under this alternative, the NRC would not pursue amending its regulations and would retain the current requirements in paragraph 50.71(e)(3)(iii). COL holders who are not pursuing construction, and COL applicants who have requested suspension of the application review, would continue to send in an annual letter stating that no FSAR information has been revised, deleted, or added since the last submittal and that there have been no new departures or changes to the departures described in the application.

2.3.1.2 Assessment of Alternative 1

The “no-action” alternative would retain the current regulatory language and retain the applicability of the requirements in Section 50.71. This alternative would retain the reporting burden on a COL applicant that has requested that the NRC suspend its review and a COL holder that is not pursuing construction.

2.3.2 Alternative 2: Rulemaking to Amend 10 CFR 50.71 for an Application in Suspended Review Status and for a COL Holder Not Pursuing Construction.

2.3.2.1 Description of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to amend the regulations so that a COL applicant that requested suspension of the NRC review and a COL holder that is not pursuing construction are not required to update the FSAR until the NRC is notified to resume its review of the application or until the COL holder has notified NRC that it plans to begin construction, or, in the case of construction cessation, plans to resume construction.

2.3.2.2 Assessment of Alternative 2

Under Alternative 2, the reporting burden on the COL applicant with an application in suspended status and the COL holder that is not pursuing construction would be decreased.

2.4 Regulatory Scope

Under Alternative 2, the NRC would pursue rulemaking to revise paragraph 50.71(e)(3)(iii) to eliminate its applicability to and reduce the burden for a COL applicant that has requested suspension of the NRC review of its application or for a COL holder that has decided to delay or suspend construction of the facility.

2.5 NRC Guidance, Policy, and Implementation Issues

2.5.1 NRC Guidance

Under the rulemaking alternative discussed above, the NRC would not pursue development of new guidance because the statements of considerations for the proposed and final rules would have sufficient information to describe and implement the requirements.

2.5.2 Policy Issues

Combined license applicants and licensees have, on their own initiative, informed the NRC of plans to either delay or cease construction for the purpose of fee avoidance. Applicants and licensees currently meet regulatory requirements by submitting letters annually stating that no FSAR information has been revised, deleted, or added since the last submittal and that there have been no new departures or changes to the departures described in the application. Therefore, the regulatory changes being considered are consistent with current practices and do not conflict with NRC policy.

2.6 Impacts

2.6.1 Alternative 1: No-Action

Under the “no-action” alternative, the NRC would continue to require annual updates to the FSAR for a COL applicant who has requested suspension of the NRC review of its application or for a COL holder that is not pursuing construction.

2.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants and licensees because there would be no change in the current requirements.

2.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

2.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 *Alternative 2: Rulemaking to Amend 10 CFR 50.71 for an Application in Suspended Review Status and for a COL Holder not Pursuing Construction*

Under Alternative 2, the NRC would pursue rulemaking to amend the regulations so a COL applicant who requested suspension of the NRC review and a COL holder who is not pursuing construction are not required to update the FSAR until the NRC is notified to resume its review of the application or until the COL holder has notified the NRC that it plans to begin construction, or, in the case of construction cessation, plans to resume construction.

2.6.2.1 *Impacts on Public Health, Safety, and Security*

There would be no increase or reduction in public health, safety, and security from this alternative because it would not apply to an operating plant. In addition, once there is a change in the status of the COL application or the plans for construction, the existing regulatory requirements assuring adequate protection of the public health, safety, and security would apply.

2.6.2.2 *Impacts on Applicants and Licensees*

Under Alternative 2, there would be a reduction in the reporting burden for an FSAR update involving no or minimal changes, for a COL applicant that has an application in suspended status and for a COL holder that has no immediate plans for construction. The staff estimates that this alternative could save COL applicants and holders 20 to 40 hours per year in administrative resource costs. This results in averted costs of approximately \$93,000 (7 percent NPV) and \$130,000 (3 percent NPV), as shown in Table J-2. Once the COL applicant asks the NRC to reinstate its review of the COL application or the COL holder decides to pursue or resume construction, the COL applicant or COL holder would need to notify the NRC and address changes in its FSAR.

Table J-2 Industry Averted Costs, Alternative 2

Year	Activity	Years	Count	Labor Hours	Rate	Cost		
						Undiscounted	7% NPV	3% NPV
2024-2030	Reduced Reporting Burden for COL holders and applicants	7	6	30	\$134	\$169,205	\$92,881	\$129,908
Total:						\$169,205	\$92,881	\$129,908

2.6.2.3 *Impacts on the NRC*

Overall, Alternative 2 would initially result in an incremental cost to the NRC to undertake the rulemaking, estimated to be approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table J-3.

Table J-3 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Benefits and Costs

This alternative would result in net averted costs to the NRC and industry of approximately \$61,000 using a 7 percent NPV and \$93,000 using a 3 percent NPV.

2.7 **Backfitting and Issue Finality**

Neither of the alternatives presented in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect issue finality under Part 52. Alternative 1 would maintain the status quo of providing FSAR updates annually, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would change the NRC reporting requirements for suspended applications or for licensees that have no immediate plans for construction. These reporting requirements are not within the scope of the NRC's backfitting and issue finality requirements because they do not involve a procedure or organization required to operate a facility. Therefore, neither of these alternatives would constitute backfitting or affect issue finality.

2.8 **Stakeholder Feedback**

2.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

2.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 **Staff Recommendation**

The NRC staff recommends pursuing the rulemaking described in Alternative 2. This alternative provides an opportunity to simplify NRC regulations and remove unnecessary burden on COL applicants that have applications in suspended review status and on COL holders that have no plans for construction or decide to cease construction by not requiring any reporting until notification of a change in status is submitted to the NRC.

3.0 REFERENCES TO ISSUE FINALITY IN 10 CFR 50.109

In general, the backfitting requirements (under Section 50.109) and issue finality requirements (under various sections in Part 52) require the NRC, before imposing certain requirements and staff positions, to perform a formal, systematic review to ensure that the NRC has properly defined and justified the proposed imposition. Certain provisions of Section 50.109 address standard design approvals (SDAs) under Part 52, Subpart E; early site permits (ESPs) under Part 52, Subpart A; and manufacturing licenses (MLs) under Part 52, Subpart F. The scope of

this item in SECY-19-0084, “Status of Rulemaking to Align Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150-AI66)” (NRC 2019-TN6210) included only SDAs and MLs. For this regulatory basis document, the scope was expanded to include ESPs, which, as described below, have an issue similar to SDAs and MLs regarding backfitting and issue finality regulations. Provisions in Section 52.145, “Finality of standard design approvals; information requests,” contain issue finality regulations for SDAs; provisions in Section 52.39, “Finality of early site permit determinations,” contain issue finality regulations for ESPs; and provisions in Section 52.171, “Finality of manufacturing licenses; information requests,” contain issue finality regulations for MLs. The NRC is considering amending Section 50.109 to clarify how backfitting and issue finality apply for SDAs, ESPs, and MLs.

3.1 Existing Regulatory Framework

Paragraph 50.109(a)(3) allows the NRC to take a backfitting action only if the proposed action is justified with a backfit analysis or meets one of the three exceptions to the requirement to perform a backfit analysis listed in paragraph 50.109(a)(4): (1) when the NRC’s proposed action is necessary to bring a facility into compliance (paragraph 50.109(a)(4)(i)); (2) when the NRC’s proposed action is necessary to ensure adequate protection (paragraph 50.109(a)(4)(ii)); and (3) when the NRC’s proposed action defines or redefines the level of protection deemed adequate to ensure public health and safety or the common defense and security (paragraph 50.109(a)(4)(iii)).

The regulations in paragraphs 50.109(a)(1)(iv) and (v) specify the date upon which SDAs and MLs are considered within the scope of the Part 50 backfitting provisions. In addition, paragraph 50.109(a)(1)(vii) addresses the applicability of the Part 50 backfitting provisions to COLs that reference an SDA, an ESP, or an ML.

For a COL that references an SDA, paragraph 50.109(a)(1)(vii) states that the provisions in Section 52.145 apply with respect to design matters resolved in the SDA. For holders of COLs referencing an ML, paragraph 50.109(a)(1)(vii) states that the provisions of Section 52.171 apply with respect to matters resolved in the ML proceeding. For a COL that references an ESP, paragraph 50.109(a)(1)(vii) states that the provisions of Section 52.39 apply with respect to the site characteristics, design parameters, and terms and conditions specified in the ESP.

For SDAs, the regulations in paragraph 52.145(a) provide for issue finality under certain conditions. This provision requires the NRC and the ACRS to use an SDA when reviewing a facility license application that incorporates the SDA by reference “unless there exists significant new information that substantially affects the [SDA’s approval] or other good cause.”

For ESPs, the regulations in paragraph 52.39(a) provide for issue finality after the ESP has been issued and during the term of a renewed ESP, when making findings for issuance of a construction permit or COL or any enforcement hearing, and when conducting hearings as specified in paragraph 52.39(c).

For MLs, issue finality is provided in paragraph 52.171(a)(1), which states that such issue finality extends through the term of the ML.

In addition, paragraph 52.171(a)(2) provides that any modification to the design of a manufactured power reactor that is imposed by the Commission under paragraph 52.171(a)(1) will apply to “all reactors manufactured under the license... except... [cases where] the modification has been rendered technically irrelevant by [a license amendment or departure.]”

Paragraph 52.171(a)(3) delineates the nature of finality associated with the referencing of a manufactured power reactor in subsequent NRC licensing proceedings. This regulation describes how, when making findings to support the issuance of a construction permit, operating license, or COL for an application that references an ML, or in most enforcement hearings for which a power reactor manufactured under Part 52, Subpart F, is referenced or used, issue finality applies to all matters resolved in the issuance or renewal of the ML.

3.2 Regulatory Issues

The requirements pertaining to backfitting and issue finality in Parts 50 and 52, respectively, overlap in some areas and create inconsistencies. The current inconsistencies in the regulations may lead to confusion about the applicable criteria for imposing changes to SDAs, MLs, and ESPs.

3.2.1 *Consistency Issues for Standard Design Approvals*

Issue finality under Section 52.145 applies when the NRC and ACRS are reviewing an individual facility license application incorporating an SDA. However, generic changes to an SDA are governed by the backfitting process in Section 50.109, as discussed in the statement of considerations (SOC) for the 2007 Part 52 final rulemaking (72 FR 49352, August 28, 2007; TN4796):

Section 52.145 Finality of Standard Design Approvals; Information Requests

This section states that a valid FDA [final design approval] must be relied upon by the ACRS and NRR [NRC's Office of Nuclear Reactor Regulation] in any review of a license application that references the FDA unless significant new information substantially affects the staff's FSER [final safety evaluation report]. The Commission, Atomic Safety Licensing Board Panel, or presiding officers are not bound by NRC staff determinations in the FDA or FSER for the standard plant design. Therefore, there is no issue preclusion in the mandatory hearing for a combined license that references an FDA. Generic changes to the standard design can be made as a compliance backfit or under the backfit process in 10 CFR 50.109.

The inconsistency exists in paragraph 50.109(a)(1)(vii), which states that, if a COL references an SDA, the provisions in Section 52.145 apply with respect to the design matters resolved in the SDA. The text of Section 52.145 and the associated SOC for the 2007 Part 52 final rule above do not support this construct.

In addition, paragraph 50.109(a)(1)(vii) conflicts with the finality requirements for COLs referencing SDAs in Section 52.98 (emphasis added):

After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license *which are not derived from a referenced standard design certification or manufacturing license*, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.

This point is reinforced by the Commission's SOC for Section 52.98 in the 2007 Part 52 final rule: "The change processes in 10 CFR Part 50 apply to a combined license that does not reference a design certification rule or a reactor manufactured under a manufacturing license" (72 FR 49352, August 28, 2007). In summary, it appears that the statement in paragraph 50.109(a)(1)(vii) about a COL that references an SDA conflicts with the Commission's intent and Section 52.98.

3.2.2 Consistency Issues for Early Site Permits

A similar inconsistency issue in paragraph 50.109(a)(1)(vii) exists for ESPs. Paragraph 50.109(a)(1)(vii) states that, if a COL references an ESP, then the provisions in Section 52.39 apply with respect to the site characteristics, design parameters, and terms and conditions specified in the ESP once the COL is issued. This language conflicts with the relevant provisions of Part 52. Paragraph 52.26(d) explains that an ESP is no longer operative once the COL is issued: "Upon issuance of a construction permit or combined license, a referenced early site permit is subsumed, to the extent referenced, into the construction permit or combined license." The finality requirements for COLs are contained in Section 52.98 (emphasis added):

After issuance of a combined license, the Commission may not modify, add, or delete any term or condition of the combined license, the design of the facility, the inspections, tests, analyses, and acceptance criteria contained in the license *which are not derived from a referenced standard design certification or manufacturing license*, except in accordance with the provisions of § 52.103 or § 50.109 of this chapter, as applicable.

Therefore, the language of paragraph 50.109(a)(1)(vii) with respect to ESP finality requirements after issuance of a COL conflicts with the ESP and issue finality regulations in Part 52.

3.2.3 Consistency Issues for Manufacturing Licenses

Paragraph 50.109(a)(1)(v) provides that MLs are within the scope of the backfitting provisions beginning when the ML is issued. The remaining backfitting requirements of Section 50.109 appear to apply to MLs except as described in paragraph 50.109(a)(1)(vii). Paragraph 50.109(a)(1)(vii) states that, for holders of COLs referencing an ML, the provisions of Section 52.171 apply with respect to matters resolved in the ML proceeding. Thus, other applicants referencing an ML, such as CP and OL applicants, would appear to be within the scope of the Section 50.109 backfitting provisions. However, paragraph 52.171(a)(3) also provides issue finality for construction permits and operating licenses that reference MLs.

Another potential area of confusion is that the language in paragraph 52.171(a) identifying the criteria for making changes to MLs is different than the language identifying the criteria for making changes to MLs in paragraph 50.109(a). Paragraph 50.109(a)(3) requires a proposed backfitting action to be a cost-justified, substantial increase in the overall protection of the public health and safety or common defense and security, unless the proposed action meets one of the exceptions in paragraph 50.109(a)(4). The criteria in Section 52.171 do not include the cost-justified, substantial increase in the overall protection test in paragraph 50.109(a)(3) or the defining or redefining of what level of protection should be regarded as adequate criterion in paragraph 50.109(a)(4)(iii). It is therefore not clear whether these criteria apply to MLs.

The language in Part 52 and the SOC for the 2007 Part 52 final rule clearly show that Section 52.171 was meant to be the controlling regulation for addressing issue finality for MLs. Paragraph 52.171(a)(1) states,

Notwithstanding any provision in 10 CFR 50.109, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured, or the requirements for the manufacture of the nuclear power 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 manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

The Commission explained its view of finality for MLs in great detail in the SOC for the 2007 Part 52 final rule:

In light of the NRC's review and approval of a final design as part of issuance of a manufacturing license, the final rule provides a greater degree of finality to a manufacturing license as compared with a standard design certification. Under § 52.171(a)(1), the same degree of issue finality accorded to the "certified design" applies throughout the term of the manufacturing license. Under this provision, the NRC may not impose any change or modification to the approved design (including site parameters, or design characteristics) for the manufacturing license unless the NRC determines that the change or modification is necessary either for adequate protection or for compliance with requirements applicable and in effect at the time the manufacturing license was issued. Similarly, the manufacturing license holder may not make changes to the design under the provisions of 10 CFR 50.59. Any change to the design will require a license amendment. The Commission regards this as similar to the level of change control imposed on designs which are the subject of a standard design certification. The Commission is imposing this stringent level of change control because one of the key reasons for licensing manufactured reactors is to enhance standardization—one of the original objectives of the 1989 Part 52 rulemaking. Unlike design certification, which is an approval of a "paper design," the NRC's proposed concept of a manufacturing license is pre-approval of the procurement, manufacturing, and quality assurance processes that translates the approved reactor design into a manufactured assembly in a controlled environment, with the capability to optimize techniques and procedures based upon feedback. Some of these advantages may be lost if each "manufactured" reactor was treated as a "one-off" custom product. Imposing the discipline of a license amendment process should ensure that a profusion of changes is not made to the approved design at random intervals.

Therefore, it appears that the provision in paragraph 50.109(a)(1)(v) implying that the backfitting criteria in Section 50.109 apply to MLs is inconsistent with the Commission's intention when it issued the 2007 Part 52 final rule.

3.3 Discussion of Alternatives

3.3.1 *Alternative 1: No-Action*

3.3.1.1 *Description of Alternative 1*

Under this alternative, the NRC would not pursue amending its regulations and would retain the current regulatory language in Sections 50.109, 52.145, 52.39, and 52.171.

3.3.1.2 *Assessment of Alternative 1*

Under Alternative 1, the existing backfitting requirements related to SDAs, ESPs, and MLs would be retained in Section 50.109, while the more specific provisions would continue to appear in Part 52. This alternative would not resolve the current inconsistencies in backfitting and issue finality requirements for SDAs, ESPs, and MLs, and therefore would not resolve the underlying concerns.

3.3.2 *Alternative 2: Rulemaking to Eliminate Certain 10 CFR 50.109 Provisions for SDAs, ESPs, and MLs and Revisions to Supporting Guidance*

3.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to make the following changes to its regulations:

- Delete paragraph 50.109(a)(1)(v) for MLs.
- Delete the phrase in paragraph 50.109(a)(vii) referencing how Section 52.39 applies to a COL referencing an ESP.
- Delete the sentence in paragraph 50.109(a)(vii) regarding how Section 52.145 applies to a combined license referencing an SDA.
- Delete the sentence in paragraph 50.109(a)(vii) regarding how Section 52.171 applies to a COL using a reactor manufactured under an ML.

In addition, the NRC would update its guidance related to backfitting (e.g., Management Directive [MD] 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests" (NRC 2019-TN6226), and draft NUREG-1409, "Backfitting Guidelines," Revision 1 [NRC 2020-TN6384].)

3.3.2.2 *Assessment of Alternative 2*

Alternative 2 would correct inconsistencies in NRC's regulations and provide clarity on the backfitting and issue finality requirements applicable to SDAs, ESPs, and MLs. For an SDA referenced by a COL, Section 50.109 would apply with respect to the design matters resolved in the SDA. For an ESP referenced by a COL, Section 50.109 would apply to the site characteristics, design parameters, and terms and conditions specified in the ESP and subsumed into the COL once the COL is issued. For an ML, Section 52.171 would apply in all cases.

3.3.3 *Alternative 3: Develop New Guidance or Revise Existing Guidance on Backfitting and Issue Finality*

3.3.3.1 *Description of Alternative 3*

Under this alternative, the existing regulations would remain unchanged and the NRC would pursue developing new guidance or revise existing guidance to clarify the applicability of backfitting and issue finality to SDAs, ESPs, and MLs.

3.3.3.2 *Assessment of Alternative 3*

Under Alternative 3, the NRC would develop new guidance or revise existing guidance (i.e., MD 8.4 and NUREG-1409) to address the applicability of the different requirements in Section 50.109 and Part 52. Because guidance cannot change the meaning of regulations, and the regulations at issue here would remain unchanged, this alternative would not resolve the current inconsistencies in backfitting and issue finality requirements for SDAs, ESPs, and MLs, and therefore would not resolve the underlying concerns.

3.4 **Regulatory Scope**

Under Alternative 2, the NRC would pursue amending Section 50.109, and potentially Sections 52.145, 52.39, and 52.171, if it is determined that additional clarification in these sections would be beneficial. The changes would result in a clear statement of the applicable backfitting and issue finality provisions for SDAs, ESPs, and MLs. In Alternative 3, the NRC would develop new guidance or revise MD 8.4 and NUREG-1409.

3.5 **NRC Guidance, Policy, and Implementation Issues**

3.5.1 *NRC Guidance*

If the NRC pursues the rulemaking described under Alternative 2, the NRC would consider updating its guidance. Revisions to MD 8.4 and NUREG-1409 would be necessary to remove some references to Section 50.109 for the backfitting of SDAs, ESPs, and MLs.

Alternative 3 also would include updating guidance. However, as described in Section 4.3 above, Alternative 3 would not address the underlying inconsistencies in the regulations.

3.5.2 *Policy Issues*

Under Alternative 2 discussed above, the NRC would change how the backfit rule is applied. However, as discussed in Section 3.3.2 of this appendix, the changes would involve revising the requirements to be consistent with what was intended in the 2007 Part 52 rule. Therefore, the regulatory changes being considered do not involve a change to NRC policy.

3.6 **Impacts**

3.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would not pursue amending its regulations and would retain the current regulatory language pertaining to backfitting and issue finality for SDAs, ESP, and MLs in Section 50.109.

3.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current regulatory requirements, there would be no increase or reduction in public health, safety, and security.

3.6.1.2 Impacts on Licensees

Because this alternative would not change the current regulatory requirements, this alternative would have no incremental impacts on licensees.

3.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

3.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

3.6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would pursue rulemaking to amend its regulations pertaining to backfitting and issue finality for SDAs, ESP, and MLs in Section 50.109.

3.6.2.1 Impacts on Public Health, Safety, and Security

The regulatory changes under consideration under the rulemaking alternative would not result in changes to any actual technical requirements or standards for safety or security. Therefore, this alternative would not result in any impacts on public health, safety, and security.

3.6.2.2 Impacts on Licensees and Applicants

The regulatory changes under consideration for rulemaking would clarify the NRC's backfitting and issue finality regulations, which apply to the NRC and not to licensees or applicants. The alignment of these regulations would improve clarity and increase regulatory certainty. Therefore, this alternative would have a positive qualitative impact on licensees and applicants.

3.6.2.3 Impacts on the NRC

There would be a one-time cost to the NRC to undertake the rulemaking process to amend this regulation and revise applicable guidance, estimated to be approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table J-4. In addition, the changes would have a beneficial qualitative impact resulting from improved clarity and increased regulatory certainty.

Table J-4 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Guidance Documents for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Guidance Documents for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

3.6.2.4 Additional Considerations

No additional considerations were identified under this alternative.

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 Summary of Benefits and Costs

Alternative 2 results in costs to the NRC to amend the regulation, approximated to be (\$106,000) using a 7 percent NPV, and the qualitative benefit of improved clarity and increased regulatory certainty resulting from the elimination of inconsistent regulations.

3.6.3 Alternative 3: Guidance

Under this alternative, the NRC would revise guidance pertaining to backfitting protection and issue finality for SDAs, ESP, and MLs in Section 50.109.

3.6.3.1 Impacts on Public Health, Safety, and Security

This alternative would not result in changes to any actual technical requirements or standards for safety or security. Therefore, this alternative would not result in any impacts on public health, safety, and security.

3.6.3.2 Impacts on Licensees

The guidance alternative would not result in changes to requirements applicable to licensees. Therefore, this alternative would have no incremental impacts on licensees.

3.6.3.3 Impacts on the NRC

There would be a one-time cost to the NRC to prepare guidance, estimated to be approximately (\$45,000) using a 7 percent NPV and (\$50,000) using a 3 percent NPV, as shown in Table J-5.

Table J-5 NRC Regulatory Guide Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Guidance Documents independently	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Guidance Documents independently	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
Total:					(\$53,481)	(\$45,184)	(\$49,677)

3.6.3.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.3.5 *Summary of Benefits and Costs*

The NRC would incur costs of approximately (\$45,000) using a 7 percent NPV, to prepare and issue guidance.

3.7 Backfitting and Issue Finality

None of the alternatives presented in this section would constitute backfitting under Section 50.109 or affect issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo of the existing regulatory language and guidance, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would clarify the NRC's backfitting and issue finality regulations, which apply to the NRC and not to licensees or applicants. Under Alternative 3, the NRC changes to guidance documents would not affect any requirement or staff position applicable to a licensee or applicant.

3.8 Stakeholder Feedback

3.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

3.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The NRC staff recommends pursuing Alternative 2, "Rulemaking to Eliminate Certain 10 CFR 50.109 Provisions for SDAs, ESPs, and MLs and Revisions to Supporting Guidance," to eliminate the inconsistencies between backfitting provisions in Section 50.109 and issue finality provisions in Part 52 that apply to SDAs, ESPs, and MLs.

APPENDIX K – MISCELLANEOUS TOPICS

This appendix discusses the U.S. Nuclear Regulatory Commission's (NRC's) consideration to amend various regulations applicable to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants" (TN251). These regulations cover the following topics:

- notice of issuance of the Commission finding regarding inspections, tests, analyses, and acceptance criteria (ITAAC) in 10 CFR Part 2, "Agency Rules of Practice and Procedure" (TN6204)
- definitions in 10 CFR Part 21, "Reporting of Defects and Noncompliance" (TN5874), applicable to nuclear power plants licensed under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities" (TN249) and Part 52
- requirements for a plant safety parameter display console in paragraph 50.34(f)(2)(iv)
- change process for the technical specifications bases document in paragraph 50.36(a)(1)
- requirements to estimate the effect of any change to or error in an acceptable evaluation model in paragraph 50.46(a)(3)
- requirements to complete repairs in accordance with American Society of Mechanical Engineers (ASME), *Boiler and Pressure Vessel Code*, Section III (ASME 2019-TN6332) requirements in Section 50.55a, "Codes and standards"
- requirements for completeness and accuracy of information in paragraph 52.6(b)
- requirements to specify the resolution of applicable unresolved safety issues and medium- and high-priority generic safety issues in paragraphs 52.47(a)(21) and 52.79(a)(20)
- requirements for the closeout of ITAAC in paragraph 52.97(a)(2)
- requirements that address reporting the completion of power ascension testing.

1.0 NOTICE OF ISSUANCE IN 10 CFR 2.106(B)(2)(II)

To approve a licensee's operation of a facility under a COL, the Commission must make a finding under paragraph 52.103(g) that "the acceptance criteria in the combined license are met." The requirements for notices of issuance in Section 2.106(b)(2) include that a finding has been made under paragraph 52.103(g). The 2.106(b)(2)(ii) notice requirements include language about paragraph 52.103(g) findings that could be misread to mean that the NRC must make additional findings under paragraph 52.103(g) beyond those findings set forth in paragraph 52.103(g). The NRC is considering whether to revise paragraph 2.106(b)(2)(ii) to reflect the actual language of paragraph 52.103(g).

1.1 Existing Regulatory Framework

The language of paragraph 52.103(g) states, in part, "The licensee shall not operate the facility until the Commission makes a finding that the acceptance criteria in the combined license are met, except for those acceptance criteria that the Commission found were met under 10 CFR 52.97(a)(2)." In comparison, the requirements of paragraph 2.106(b)(2)(ii) provide that a notice of issuance of a finding under paragraph 52.103(g) will be issued when the Commission has not only determined that the acceptance criteria have been met but also that the applicable ITAAC

have been performed and the licensee complies with the requirements of the Atomic Energy Act of 1954, as amended (AEA; 42 U.S.C. § 2011 *et seq.*; TN663) and 10 CFR Chapter I (TN6351), which encompasses the entirety of the NRC's regulations.

1.2 Regulatory Issues

The requirements in paragraph 2.106(b)(2)(ii) that go beyond finding that the acceptance criteria have been met (i.e., a finding that the license complies with the requirements of the AEA and 10 CFR Chapter I) are findings that are made upon the issuance of the COL under Section 52.97 and need not be made again during the paragraph 52.103(g) ITAAC verification process. The regulation in paragraph 52.103(b) provides the public with an opportunity to request a hearing under paragraph 52.103(a) that one or more of the acceptance criteria of the ITAAC in the COL have not been met, or will not be met, and the specific operational consequences of such nonconformance with the ITAAC would mean that there would not be reasonable assurance of adequate protection of public health and safety if the facility were to operate. Although ITAAC hearings are supposed to be narrowly focused on the status of the acceptance criteria, a litigant wishing to challenge operation of the facility under paragraph 52.103(b) may misread paragraph 2.106(b)(2)(ii) to mean that a broad, additional opportunity to raise challenges under the AEA and the Commission's regulations is available during the ITAAC verification process. Even if such challenges may not be within the scope of an ITAAC hearing, if raised, they may require the parties to unnecessarily expend resources to address them.

1.3 Discussion of Alternatives

1.3.1 *Alternative 1: No-Action*

1.3.1.1 *Description of Alternative 1*

Under this alternative, the NRC would not pursue amending the regulations and would retain the current language of paragraph 2.106(b)(2)(ii).

1.3.1.2 *Assessment of Alternative 1*

Alternative 1 would maintain the status quo of differing language regarding regulatory findings in paragraphs 2.106(b)(2)(ii) and 52.103(g). This alternative is contrary to one of the Commission's Principles of Good Regulation (NRC 2014-TN6227), "Clarity," in that it provides conflicting information about the applicable regulatory finding. Moreover, although no practical issues have yet occurred as a result of the conflicting language because no paragraph 52.103(g) findings have been issued and no ITAAC hearings have occurred, a dispute about the applicable regulatory findings could arise during the ITAAC hearing process, which may cause delay and unnecessary resource expenditure.

1.3.2 *Alternative 2: Rulemaking to Amend 10 CFR 2.106(b)(2)(ii) to Conform to the Language of 10 CFR 52.103(g)*

1.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue amending paragraph 2.106(b)(2)(ii) to conform to the language of paragraph 52.103(g) with respect to the necessary regulatory findings.

1.3.2.2 Assessment of Alternative 2

Alternative 2 would harmonize the language in Section 2.106 with the language in paragraph 52.103(g) and promote clarity in the applicable requirements for the issuance of a notice of a finding under paragraph 52.103(g) and legal standards for a paragraph 52.103(g) finding, thereby avoiding unnecessary litigation about whether the requirements have been met.

1.4 Regulatory Scope

The NRC is considering amending paragraph 2.106(b)(2)(ii) to conform to the language of paragraph 52.103(g) with respect to the necessary regulatory findings.

1.5 NRC Guidance, Policy, and Implementation Issues

The NRC has developed draft *Federal Register* notice templates for issuance of the paragraph 52.103(g) findings that conform to the legally correct language for the findings. Thus, the NRC's notices of issuance will reflect the required finding in paragraph 52.103(g), whether or not the NRC pursues rulemaking under Alternative 2. Therefore, no amendments to guidance are needed.

1.6 Impacts

1.6.1 *Alternative 1: No-Action*

1.6.1.1 *Impacts on Public Health, Safety, and Security*

Under this alternative, there would be no increase or reduction in public health, safety, and security.

1.6.1.2 *Impacts on Licensees*

Because Alternative 1 is the status quo, confusion may result about the applicable legal and regulatory standards for the paragraph 52.103(g) finding; thus, there could be a potential for stakeholders to misinterpret the narrow ITAAC hearing opportunity provided in paragraph 52.103(b) and raise broad challenges under the AEA and the Commission's regulations that are outside the scope of an ITAAC hearing. It is possible that these challenges could result in an unnecessary expenditure of resources by the public, NRC, and licensee.

1.6.1.3 *Impacts on the NRC*

The status quo alternative inhibits the NRC's ability to regulate in a coherent, logical, and practical manner by creating ambiguity in the applicable legal and regulatory standards for the paragraph 52.103(g) finding. Thus, stakeholders may misinterpret the nature of the hearing opportunity provided under paragraph 52.103(b). The impact of this misunderstanding may, similar to the potential impact on licensees, cause unnecessary delay in NRC actions and expenditure of resources.

1.6.1.4 *Additional Considerations*

No additional considerations were identified under this alternative.

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

1.6.2 Alternative 2: Rulemaking to Amend 10 CFR 2.106(b)(2)(ii) to Conform to the Language of 10 CFR 52.103(g)

1.6.2.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no increase or reduction in public health, safety, and security because the recommended changes to the language in paragraph 2.106(b)(2)(ii) would better align with the language of paragraph 52.103(g).

1.6.3 Impacts on Licensees

Under Alternative 2, the conflict between the language of paragraphs 2.106(b)(2)(ii) and 52.103(g) would be resolved and would promote regulatory clarity that should avoid stakeholder misreading of the applicable regulatory standards that could result in unnecessary litigation that consumes time and resources because of confusion related to the scope of issues within the scope of the proceeding. The NRC did not quantify this potential burden reduction on licensees.

1.6.4 Impacts on the NRC

Under this rulemaking alternative, the conflict between the language of paragraphs 2.106(b)(2)(ii) and 52.103(g) would be resolved and would enable the NRC to clarify the applicable regulatory finding, consistent with one of the Principles of Good Regulation, “Clarity.” Clarifying this language may also reduce the potential of unnecessary litigation occurring as a result of a misunderstanding of the applicable regulatory findings. Alternative 2 would result in rulemaking costs to the NRC of approximately (\$32,000) using a 7 percent net present value (NPV) and (\$37,000) using a 3 percent NPV, as shown in Table K-1.

Table K-1 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

1.6.5 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

1.6.6 Summary of Benefits and Costs

This alternative would result in net costs to the NRC of (\$32,000) using a 7 percent NPV. However, this rulemaking change would avoid some situations in which a petitioner requests a hearing on issues that are outside the scope of an ITAAC proceeding. The staff estimates that

if this situation occurred, the time spent by the petitioner, the NRC, and the Commission could approach the rulemaking costs estimated in Table K-1.

1.7 Backfitting and Issue Finality Considerations

Neither of the alternatives presented by the NRC in this appendix section, if implemented by the NRC, would constitute backfitting under Section 50.109, “Backfitting,” or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, and Alternative 2 would clarify in paragraph 2.106(b)(2)(ii) when a notice of issuance of a paragraph 52.103(g) finding can be issued, thereby clarifying the legal standard that must be met for the Commission to make the finding. Neither alternative would impose on licensees a change in requirements or NRC staff positions, so neither alternative would constitute backfitting under Part 50 or affect issue finality of an approval issued under Part 52.

1.8 Stakeholder Feedback

1.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking (NRC 2019-TN6224). There were no comments or suggestions related to this matter.

1.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

1.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Amend paragraph 2.106(b)(2)(ii) to Conform to the Language of 10 CFR 52.103(g).” Amending paragraph 2.106(b)(2)(ii) to conform to the language of paragraph 52.103(g) properly aligns requirements related to the regulatory finding to be made with respect to approving operation under a COL.

2.0 DEFINITIONS IN 10 CFR 21.3

The regulations in Part 21 apply to individuals and entities that construct a production or utilization facility licensed for manufacture, construction, or operation under Parts 50 and 52. The definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” in Section 21.3, “Definitions,” are applicable to holders of licenses issued under Parts 50 and 52; however, these terms do not explicitly state their applicability to Part 52 licensees. The NRC is considering whether to amend the regulations to clarify the applicability of these terms to licensees under Part 52 by referencing this part in the definitions.

2.1 Existing Regulatory Framework

The regulations in Section 21.3 define the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” for applicability in Part 21 and other parts

of the regulations. However, unlike other definitions in this section that apply to Part 52 licensees, these terms do not explicitly state their applicability to Part 52 licensees.

Section 50.55, “Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses,” contains conditions of construction permits (CPs) issued under Part 50 and early site permits (ESPs), COLs, and MLs issued under Part 52. Paragraph 50.55(e)(1), “Definitions,” states that, for purposes of paragraph 50.55(e), the definitions in Section 21.3 apply.

2.2 Regulatory Issues

During the revision of Part 21 to address its applicability to Part 52 licensees (72 FR 49352, August 28, 2007; TN4796), the NRC unintentionally omitted “10 CFR Part 52,” from the definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” in Section 21.3. This omission created inconsistencies with other definitions in Section 21.3 that are applicable to Part 52 licensees. In addition, the inconsistencies may result in confusion and expenditure of unnecessary resources to address the applicability of these terms for an ESP, a COL, and an ML.

2.3 Discussion of Alternatives

2.3.1 *Alternative 1: No-Action*

2.3.1.1 *Description of Alternative 1*

Under this alternative, the NRC would not pursue amending its regulations and the language in the current regulations would remain.

2.3.1.2 *Assessment of Alternative 1*

Alternative 1 would maintain the applicability of the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” to nuclear power plants licensed under only Part 50.

2.3.2 *Alternative 2: Rulemaking to Amend 10 CFR 21.3 to Include Activities Under Part 52*

2.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue amending the regulations in Section 21.3 to add Part 52 to the definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication.”

2.3.3 *Assessment of Alternative 2*

Alternative 2 would address the inconsistencies in the regulations by clearly identifying the applicability of the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” to Part 52 licensees. In addition, this alternative would reduce confusion and resources expended to address the existing inconsistencies in the regulations, including Section 50.55, which references the definitions in Section 21.3.

2.4 Regulatory Scope

The NRC is considering amending the regulations in Section 21.3 to reference Part 52 in the definitions of “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” to clarify their applicability to Part 52 licensees.

2.5 NRC Guidance, Policy, and Implementation Issues

2.5.1 NRC Guidance

The NRC does not plan to develop new regulatory guidance as part of the actions for resolving the issue. The 2018 issuance of Regulatory Guide (RG) 1.234 (NRC 2018-TN6309), “Evaluating Deviations and Reporting Defects and Noncompliance Under Part 21,” endorses the Nuclear Energy Institute (NEI) document, NEI 14-09 (NEI 2016-TN6314), “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance.” A section in NEI 14-09 entitled, “Clarification of Dedication for Part 52,” states:

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

Thus, Alternative 2 would align with existing guidance in RG 1.234 and NEI 14-09.

2.5.2 Policy Issues

Under Alternative 2, no policy issue would need to be brought to the Commission. Alternative 2 would add clarity to the definitions applicable to Parts 50 and 52 licensees.

2.6 Impacts

2.6.1 Alternative 1: No-Action

2.6.1.1 Impacts on Public Health, Safety, and Security

Under the “no-action” alternative, there would be no increase or reduction in public health, safety, and security.

2.6.1.2 Impacts on Licensees

Under this alternative, there would be no significant impact on licensees. The inconsistencies in the regulations would remain, but the existing guidance in RG 1.234 and NEI 14-09 would continue to guide applicants and licensees.

2.6.1.3 Impacts on the NRC

Under this alternative, there would be no significant impact on the NRC. The inconsistencies in the regulations would remain, but the existing guidance in RG 1.234 and NEI 14-09 would continue to apply the definitions to Parts 50 and 52 licensees.

2.6.1.4 Additional Considerations

No additional considerations were identified under this alternative. This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

2.6.2 Alternative 2: Rulemaking to Amend 10 CFR 21.3 to Include 10 CFR Part 52 Licensees

Under Alternative 2, the NRC would undertake a rulemaking to clarify the applicability of the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” in Section 21.3, to Part 52 licensees.

2.6.2.1 Impacts on Public Health, Safety, and Security

Because Alternative 2 would not change any NRC process and would add clarity to the definitions in Part 21, there would be no increase or reduction in public health, safety, and security.

2.6.2.2 Impacts on Licensees

Under Alternative 2, a potential benefit to entities unfamiliar with application of the regulation would result from improved clarity of the applicability of terms. There would likely be minimal impact on licensees because the existing guidance in RG 1.234 and NEI 14-09 provides clarity on the use of these terms, but this rulemaking alternative would provide regulatory certainty.

2.6.2.3 Impacts on the NRC

Under Alternative 2, the NRC would have incremental costs to undertake rulemaking to amend Section 21.3. These costs would be approximately (\$65,000) using a 7 percent NPV and (\$74,000) using a 3 percent NPV, as shown in Table K-2.

Table K-2 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
Total:					(\$81,937)	(\$64,846)	(\$73,925)

2.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

2.6.2.5 Summary of Benefits and Costs

Alternative 2 would result in a net cost to the NRC of approximately (\$65,000) using a 7 percent NPV.

2.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC in this appendix section, if implemented by the NRC, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would clarify the applicability of certain definitions in NRC reporting requirements. Reporting requirements such as the Part 21 requirements discussed in this appendix section do not meet the definition of backfitting and therefore are not within the scope of the NRC’s backfitting and issue finality requirements. Therefore, Alternative 2 would not constitute backfitting or affect issue finality.

2.8 Stakeholder Feedback

2.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

2.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

2.9 STAFF RECOMMENDATION

The NRC staff recommends Alternative 2, “Rulemaking to Amend Section 21.3 to Include Activities Under Part 52.” Amending the regulations in 10 CFR 21.3 would clarify the applicability of the terms “Commercial grade item,” “Critical characteristics,” “Dedicating entity,” and “Dedication” to Part 52 licensees.

3.0 REQUIREMENT FOR SAFETY PARAMETER DISPLAY SYSTEM CONSOLE IN 10 CFR 50.34(F)(2)(IV)

After the 1979 accident at Three Mile Island (TMI), Unit 2, the NRC issued NUREG-0660, Volume 1, "NRC Action Plan Developed as a Result of the TMI-2 Accident," (TMI Action Plan; TN6319). NUREG-0660, Action Item I.D.2, required operating reactors and plants under construction to have a plant safety parameter display console. To meet the TMI Action Plan requirement, licensees operating facilities subject to the Action Plan retrofitted their existing control rooms with a stand-alone, console-based, Safety Parameter Display System (SPDS). Action Item I.D.2 was later added to the NRC's regulations. The NRC is considering whether to amend that regulation to clarify the provision requiring a "console" in light of advances in human-system interface technology that have resulted in effective alternatives to stand-alone consoles for displaying important plant parameters and trends (e.g., integrated digital displays).

3.1 Existing Regulatory Framework

In Part 52 applicants for a standard design certification (DC), COL, standard design approval (SDA), or ML are required by paragraphs 52.47(a)(8), 52.79(a)(17), 52.137(a)(8), and 52.157(f)(12), respectively, to provide information in their applications necessary to demonstrate compliance with any technically relevant portions of the requirements in paragraph 50.34(f), "Additional TMI-related requirements." The regulation in paragraph 50.34(f)(2)(iv) requires that each applicant "[p]rovide a plant safety parameter display console that will display to operators a minimum set of parameters defining the safety status of the plant, capable of displaying a full range of important plant parameters and data trends on demand, and capable of indicating when process limits are being approached or exceeded."

3.2 Regulatory Issues

The current regulatory language in paragraph 50.34(f)(2)(iv) requiring a "console" does not clearly convey the range of SPDS design options acceptable to the NRC. The primary purpose of the SPDS is to present information that personnel can use to determine the safety status of a nuclear power plant during normal, abnormal, and emergency conditions, including severe accidents, and to determine whether conditions warrant corrective actions by operators to avoid or mitigate a degraded core. Revising the regulation to remove the term "console" will better convey that the purpose of the SPDS requirements is functional and not necessarily focused on whether there is a dedicated console. Multiple DC applicants have previously requested and been granted exemptions from the console requirement, and the Advanced Power Reactor 1400 (APR1400) DC proceeding (84 FR 23439, May 22, 2019; TN6255) was the first in which the NRC found an SPDS design without a stand-alone console to be acceptable. For the APR1400 design, the NRC found that sufficient functions for processing and displaying information in the control room digital display obviated the need for a separate SPDS console. Amending the regulations to remove the term "console" would avoid creating a perceived need for exemptions in the future and, therefore, reduce unnecessary burden on applicants and the NRC.

3.3 Discussion of Alternatives

3.3.1 Alternative 1: No-Action

3.3.1.1 Description of Alternative 1

Under this alternative, the NRC would not pursue rulemaking and the current rule language in paragraph 50.34(f)(2)(iv) that uses the terminology “Provide a plant safety parameter display console...” would remain.

3.3.1.2 Assessment of Alternative 1

Under the “no-action” alternative, the current regulatory language may lack clarity about whether an applicant with a non-stand-alone SPDS design that meets applicable functional requirements may require an exemption because some past DC applicants have read the requirement that way. In addition, because the language does not clearly communicate the functional requirement, inefficient communications among the NRC, applicants, and stakeholders may result.

3.3.2 Alternative 2: Rulemaking to Amend 10 CFR 50.34(f)(2)(iv)

3.3.2.1 Description of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to amend paragraph 50.34(f)(2)(iv) to remove the requirement for an SPDS console but retain the SPDS functional requirement.

3.3.2.2 Assessment of Alternative 2

Under this rulemaking alternative, the regulations would address the regulatory issue by retaining the overarching purpose of the console requirement while removing technology-specific terminology and alleviate the need for an applicant to pursue an unnecessary exemption.

3.4 Regulatory Scope

Under Alternative 2, the NRC would amend paragraph 50.34(f)(2)(iv) to eliminate the requirement for a stand-alone console but not change the functional requirement for the display of safety parameters.

3.5 NRC Guidance, Policy, and Implementation Issues

3.5.1 NRC Guidance

The NRC published SPDS review guidance in NUREG-0737 (Supplement 1), “Clarification of TMI Action Plan Requirements”(NRC 1983-TN5967); NUREG-0696, “Functional Criteria for Emergency Response Facilities” (NRC 1981-TN5966); and NUREG-0835, “Human Factors Acceptance Criteria for the Safety Display System” (NRC 1981-TN6323). The NRC followed up with additional clarifications in NUREG/CR-4797, “Progress Reviews of Six Safety Parameter Display Systems” (Liner and DeBor 1986-TN6390) issued in 1986, and NUREG-1342, “A Status Report Regarding Industry Implementation of Safety Parameter Display System” (NRC 1989-TN6322) issued in April 1989.

The NRC has since consolidated guidance for the review of an SPDS in NUREG-0700, “Human-System Interface Design Review Guidelines,” Revision 2 (NRC 2002-TN6324), and recently updated that guidance in NUREG-0700, Revision 3 (NRC 2019-TN6347), for applicability to instances in which the SPDS has been integrated in a control room design in a manner other than as a stand-alone console. Because NUREG-0700 has consolidated the human factors engineering review guidance for an SPDS, and that guidance no longer presumes a stand-alone console, no additional guidance or guidance revisions would be required to support the rulemaking discussed under Alternative 2.

3.5.2 *Policy Issues*

Under Alternative 2, the NRC regulations would be amended to clarify that an acceptable SPDS design involves meeting functional SPDS requirements. The NRC has previously found SPDS designs that do not include a stand-alone console to be acceptable in several DC proceedings, either by granting an exemption from the “console” requirement or, in the recent APR1400 DC, by finding the SPDS DC acceptable during the staff’s review. As a result, Alternative 2 does not affect a current policy, create a conflict between policies, or create an unresolved policy issue. Therefore, there would be no policy issue that would need to be brought to the Commission.

3.6 **Impacts**

3.6.1 *Alternative 1: No-Action*

3.6.1.1 *Impacts on Public Health, Safety, and Security*

Under the status quo alternative, there would be no change in requirements and, therefore, no increase or reduction in public health, safety, and security.

3.6.1.2 *Impacts on Licensees*

Under the “no-action” alternative, the NRC would not pursue amending the regulations and applicants would continue to perceive the need for an exemption and potentially expend resources unnecessarily.

3.6.1.3 *Impacts on the NRC*

Under the “no-action” alternative, the NRC would continue to expend resources to respond to applicant requests for clarification on and possible exemptions from SPDS requirements.

3.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.1.5 *Summary of Benefits and Costs*

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

3.6.2 *Alternative 2: Rulemaking to Amend 10 CFR 50.34(f)(2)(iv)*

3.6.2.1 *Impacts on Public Health, Safety, and Security*

This alternative would result in no change to the substantive requirement and, therefore, no increase or reduction in public health, safety, and security.

3.6.2.2 *Impacts on Licensees*

Alternative 2 would reduce the burden on applicants to seek clarification or apply for an exemption from paragraph 50.34(f)(2)(iv). This alternative would have a one-time administrative burden reduction of approximately 60 hours for each applicant. For the purposes of this analysis, the NRC assumed one exemption request would be averted per year from the issuance of the final rule through 2030, after which the estimate becomes too speculative. This change could facilitate the ability of licensees to better integrate an SPDS into other displays, thereby enabling a more cost-effective design that could better support reliable operator performance and monitoring of plant parameters under accident conditions. Alternative 2 would result in averted costs to licensees of approximately \$32,000 (7 percent NPV) and \$45,000 (3 percent NPV), as shown in Table K-3.

Table K-3 Industry Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024-2030	Averted exemption request from licensee	7	62	\$134	\$57,968	\$31,820	\$44,506
Total:					\$57,968	\$31,820	\$44,506

3.6.2.3 *Impacts on the NRC*

Alternative 2 would reduce the resources needed for reviewing and approving unnecessary exemption requests. The NRC would see an incremental cost saving in time and resources. There would be a one-time cost to the NRC to undertake the rulemaking to amend paragraph 50.34(f)(2)(iv). Alternative 2 would result in costs to the NRC of approximately (\$17,000) using a 7 percent NPV and (\$15,000) using a 3 percent NPV, as shown in Table K-4.

Table K-4 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024-2030	Averted NRC review of exemption request	7	31	\$131	\$28,274	\$15,520	\$21,708
Total:					(\$12,695)	(\$16,828)	(\$15,238)

3.6.2.4 *Additional Considerations*

No additional considerations were identified under this alternative. This alternative would have no incremental impacts on State, local, or Tribal governments.

3.6.2.5 *Summary of Benefits and Costs*

Alternative 2 would result in net averted costs to industry and the NRC of approximately \$15,000 using a 7 percent NPV and \$29,000 using a 3 percent NPV, due to rulemaking costs.

3.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would not apply to existing licensees or applicants within the scope of backfitting or issue finality provisions. Therefore, neither of these alternatives would constitute backfitting or affect issue finality.

3.8 Stakeholder Feedback

3.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

3.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

3.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Amend 10 CFR 50.34(f)(2)(iv),” to remove the requirement for an SPDS console but retain the requirement for the SPDS function. This alternative would provide benefits to future applicants for nuclear power plants. The NRC would incur the costs of amending regulations and the net result would be an averted cost of approximately \$15,000 (7 percent NPV) to industry and the NRC.

4.0 TECHNICAL SPECIFICATIONS BASES CONTROL PRIOR TO THE 10 CFR 52.103(G) FINDING

The regulations in Section 50.36, “Technical specifications,” require an applicant to propose technical specifications (TSs) in its application for a DC, an ML, or a license authorizing operation of a production or utilization facility. These regulations also require that the application for a license authorizing operation of a production or utilization facility include “a summary statement of the bases or reasons for such specifications, other than those covering administrative controls.” This “summary statement” is typically provided in a TS bases document. For COL holders, the regulations in Part 52 and existing NRC guidance do not address the change process for revising the plant-specific TS bases document during the period after COL issuance until the Commission’s finding under paragraph 52.103(g) that authorizes operation of the facility. During this time, current COL holders may elect, but are not required, to implement the TSs Bases Control Program in Section 5.5, “Programs and Manuals,” of their plant-specific TSs, to effect changes to the plant-specific TS bases document. Implementing the TSs Bases Control Program is not required because a license condition in each of the existing COLs states that the plant-specific TSs (including the TSs Bases Control Program) are not in effect until after the paragraph 52.103(g) finding has been made. To address this period of no defined regulatory controls for changing the plant-specific TS bases document, the NRC is

considering amending the regulations to clarify the process by which a COL holder would implement changes to the plant-specific TS bases document prior to the paragraph 52.103(g) finding being made.

4.1 Existing Regulatory Framework

Paragraph 52.79(a)(30) requires a COL application to contain a final safety analysis report (FSAR) with proposed TSs “prepared in accordance with the requirements of §§ 50.36 and 50.36a.” For COL applications, paragraph 50.36(a)(1) requires the inclusion of proposed TSs and a “summary statement of the bases or reasons for such specifications, other than those covering administrative controls,” but the bases do not become part of the TSs.

In DC/COL-ISG-008, “Final Interim Staff Guidance Necessary Content of Plant-Specific Technical Specifications When a Combined License Is Issued” (NRC 2008-TN6327), the NRC clarified its position that the plant-specific TSs issued with a COL must be usable for facility operation when the COL is issued to satisfy Section 182a of the AEA, which requires that applicants for nuclear power plant operating licenses will state (emphasis added) the following:

[S]uch technical specifications, including information of the amount, kind, and source of special nuclear material required, the place of the use, the specific characteristics of the facility, and such other information as the Commission may, by rule or regulation, deem necessary in order to enable it to find that the utilization... of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public. *Such technical specifications shall be a part of any license issued.*

Appendix A of a COL contains the plant-specific TSs that govern the licensee’s operation of the nuclear power plant to ensure that the assumptions relied upon in the plant’s FSAR will be maintained valid throughout the operating life of the plant. Appendix A also includes the plant-specific TSs for administrative controls as required by paragraph 50.36(c)(5). The TSs Bases Control Program in plant-specific TS Section 5.5, “Programs and Manuals,” of COL Appendix A, specifies a process for making changes to the plant-specific TS bases document.

Consistent with the NRC guidance in Volume 1, “Specifications,” and Volume 2, “Bases,” of each of the Standard Technical Specifications (STs),¹ bases are only provided for plant-specific TS Chapter 2, “Safety Limits,” as required by paragraph 50.36(c)(1), which requires TSs for safety limits; plant-specific TS Chapter 3, “Limiting Conditions for Operation (LCOs),” as required by paragraph 50.36(c)(1), which requires TSs for limiting safety system settings; and paragraph 50.36(c)(2), which requires TSs for operational limits, system operability requirements, and action requirements; and paragraph 50.36(c)(3), which requires TSs for surveillance requirements. Also consistent with STs, bases are not provided for TS requirements in plant-specific TS Chapter 1, “Use and Application,” which establishes the rules for applying the specifications in the other plant-specific TS chapters; Chapter 4, “Design

¹ NUREGs 1430, “Standard Technical Specifications: Babcock and Wilcox Plants” (TN6349); 1431, “Standard Technical Specifications: Westinghouse Plants” (TN6350); 1432, “Standard Technical Specifications: Combustion Engineering Plants” (TN6353); 1433, “Standard Technical Specifications: General Electric BWR/4 Plants” (TN6354); 1434, “Standard Technical Specifications: General Electric BWR/6 Plants” (TN6355); and 2194, “Standard Technical Specifications: Westinghouse Advanced Passive 1000 (AP1000) Plants”(TN6356).

Features,” which are specifications required by paragraph 50.36(c)(4); and Chapter 5, “Administrative Controls,” which are specifications required by paragraph 50.36(c)(5).

To date, COLs issued by the Commission explicitly state that plant-specific TSs, which constitute Appendix A of a COL, will not become effective for a facility licensed under Part 52 until the Commission has made the finding prescribed by paragraph 52.103(g). For example, paragraph 2.D(9) of the COL for Vogtle Electric Generating Plant Units 3 and 4 (VEGP 3&4) states, in part:

The [plant-specific] technical specifications in Appendix A to this license become effective upon a Commission finding that the acceptance criteria in this license (ITAAC) are met in accordance with 10 CFR 52.103(g).

In accordance with paragraph 52.98(c), the COL holder may update or change the FSAR before the paragraph 52.103(g) finding, which authorizes the COL holder to operate the plant. FSAR changes are governed by paragraph 52.98(c), which references the change process in the COL’s referenced DC rule Appendix to Part 52. Changes to design control document (DCD) Tier 1 and Tier 2 information, which is incorporated in the FSAR, are governed by Section VIII of the referenced DC rule. Changes to site-specific information in the FSAR are governed by the applicable Part 50 change processes. If criteria established by these change requirements are satisfied, a licensee may make FSAR changes without prior NRC approval. The licensee may also make changes to plant-specific TSs before the paragraph 52.103(g) finding through a license amendment under Section 50.90, “Application for amendment of license, construction permit, or early site permit.” For example, a COL holder for an Advanced Passive 1000 (AP1000) plant may make changes to the plant-specific TSs under Part 52, Appendix D, “Design Certification Rule for the AP1000 Design,” Section VIII, “Processes for Changes and Departures,” Subsection C, “Operational Requirements,” paragraph 6, which states, “Changes to plant-specific TSs will be treated as license amendments under § 50.90.”

The NRC and COL applicants have taken the position that the intent of the phrase “in accordance with the requirements of... 50.36,” in paragraph 52.79(a)(30) requires that the TS bases document included in the COL application in accordance with paragraph 50.36(a)(1) be the bases for the plant-specific TSs. The COL applicant proposes plant-specific TSs based on the information in the FSAR and summarizes the reasons for such TSs in the plant-specific TS bases document. During its review of a COL application, the NRC confirms the fidelity of the plant-specific TS bases with the more detailed information about the facility in the FSAR.

4.2 Regulatory Issues

The regulations do not address changes to plant-specific TS bases, whether to correct editorial and technical errors, improve readability and clarity, or otherwise improve quality apart from any plant-specific TS changes or plant design changes. For a COL, the plant-specific TS administrative controls become effective after the Commission’s paragraph 52.103(g) finding has been made. The TSs Bases Control Program applies the provisions of 10 CFR 50.59 to such bases changes. This regulation stipulates when prior NRC approval of a plant-specific TS bases change through a license amendment under Section 50.90 is required. However, most changes to plant-specific TS bases do not require prior NRC approval if the stipulated criteria are met. The TSs Bases Control Program also requires maintaining the bases consistent with the updated FSAR.

However, before the Commission's paragraph 52.103(g) finding has been made, a COL holder may elect, but is not required, to implement the TSs Bases Control Program, which is not in effect until the paragraph 52.103(g) finding has been made.

The license condition in each COL issued to date states that the plant-specific TSs, as amended, become effective when the Commission makes its paragraph 52.103(g) finding; this is because TSs pertain to assuring safe facility operation after the plant is built. Adequate protection of public health and safety is reasonably ensured by operating the facility in accordance with the plant-specific TSs, as amended, and other conditions stated in the COL, because the paragraph 52.103(g) finding provides reasonable assurance that the facility has been constructed as stipulated in the referenced certified design rule, approved exemptions, and the updated FSAR. But this license condition left the plant-specific TS bases without a defined change control process between COL issuance and the paragraph 52.103(g) finding.

Based on the applicable regulations for TSs described above, there is no guidance on the change process applicable to plant-specific TS bases independent of any plant-specific TS changes or plant design changes that require a license amendment, during the period between issuance of the COL and the Commission's paragraph 52.103(g) finding. A change process for the plant-specific TS bases exists in Appendix A of the COL, but it is not effective until after the authorizing facility operation finding has been made.

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

Before the paragraph 52.103(g) finding, a COL holder could change the plant-specific TS bases without prior NRC approval contrary to the restrictions of the TSs Bases Control Program, or could fail to maintain the plant-specific TS bases consistent with the FSAR. Under the current regulations, without a requirement for a bases change process prior to the paragraph 52.103(g) finding, existing COL holders risk making bases changes without prior NRC approval that would require a license amendment under the requirements in effect after the paragraph 52.103(g) finding. After the plant-specific TSs are made effective by the paragraph 52.103(g) finding, the TSs Bases Control Program would also become effective. Because the program specifies that changes to the bases implemented without prior NRC approval shall be periodically² provided to the NRC, eventually, such changes and inconsistencies in the plant-specific TS bases would come to light and the bases would need to be brought into conformance with the program's requirements. A licensee could avoid such issues by voluntarily adhering to the program's

² Paragraph d of TSs Bases Control Program requires submission of bases updates consistent with the FSAR update schedule of Paragraph 50.71(e) of 10 CFR 50.71, "Maintenance of records, making of reports." Paragraph 50.71(e)(3)(iii) states, "During the period from the docketing of an application for a combined license under subpart C of part 52 of this chapter until the Commission makes the finding under § 52.103(g) of this chapter, the update to the FSAR must be submitted annually." Paragraph 50.71(e)(4) states, "Subsequent revisions must be filed annually or 6 months after each refueling outage provided the interval between successive updates does not exceed 24 months. The revisions must reflect all changes up to a maximum of 6 months prior to the date of filing." Providing bases updates in accordance with this schedule ensures that paragraph c of the TSs Bases Control Program is met. Paragraph c states, "The Bases Control Program shall contain provisions to ensure that the Bases are maintained consistent with the FSAR."

requirements after COL issuance until the paragraph 52.103(g) finding. Assuring that information about program requirements and their timing is available to both existing and future COL holders would be beneficial.

4.3 Discussion of Alternatives

4.3.1 Alternative 1: No-Action

4.3.1.1 Description of Alternative 1

Under this alternative, the current regulatory structure would remain in place in which plant-specific TS bases control is not addressed during the period between the issuance of a COL and the Commission's finding under paragraph 52.103(g). Future COLs would include the currently used license condition, which makes the plant-specific TSs effective with the paragraph 52.103(g) finding.

4.3.1.2 Assessment of Alternative 1

Under Alternative 1, the regulatory issue would remain and the method and control of changing the plant-specific TS bases would be at the licensee's discretion. In addition, conformance of the plant-specific TS bases with the FSAR and accuracy of the TS summary description would not be ensured.

However, sufficient incentive exists under the status quo for present and future COL holders to voluntarily keep the plant-specific TS bases consistent with the updated FSAR and the plant-specific TSs, as amended, during plant construction. That incentive is to avoid a delay in initial fuel loading after the Commission's paragraph 52.103(g) finding potentially caused by (1) the administrative burden on the licensee to achieve compliance with the TSs Bases Control Program by reconciling the plant-specific TS bases with the potentially many significant changes, made during facility construction, to the licensing basis, facility design, and plant-specific TSs; (2) the time that the NRC would need to verify the quality and accuracy of the plant-specific TS bases, upon which the NRC's endorsement of the facility's readiness to load fuel is partially contingent; and (3) performance of corrective action for a TSs Bases Control Program noncompliance identified by the NRC's oversight program.

4.3.2 Alternative 2: Rulemaking to Amend 10 CFR Part 52 to Include a Change Process for Plant-Specific TS Bases

4.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to amend the regulations in each appendix to Part 52 to use the TSs Bases Control Program in Appendix A of the COL for plant-specific TS bases changes before the paragraph 52.103(g) finding. Specifically, the NRC would amend the language in paragraph VIII.C.6 of each unexpired appendix to Part 52 to state, "After issuance of a license, the generic (DCD) TSs have no further effect on the plant-specific TSs. Changes to plant-specific TSs will be treated as license amendments under 10 CFR 50.90. After issuance of a license, changes to the plant-specific TS bases will be controlled by the TSs Bases Control Program in Section 5.5, 'Programs and Manuals,' of the plant-specific TSs."

4.3.2.2 Assessment of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to amend the regulations to remove uncertainty regarding the requirements for making changes to the plant-specific TS bases and when the requirements would take effect. This rulemaking alternative would address the regulatory issue by eliminating the inconsistencies raised by having plant-specific TSs that are usable for facility operation when the COL is issued to satisfy Section 182a of the AEA, and at the same time not having the plant-specific TSs in effect until after the paragraph 52.103(g) finding is made.

4.3.3 *Alternative 3: Revise Guidance to Encourage Existing and Future COL Holders to Voluntarily Implement an Effective Process for Maintaining the Plant-Specific TS Bases Consistent with the Plant Design, the Updated FSAR, and the Plant-Specific TSs as Amended.*

4.3.3.1 Description of Alternative 3

The plant-specific TS regulatory structure for controlling changes to plant-specific TS bases would remain in place, as under Alternative 1, but the NRC would update staff guidance about such controls outside of rulemaking. This alternative would establish guidance that the COL holder voluntarily maintain the plant-specific TS bases consistent with changes to the plant design, the FSAR, and the plant-specific TSs as such changes occur between COL issuance and authorization of plant operation. The guidance would encourage COL holders to voluntarily implement the TSs Bases Control Program before the paragraph 52.103(g) finding. The guidance would emphasize that as of the paragraph 52.103(g) finding being made, the COL holder must have brought the plant-specific TS bases into conformance with the TSs Bases Control Program of plant-specific TS Section 5.5.

Future COL holders would be allowed to propose an updated license condition about when the plant-specific TSs become effective, so that the TSs Bases Control Program becomes effective upon COL issuance. The revised license condition would be consistent with the change indicated by underlined text in the following passage:

The [plant-specific] technical specifications in Appendix A to this license become effective upon a Commission finding that the acceptance criteria in this license (ITAAC) are met in accordance with 10 CFR 52.103(g); ~~except that the TS[s]~~ Bases Control Program in [plant-specific] technical specification section 5.5, "Programs and Manuals," becomes effective upon issuance of this license.

4.3.3.2 Assessment of Alternative 3

Current and future COLs would have an incentive to avoid delaying the initial fuel loading, as described above under the first alternative. The contemplated changes would establish guidance that COL holders voluntarily maintain the plant-specific TS bases in conformance with changes to the plant's design and licensing basis, and plant-specific TSs may reduce the licensee resources needed to achieve compliance with the TSs Bases Control Program, thereby assuring bases of adequate quality.

A revised license condition for when plant-specific TSs become effective would remove the gap in requirements for future COL holders for controlling changes to plant-specific TS bases during the period between when the COL is issued and when the paragraph 52.103(g) finding is made.

4.4 Regulatory Scope

If Alternative 2 is selected, the NRC would pursue amending the regulations in paragraph VIII.C.6 of each unexpired appendix to Part 52 to include a TS bases change process for the period between COL issuance and the paragraph 50.103(g) finding.

If Alternative 3 is selected, the NRC would revise existing guidance.

4.5 NRC Guidance, Policy, and Implementation Issues

4.5.1 NRC Guidance

Under Alternatives 2 and 3, the NRC would update existing guidance in RG 1.206, Revision 1, “Applications for Nuclear Power Plants” (NRC 2018-TN6192), to state that after issuance of a license, changes to the plant-specific TS bases will be controlled (under Alternative 2), or should be controlled (under Alternative 3) by the TSs Bases Control Program in Section 5.5, “Programs and Manuals,” of the plant-specific TSs.

4.5.2 Policy Issues

Under the alternatives discussed above, no policy issues would need to be brought to the Commission.

4.6 Impacts

4.6.1 7.1 Alternative 1: No-Action

4.6.1.1 Impacts on Public Health, Safety, and Security

Under the “no-action” alternative, the NRC would not pursue changes to the current requirements; therefore, there would be no increase or reduction in public health, safety, and security.

4.6.1.2 Impacts on Licensees

Under the “no-action” alternative, there would be no incremental impacts on the licensee because the plant-specific TS bases would continue to be updated at the licensee’s discretion. The licensees would continue to meet the current requirements to submit changes to its plant-specific TSs as license amendment requests (LARs) for NRC approval.

4.6.1.3 Impacts on the NRC

Under the “no-action” alternative, there would be no incremental impacts on the NRC because the plant-specific TS bases would continue to be updated at the licensee’s discretion. The NRC would continue to review changes to plant-specific TSs submitted as LARs as required by the current regulations.

4.6.1.4 Additional Considerations

No additional considerations were identified under this alternative. This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

4.6.2 *Alternative 2: Rulemaking to Amend 10 CFR Part 52 to Include a Change Process for TS Bases*

4.6.2.1 *Impacts on Public Health, Safety, and Security*

Under the rulemaking alternative, there would be no incremental increase or reduction in public health, safety, and security because the changes to the regulations would provide certainty and consistency as to the control of TS bases changes.

4.6.2.2 *Impacts on Licensees*

Under the rulemaking alternative, there would be no impact on licensees that have voluntarily performed changes to the plant-specific TS bases in accordance with the TSs Bases Control Program included in Section 5.5, "Programs and Manuals," of the plant-specific TSs, and future COL holders.

Requiring the use of the TSs Bases Control Program by existing and future COL holders to manage changes to the plant-specific TS bases would reduce future and existing COL holders' risk of incurring delays in the initial fuel load resulting from TS Bases Control Program violations related to plant-specific TS bases that had diverged from the plant-specific TS or the updated FSAR prior to the Commission's findings under paragraph 52.103(g). This reduction in schedule risk would likely offset the licensee's cost of implementing the TSs Bases Control Program at license issuance until the paragraph 52.103(g) finding.

Overall, the rulemaking alternative would reduce the possibility of a plant-specific TS misinterpretation and nonconformance. The NRC did not quantify this potential burden reduction.

4.6.2.3 *Impacts on the NRC*

Under this rulemaking alternative, the contemplated changes to the regulations would provide the NRC with confidence that plant-specific TS bases changes are vetted through an acceptable process and would decrease the likelihood that errors would be introduced into the plant-specific TS bases that would require later correction. Overall, the rulemaking alternative may reduce the NRC resources needed to review TS bases changes after the paragraph 52.103(g) finding. Alternative 2 would result in rulemaking costs to the NRC of approximately (\$106,000) using a 7 percent NPV and (\$121,000) using a 3 percent NPV, as shown in Table K-5.

Table K-5 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2022	Develop Reg Guide for Proposed Rule	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024	Develop/Issue Reg Guide for Final Rule	1	204	\$131	(\$26,740)	(\$19,066)	(\$23,066)
Total:					(\$135,418)	(\$105,739)	(\$121,462)

4.6.2.4 Additional Considerations

No additional considerations were identified under the rulemaking alternative. This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.2.5 Summary of Benefits and Costs

Under Alternative 2, the benefits would be elimination of uncertainty regarding requirements for making changes to the plant-specific TS bases between the issuance of the COL and the paragraph 52.103(g) finding. Using a proven standard approach to controlling changes to plant-specific TS bases would assure the bases are maintained consistent with the updated FSAR and plant design during plant construction before the plant-specific TS operational programmatic specifications become effective. Alternative 2 would result in rulemaking costs to the NRC of (\$106,000) using a 7 percent NPV.

4.6.3 Alternative 3: Revise Guidance to Encourage Existing and Future COL Holders to Voluntarily Implement an Effective Process for Maintaining the Plant-Specific TS Bases Consistent with the Plant Design, the Updated FSAR, and the Plant-Specific TS as Amended

4.6.3.1 Impacts on Public Health, Safety, and Security

Under this alternative, there would be no increase or reduction in public health, safety, and security because the NRC would not pursue rulemaking to change the current requirements.

4.6.3.2 Impacts on Licensees

Under this alternative, there would be an incremental impact on COL holders who have not received the Commission’s finding under paragraph 52.103(g). This alternative would provide clarity to existing and future COL holders about the voluntary use of the TSs Bases Control Program prior to its implementation becoming mandatory (effective), and the importance of bringing the bases into conformance with the program before the paragraph 52.103(g) finding. The licensee’s costs for implementing the TSs Bases Control Program at COL issuance would likely be offset by reducing the risk of delays in initial fuel loading, described above, and avoiding the attendant costs of such delays.

4.6.3.3 Impacts on the NRC

Under this alternative, there would be an incremental cost to the NRC to revise guidance that COL holders should voluntarily implement the TS Bases Control Program prior to the paragraph

52.103(g) finding. The guidance would explain the benefits of voluntary adoption and emphasize that as of the paragraph 52.103(g) finding being made, the COL holder must have brought the plant-specific TS bases into conformance with the TSs Bases Control Program. The guidance would also recommend encouraging future COL applicants to propose the above described improved license condition. These costs would have the benefit of assuring clarity and consistency in the process used by COL holders for making changes to the plant-specific TS Bases. The guidance costs are estimated to be approximately (\$45,000) using a 7 percent NPV and (\$50,000) using a 3 percent NPV, as shown in Table K-6.

Table K-6 NRC Costs, Alternative 3

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Regulatory Guide	1	204	\$131	(\$26,740)	(\$23,356)	(\$25,205)
2022	Finalize/Issue Regulatory Guide	1	204	\$131	(\$26,740)	(\$21,828)	(\$24,471)
Total:					(\$53,481)	(\$45,184)	(\$49,677)

4.6.3.4 Additional Considerations

No additional considerations were identified under this alternative. This alternative would have no incremental impacts on State, local, or Tribal governments.

4.6.3.5 Summary of Benefits and Costs

Alternative 3 results in costs to the NRC of (\$45,000) using a 7 percent NPV.

4.7 Backfitting and Issue Finality Considerations

Alternative 2 could affect the issue finality of existing COL holders, but Alternatives 1 and 3 would not constitute backfitting under Section 50.109 or affect the issue finality of any Part 52 approval. Alternative 1 would maintain the status quo of leaving control of the plant-specific TS Bases to the COL holder's discretion, thereby imposing no change in requirements or NRC staff positions. Alternative 3 would promote but not require use of the TSs Bases Control Program prior to the paragraph 52.103(g) finding. Therefore, Alternatives 1 and 3 would not constitute backfitting or affect issue finality.

Alternative 2 would require existing COL holders to use the TSs Bases Control Program after issuance of a COL and prior to the paragraph 52.103(g) finding. This would be a new requirement that would affect the issue finality of these licensees. If Alternative 2 were selected, then the NRC would address the applicable issue finality criteria in the proposed rule.

4.8 Stakeholder Feedback

4.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, NEI made a presentation about its suggestions for this rulemaking. Representatives from the NEI requested that the NRC clarify whether the licensee should be using the TS Bases Control Program to implement changes to the TS Bases prior to the paragraph 52.103(g) finding, and to clarify the appropriate change process to use.

4.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

4.9 Staff Recommendations

The NRC staff recommends Alternative 1, “No-Action.”

While the rulemaking alternative would remove any apparent inconsistency raised by having TSs that are usable for facility operation when the COL is issued to satisfy Section 182a of the AEA (42 U.S.C. § 2011 *et seq.*), and at the same time not having the plant-specific TSs in effect until after the paragraph 52.103(g) finding is made, the cost of the rulemaking and backfitting processes would be considerable and justifying the backfit would be unlikely.

The staff believes COL holders already have an incentive to maintain the plant-specific TS bases consistent with changes in the design and licensing basis, and to the plant-specific TSs before the paragraph 52.103(g) finding, without the need for additional guidance (Alternative 3). Avoiding delays in initial fuel loading caused by issues related to bases deficiencies is sufficient to ensure the bases are maintained in conformance with their regulatory purpose of summarizing the reasons for each of the plant-specific TS requirements for specifications other than those for administrative controls.

5.0 REQUIREMENTS FOR REPORTING ERRORS AND CHANGES IN ECCS MODELS

Paragraph 50.46(a)(3) requires certain applicants or holders of certain licenses or approvals to estimate the effect of errors in or changes to emergency core cooling system (ECCS) evaluation models, or in the application of such models, and report the errors or changes and their estimated effects to the NRC. The requirement applies to applicants for or holders of operating licenses (OLs), CPs, DCs, SDAs, COLs, and MLs. However, for applicants for and holders of SDAs and applicants for DCs,³ reporting has no safety significance until the applicable ECCS model is referenced by a COL, CP, or OL applicant. Therefore, the NRC is considering whether to change this provision to remove reporting requirements for these entities.

5.1 Existing Regulatory Framework

The regulation in Section 50.46 requires boiling or pressurized light water reactors fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding to be provided with an ECCS designed so that its calculated performance following postulated loss-of-coolant accidents (LOCAs) conforms to certain criteria, specified in paragraph 50.46(b). Paragraph 50.46(b)(1) through (5) provides ECCS acceptance criteria, which specify the following:

- The peak fuel cladding temperature shall not exceed 2,200 degrees F.
- The calculated total oxidation shall not exceed 0.17 times the total cladding thickness before oxidation.

³ “Applicants for DCs” includes applicants both before and after the Commission has adopted a final DC rule.

- The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam shall not exceed 0.01 times the hypothetical amount that would be generated if all the metal in the cladding, excluding the cladding surrounding the plenum volume, were to react.
- Calculated changes in core geometry shall be such that the core remains amenable to cooling.
- After any calculated successful initial operation of the ECCS, the calculated core temperature shall be maintained at an acceptably low value and decay heat shall be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

The regulation in paragraph 50.46(a)(3) contains requirements related to ECCS evaluation model error reporting. As discussed in paragraph 50.46(a)(3)(i), these requirements apply to the following entities:

- applicants for or holders of OLs
- applicants for or holders of CPs
- applicants for standard DCs under Part 52 (including applicants after the Commission has adopted a final DC regulation)
- applicants for or holders of SDAs under Part 52
- applicants for or holders of COLs under Part 52
- applicants for or holders of MLs under Part 52.

Applicants for or holders of these licenses or approvals must estimate the effects of any change to or error in an acceptable evaluation model (or the application of such a model)⁴ to determine whether the change or error is significant. As defined in paragraph 50.46(a)(3)(i), a significant change or error is defined as one that results in a calculated peak fuel cladding temperature that differs by more than 50 degrees F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes or errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 degrees F.

Paragraph 50.46(a)(3)(ii) requires applicants for or holders of CPs, OLs, COLs, or MLs, to report changes or errors and their estimated effect on the limiting ECCS analysis to the Commission at least annually. Significant errors must be reported within 30 days, and the report must be accompanied by a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with the requirements of Section 50.46. The paragraph also states that changes or errors resulting in calculated ECCS performance that does not conform to the criteria of paragraph 50.46(b) are reportable events as described in paragraph 50.55(e) and Sections 50.72, "Immediate notification requirements for operating nuclear power reactors," and 50.73, "Licensee event report system." Applicants or licensees affected by such errors are required to propose immediate steps to be taken to demonstrate compliance or bring plant design or operation into compliance with Section 50.46 requirements.

The regulation in paragraph 50.46(a)(3)(iii) provides similar requirements for applicants for or holders of SDAs or applicants for DCs. Changes or errors and their estimated effects on the

⁴ Hereafter, changes to or errors in ECCS evaluation models (or in the application of such models) are referred to simply as "ECCS evaluation model changes or errors."

limiting ECCS analysis must be reported at least annually to the Commission by any applicant or licensee referencing the design approval or certification. Significant errors must be reported within 30 days and be accompanied by a proposed schedule for providing a reanalysis or taking other action as needed to show compliance with Section 50.46 requirements. The affected applicant or holder of the SDA or applicant for a DC is required to propose immediate steps to be taken to demonstrate compliance or bring plant design into compliance with Section 50.46 requirements.

The regulation in paragraph 50.46(c)(1) defines LOCAs, in part, as hypothetical accidents that would result from the loss of reactor coolant at a rate in excess of the capability of the reactor coolant makeup system, and paragraph 50.46(c)(2) defines an evaluation model as the calculational framework for evaluating the behavior of the reactor during a postulated LOCA.

The regulation in paragraph 50.46(d) notes that the requirements of Section 50.46 are in addition to any other requirements in Part 50 that are applicable to ECCS, and that the criteria set forth in paragraph 50.46(b) are an implementation of the general requirements with respect to ECCS performance set forth elsewhere in Part 50 and particularly Criterion 35, "Emergency Core Cooling," of Appendix A, "General Design Criteria for Nuclear Power Plants," to Part 50.

The NRC has undertaken an effort to significantly revise the requirements of Section 50.46 to address a variety of technical issues described in SECY-16-0033, "Final Draft Rulemaking – 10 CFR 50.46c: Emergency Core Cooling Systems Performance During Loss-of-Coolant Accidents" (NRC 2016-TN6329). The draft final rule is currently before the Commission for its consideration. This rulemaking effort, known as the 10 CFR 50.46c rulemaking, would not substantially modify the reporting requirements for applicants for DCs or applicants for or holders of SDAs. The only change that would affect the reporting requirements for ECCS evaluation model errors or changes is that, for errors or changes considered "significant" that do not exceed the acceptance criteria, the reporting period would be extended from 30 days to 60 days. Any rulemaking resulting from this regulatory basis would be coordinated with the 10 CFR 50.46c rulemaking effort.

5.2 Regulatory Issues

The requirement to report ECCS evaluation model changes or errors was extended to applicants for DCs and applicants for or holders of SDAs, COLs, or MLs issued under Part 52, in the 2007 rulemaking that significantly updated Part 52 and revised various other parts of the NRC's regulations.

Through experience working with Part 52 licenses, approvals, and certifications, the NRC has learned that the implementation of Section 50.46 is not wholly consistent with the statement of considerations from the 2007 Part 52 rule. With respect to reporting of defects that result in substantial safety hazards under Part 21, the Commission stated:

[T]he Commission has decided that immediate reporting of subsequently-discovered defects is not necessary in certain circumstances. For those part 52 processes which do not authorize continuing activities required to be licensed under the AEA, but are intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals, the reporting of defects or failures to comply associated with substantial safety hazards may be delayed until the time that the part 52 process is first referenced. The Commission's view is based upon its determination that a defect with respect to

part 52 processes should not be regarded as a “substantial safety hazard,” because the possibility of a substantial safety hazard becomes a tangible possibility necessitating NRC regulatory interest only when those part 52 processes are referenced in an application for a license, such as a combined license or manufacturing license.

The practical implementation of this was to include the following new definition in the existing definition of “defects” under Section 21.3:

(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 or 52 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.

This definition means that reporting of substantial safety hazards identified for standard DCs or approvals is effectively delayed until the design is referenced by a subsequent COL or ML.

Reporting of ECCS evaluation model changes and errors under Section 50.46 is separate from Part 21 reporting of substantial safety hazards. However, for standard DCs and approvals, ECCS evaluation model change and error reports are “intended solely to provide early identification and resolution of issues in subsequent licensing or regulatory approvals,” and therefore, based on the discussion in the statement of considerations in the 2007 final rule, it would be reasonable to delay reporting “until the time that the part 52 process is first referenced.” Although ECCS evaluation model errors and changes are not necessarily “substantial safety hazards,” they become a “tangible possibility necessitating NRC regulatory interest” only when the standard DC or approval is “referenced in an application for a license, such as a combined license or manufacturing license.”

5.3 Discussion of Alternatives

5.3.1 *Alternative 1: No-Action*

5.3.1.1 *Description of Alternative 1*

This alternative would maintain the current reporting requirements for ECCS evaluation model changes and errors for applicants for or holders of SDAs and applicants for standard DCs.

5.3.1.2 *Assessment of Alternative 1*

The “no-action” alternative would retain the current reporting requirements for ECCS evaluation model changes and errors for applicants for DCs or applicants for or holders of SDAs. Though the NRC understands that ECCS evaluation model errors or changes are not safety-significant until the time that the standard design is referenced by an application for a license, these entities would continue to be required to report ECCS evaluation model changes and errors. This represents an unnecessary regulatory burden.

5.3.2 *Alternative 2: Rulemaking to Revise Section 50.46 Reporting Requirements*

5.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to revise the reporting requirements in Section 50.46 for applicants for DCs or applicants for or holders of SDAs. Under this alternative, these entities would only report ECCS evaluation model changes or errors to the NRC once the standard design was referenced in a license or application for a license.

5.3.3 *Assessment of Alternative 2*

Alternative 2 would reduce the regulatory burden for the holders of and applicants for SDAs and applicants for standard DCs when the standard design is not referenced in a license or license application. However, these entities would still need to identify and assess errors in the ECCS evaluation model, so they could be appropriately reported once the design is referenced by a license or license application.

Finally, the NRC notes that the regulation in Section 50.46, while requiring reporting of ECCS evaluation model errors, also establishes as part of that reporting a process that enables ECCS evaluation model changes without prior NRC review and approval. Removal of the reporting requirements may limit a presumed flexibility on the part of a holder of or applicant for an SDA or applicant for a standard DC to make discretionary changes without prior NRC approval.

5.4 **Regulatory Scope**

This rulemaking would revise paragraph 50.46(a)(3).

5.5 **NRC Guidance, Policy, and Implementation Issues**

5.5.1 *NRC Guidance*

In 2016, the NRC issued regulatory issue summary (RIS) 2016-04, “Clarification of 10 CFR 50.46 Reporting Requirements and Recent Issues with Related Guidance not Approved for Use” (NRC 2016-TN6330), which discusses the types of changes and errors that should be evaluated and considered for reporting. This RIS would be unaffected by revisions to the Section 50.46 reporting requirements discussed above. Therefore, the NRC would not need to change the existing guidance.

5.5.2 *Policy Issues*

Under the rulemaking alternative discussed above, the regulations would be amended to align the Section 50.46 reporting requirements with Commission policy for reporting under Part 21. Therefore, it is unlikely that Alternative 2 would affect a current policy, create a conflict between policies, or create an unresolved policy issue. Therefore, there would be no policy issue that would need to be brought to the Commission.

5.6 **Impacts**

This section analyzes the two alternatives for addressing reporting of ECCS evaluation model errors and changes for standard DCs and SDAs.

5.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would continue with the existing new reactor licensing process as described in the current regulations and guidance, including requiring applicants for or holders of SDAs and applicants for standard DCs to report ECCS evaluation model changes and errors pursuant to the requirements of Section 50.46. The NRC would not pursue any changes to the current process.

5.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

5.6.1.2 *Impacts on Licensees*

This alternative would have no incremental impacts on licensees.

5.6.1.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC.

5.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.1.5 *Summary of Costs and Benefits*

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

5.6.2 *Alternative 2: Rulemaking to Revise 10 CFR 50.46 Reporting Requirements*

Under this alternative, the NRC would undertake a rulemaking to allow applicants for or holders of SDAs and applicants for standard DCs to defer reporting of ECCS evaluation model changes and errors under Section 50.46 until such time as the DC or SDA is referenced by a license or application for a license.

5.6.2.1 *Impacts on Public Health, Safety, and Security*

The rulemaking alternative would retain the requirement to report ECCS evaluation model changes and errors, but would allow applicants for or holders of SDAs and applicants for standard DCs to defer reporting until the standard DC or approval is referenced in a license or license application. Because this alternative would retain the requirement to report ECCS evaluation model changes and errors prior to the construction or operation of a facility, there would be no impacts on public health, safety, and security. The only impact on the public is that there would not be an awareness of any ECCS evaluation model errors or changes associated with the standard design until it is referenced in a license or license application.

5.6.2.2 *Impacts on Licensees*

The primary impact of this alternative would be a cost savings related to the reduction in reporting for applicants for or holders of SDAs and applicants for standard DCs. Currently, most

ECCS evaluation model errors or changes are reported annually. Changes to Section 50.46 under this alternative would defer the annual reporting until the standard design is referenced in a license or license application. Because reporting would be deferred rather than eliminated entirely, the cost savings would be those associated with the reporting rather than the identification and evaluation of ECCS evaluation model changes and errors.

Standard DCs are issued with a duration of 15 years, per Section 52.55, "Duration of certification." The NRC therefore considered the majority of the burden reduction compared to the "no-action" alternative would be from the number of reports that would likely be issued in a 15-year period.

The NRC reviewed current certified designs and found that, to date, all have only submitted annual reports under Section 50.46. The NRC estimates that the burden to a holder of or applicant for an SDA or applicant for a DC associated with preparation of a single annual report would be 100 labor hours.

An application for a COL or ML that is the first to reference a DC may incur costs associated with the NRC review of any ECCS evaluation model changes or errors and any actions that may need to be taken to bring the standard design into compliance with Section 50.46 requirements. The NRC does not expect these costs to be significant; other than for major errors, which are very rare, the NRC review effort associated with ECCS evaluation model changes or errors is usually relatively minor (tens of hours of staff time). These NRC averted costs are estimated in the next section.

The NRC notes that ECCS evaluation model changes and errors are, in general, expected to decrease over time, particularly for new reactor designs. Some of the more recent new reactor designs evaluated by the NRC have no temperature excursion during a design basis LOCA, and therefore have a very simple ECCS evaluation where errors, if they exist at all, are less significant. In addition, many prospective new applicants for DCs or SDAs are not using light water reactor designs and therefore are not subject to the provisions of Section 50.46.

Finally, the NRC notes that the regulation in Section 50.46, while requiring reporting of ECCS evaluation model errors, also establishes as part of that reporting a process that enables ECCS evaluation model changes without prior NRC review and approval. Removal of the reporting requirements may limit a presumed flexibility on the part of a holder of or applicant for an SDA or applicant for a standard DC to make discretionary changes without NRC approval.

The NRC chose to estimate the costs and averted costs to licensees on a per-licensee basis, to simplify the analysis. To capture the uncertainty associated with the remaining time on a DC approval (before the renewal report would be submitted after the regulatory change in Alternative 2) the NRC used three-point estimation techniques where the number of years vary from 5 to 15, and also similarly varied the licensee burden (and NRC review burden) of these currently annual reports to capture the possibility of no annual report being required in some years. The average number of years remaining on a DC approval (in other words, before the design is referenced) in the cost model is 10 years, and therefore the time horizon the NRC used is from 2024 to 2033, starting the year the final rule is scheduled to be issued. It should be noted that this window extends beyond the year 2030 used elsewhere in this regulatory basis, because of the nature of this cost item. The averted cost of the annual reports is offset in part by the larger report (containing all the updates and error reporting) when the design is referenced, and the time value of money that results from postponing the reporting is a part of the averted cost of this alternative. For this example, the model estimated the design would be

referenced approximately 10 years after the rule is issued. If there were a different interval of time, the averted costs would change in a proportional ratio, and would still be cost beneficial.

With the above inputs and assumptions, Alternative 2 would result in averted costs to a holder of or applicant for a DC or SDA of approximately \$41,000 (7 percent NPV) and \$54,000 (3 percent NPV), as shown in Table K-7. Because this estimate is for a single entity (to simplify the cost analysis), the averted cost increases with each additional affected entity. The NRC estimates at least four affected entities with a similar cost estimate (on different timelines), as shown in Table K-7.

Table K-7 Industry Costs and Averted Costs, Alternative 2

Year	Activity	Count	Labor Hours	Rate	Cost		
					Undiscounted	7% NPV	3% NPV
2024-2033	Averted annual ECCS reports from licensee	10	100	\$134	\$134,290	\$67,248	\$98,813
2033	Licensee ECCS report when referencing design	1	500	\$134	(\$67,145)	(\$26,040)	(\$44,391)
Total:					\$67,145	\$41,208	\$54,423

5.6.2.3 Impacts on the NRC

Alternative 2 would change the ECCS evaluation model error and change reporting requirements in Section 50.46 such that applicants for or holders of SDAs and applicants for standard DCs may defer reporting until the time that a license application or license references the standard design. The assumptions of the cost model are explained above, and the NRC review of these reports is estimated to be approximately half of the burden of the licensee preparation. The changes to reporting would result in averted costs to the NRC; however, the rulemaking costs would be greater and would result in some incremental costs to the NRC. Alternative 2 would result in costs to the NRC of approximately (\$45,000) using a 7 percent NPV and (\$47,000) using a 3 percent NPV, as shown in Table K-8. Because this estimate is for a single holder of or applicant for a DC or SDA, the averted cost increases with each additional affected entity.

Table K-8 NRC Costs and Averted Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
2024-2033	Averted NRC review of annual ECCS reports	10	50	\$131	\$65,500	\$32,801	\$48,196
2033	NRC review ECCS report when referencing design	1	250	\$131	(\$32,750)	(\$12,701)	(\$21,652)
Total:					(\$49,187)	(\$44,746)	(\$47,380)

5.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

5.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net costs to industry and the NRC of (\$3,500) using a 7 percent NPV and net averted costs of \$7,000 using a 3 percent NPV, which is essentially a break-even

amount due to the costs of rulemaking. As stated above, the averted costs are calculated for a single entity, but there could be at least four affected entities, making this alternative net cost beneficial.

5.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would allow applicants for or holders of SDAs or applicants for DCs to delay reporting of ECCS evaluation model errors or changes until the design is referenced by a license or license application. Current licensees under Part 50, holders of a COL or ML under Part 52, and COL applicants that reference an NRC approval under Part 52, would not be required to comply with this requirement because it would only apply to applicants for or holders of SDAs and applicants for DCs. Reporting requirements such as this one do not meet the definition of backfitting and therefore are not within the scope of the NRC's backfitting and issue finality requirements. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

5.8 Stakeholder Feedback

5.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

5.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

5.9 Staff Recommendation

The NRC staff recommends Alternative 2, "Rulemaking to Revise Section 50.46 Reporting Requirements," by modifying the language in Section 50.46 such that reporting of ECCS evaluation model errors or changes may be deferred for applicants for DCs or applicants for or holders of SDAs, until such time that the standard design is referenced by a license or license application.

6.0 GENERIC APPLICATION OF ASME BPV CODE, SECTION XI, TO NUCLEAR POWER PLANTS LICENSED UNDER 10 CFR PART 52

The current regulatory approach requires that repair and replacement activities at a facility licensed under Part 52 be conducted in accordance with ASME Boiler and Pressure Vessel Code (BPV Code), Section III, "Rules for Construction of Nuclear Facility Components," until the paragraph 52.103(g) finding is made by the Commission. The NRC is considering whether to allow COL holders to apply ASME BPV Code, Section XI, "Rules for Inservice Inspection of Nuclear Power Plant Components," for repair and replacement activities, rather than the

Section III requirements, once ASME BPV Code, Section III, activities have been completed for each individual system in a nuclear power plant licensed under Part 52.

6.1 Existing Regulatory Framework

The regulation in Section 50.55a incorporates by reference Sections III and XI of the ASME BPV Code. Section XI of the ASME BPV Code provides requirements for inservice examination, testing, and inspection of components and systems, and repair and replacement activities in a nuclear power plant. Application of Section XI of the ASME BPV Code begins when the requirements of the Construction Code (Section III) have been satisfied. The provisions of Section XI constitute requirements to maintain operating nuclear power plants through inspections and subsequent repairs or replacements, as deemed necessary, to return the plant to service, following plant outages, in a safe and expeditious manner.

ASME BPV Code, Section III, states that the Owner who has obtained an Owner's certificate shall be responsible for completing one or more of Form N-3, "Owner's Data Report for Nuclear Power Plant Components," to certify that the components meet the rules of the ASME BPV Code, Section III. The Owner shall certify, by signing the form, that each Certificate Holder is the holder of the appropriate certificate, and that components and their installation comply with the applicable requirements of Section III. Review of the completed Owner's Data Report Form N-3, including attached Data Reports (i.e., Form N-5) for all components and their installations, as required to verify Code compliance, plus the provisions of the Overpressure Protection Report or the Overpressure Protection Analysis, when required, shall be the Authorized Nuclear Inspector's authority to sign the Owner's Data Report. Per the ASME BPV Code, once Form N-3 is completed (which verifies that the requirements of Section III are met), Section XI could be used. Therefore, the allowance to use Section XI would be after Form N-3 is completed.

The NRC regulations in Part 52, Subpart C require COL holders to satisfy the ITAAC to support a Commission finding under paragraph 52.103(g) to allow fuel load. Many ITAAC are based on meeting Section III of the ASME BPV Code for the design and construction of nuclear power plant structures, systems, and components (SSCs). Therefore, repair and replacement activities at a facility licensed under Part 52 are to be conducted in accordance with ASME BPV Code, Section III, until the paragraph 52.103(g) finding is made by the Commission. This was further discussed during a public meeting with NEI on August 20, 2009 (NRC 2009-TN6348).

At that meeting, the NRC said that, in addition to meeting ASME BPV Code, Section III, to satisfy the applicable ITAAC, COL holders may implement the ASME BPV Code, Section XI, rules for repair and replacement activities prior to the paragraph 52.103(g) finding, if (1) the ASME BPV Code, Section III, requirements are met as evidenced by the completed N-3 Data Form and applied N stamp; and (2) the ASME BPV Code, Section XI, provisions do not conflict with the Section III requirements. If a conflict does exist, the COL holder must submit to the NRC its proposed use of Section XI provisions as an alternative to the regulations for authorization pursuant to paragraph 50.55a(z), "Alternatives to codes and standards requirements."

6.2 Regulatory Issues

Prior to the rulemaking to resequence the NRC's requirements in Section 50.55a to align with the Office of the Federal Register's guidelines for incorporating published standards by reference ("Approval of American Society of Mechanical Engineers' Code Cases; Final Rule,"

79 FR 65776, November 5, 2014; TN6333), the NRC regulations in Section 50.55a stated, in part, the following:

Each combined license for a utilization facility is subject to the following conditions in addition to those specified in § 50.55, except that each combined license for a boiling or pressurized water-cooled nuclear power facility is subject to the conditions in paragraphs (f) and (g) of this section [50.55a], but only after the Commission makes the finding under § 52.103(g) of this chapter.

The 2014 rulemaking to resequence the requirements in Section 50.55a did not intend to create an inconsistency with the requirements in Section 50.55a that had been previously issued, but it did cause some confusion because of minor administrative errors.

In developing Part 52, the NRC may have underestimated the length of time between completion of the ASME BPV Code, Section III, N-3 Data Forms, for installed systems in Part 52 nuclear power plants and the Commission finding under paragraph 52.103(g). However, at this time, the request to use ASME BPV Code, Section XI, for repairs has been a contingency, and the full extent of the need to use ASME BPV Code, Section XI, repairs is unknown. Based on experience in the construction of VEGP 3&4, the NRC found that a COL holder might need to conduct various repair activities that typically arise during the final stages of nuclear power plant construction. Prior to the Commission finding under Section 52.103(g), a COL holder must apply the repair requirements in ASME BPV Code, Section III, to use the ASME BPV Code, Section XI, provisions as long as they do not conflict with the Section III requirements (essentially meeting Section III through reconciliation), or submit a request for an alternative to those requirements (such as application of ASME BPV Code, Section XI) under paragraph 50.55a(z).

6.3 Discussion of Alternatives

6.3.1 *Alternative 1: No-Action*

6.3.1.1 *Description of Alternative 1*

This alternative would maintain the status quo of using Section III requirements for repair and replacement activities for installed systems at facilities licensed under Part 52 until after the paragraph 52.103(g) finding. COL holders may continue to use the ASME BPV Code, Section XI, provisions as long as they do not conflict with the Section III requirements (essentially meeting Section III through reconciliation), or submit a request to apply the ASME BPV Code, Section XI, provisions prior to the paragraph 52.103(g) finding as an alternative to meeting the requirements in Section 50.55a. The NRC would continue to assess the need to clarify the requirements in Section 50.55a as part of a periodic rulemaking update to Section 50.55a to incorporate the latest editions of the ASME BPV Code.

6.3.1.2 *Assessment of Alternative 1*

The “no-action” alternative would not address the regulatory issue to allow COL holders to generically apply ASME BPV Code, Section XI, for repair and replacement activities for installed systems, without prior NRC review and authorization. However, the “no-action” alternative to continue repair and replacement activities for ASME components in accordance with Section III until after the paragraph 52.103(g) finding for plants licensed under Part 52 would simplify ITAAC maintenance. ITAAC maintenance would be simplified because repair and replacement

activities for ASME components would be performed in accordance with ASME BPV Code, Section III, until the Commission's finding under paragraph 52.103(g) to satisfy ITAAC requirements for Part 52 plants that specify compliance with ASME BPV Code, Section III. In addition, unless an alternative is authorized in accordance with paragraph 50.55a(z) or the provisions of ASME BPV Code, Section XI, do not conflict with Section III requirements, then the same ASME BPV Code, Section III requirements used during construction would maintain ITAAC completion pursuant to paragraph 52.99(c)(2).

6.3.2 *Alternative 2: Rulemaking to Amend NRC Regulations to Allow Use of ASME BPV Code, Section XI, prior to the 10 CFR 52.103(g) Finding*

6.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would pursue rulemaking to amend its regulations to allow COL holders to generically apply the provisions in ASME BPV Code, Section XI, for repair and replacement activities prior to the paragraph 52.103(g) finding by the Commission.

6.3.2.2 *Assessment of Alternative 2*

Alternative 2 would relax the current NRC regulations to allow COL holders to apply the provisions in ASME BPV Code, Section XI, for repair and replacement activities in lieu of the requirements in ASME BPV Code, Section III, prior to the paragraph 52.103(g) finding by the Commission. This alternative would address the regulatory issue; however, neither the industry nor the NRC has assessed all of the differences between Section XI of the ASME BPV Code and Section III of the ASME BPV Code regarding repairs.

Pursuing this alternative would require a review of the existing requirements and whether the use of ASME BPV Code, Section XI, before the paragraph 52.103(g) finding is appropriate and provides reasonable assurance of adequate protection. In addition, research would be needed to evaluate the interconnecting aspects of the current regulations in Parts 50 and 52 regarding implementation of ASME BPV Code, Section III, during plant construction, and the ITAAC requirements for Part 52 plants that specify compliance with ASME BPV Code, Section III. For example, the definition of the ASME BPV Code, including Section III, specified for ITAAC includes alternative requests in accordance with paragraph 50.55a(z) authorized by the NRC. Pursuing rulemaking to allow the use of ASME BPV Code, Section XI, rather than Section III, would need to address whether the ITAAC that specify the implementation of Section III requirements would be satisfied by the use of Section XI provisions.

This rulemaking alternative would also need to address post-ITAAC notifications that are submitted prior to the paragraph 52.103(g) finding. For example, ITAAC maintenance involves situations in which the occurrence of an event could call into question whether a COL holder continues to meet an acceptance criterion (AC). Such situations could involve many types of maintenance activities, including component replacement. After work is complete, a post-work verification (PWV) will be used to confirm that the licensee still meets the AC. The PWV is not a performance of the inspection, test, or analysis (ITA) because the COL holder has already satisfied the requirement to perform the ITA; instead, the PWV and its results supplement the performance of the ITA to provide confidence that the COL holder continues to meet the AC. The scope of the PWV will depend upon the nature of the initiating event, the maintenance activities undertaken, and the specific ITAAC implicated by the event. If the PWV represents an alternate approach that is significantly different from the approach described in the original ITAAC notification, a supplemental ITAAC notification pursuant to paragraph 52.99(c)(2) is

necessary to provide the NRC and members of the public information that is material to the agency's determination on ITAAC. Because the PWV is a supplement to the performance of the original ITA, the PWV for a maintenance activity, such as a weld repair, could include additional conditions, such as requiring more analysis and inspections that may differ (i.e., Section XI inspection or analysis versus Section III inspection or analysis) from the original ITA set forth in the COL. However, the COL holder would need to seek an amendment to that ITA in the COL if no reasonable "alternate" PWV approach is available to demonstrate that the AC continues to be met. Whether an alternative PWV is reasonable or not depends on several factors, including the engineering justification provided and the wording of both the ITA and the AC. A reasonable alternative to the original ITA represents a different, yet acceptable, engineering equivalent for performing the activity prescribed in the ITAAC. As an example, if a test was the original prescribed ITA, then the PWV should also be a test, or possibly a combination of a test and analysis or a test and an inspection. The PWV methodology should agree with the methodology used in the original prescribed ITA.

6.4 Regulatory Scope

If the rulemaking alternative is selected, the NRC would pursue amending Section 50.55a (and possibly other related regulations) to allow COL holders to generically apply the provisions in ASME BPV Code, Section XI, for repair and replacement activities rather than the Section III requirements prior to the paragraph 52.103(g) finding by the Commission.

6.5 NRC Guidance, Policy, and Implementation Issues

6.5.1 NRC Guidance

If the NRC pursues rulemaking under Alternative 2, the NRC would need to develop guidance to describe an acceptable approach for COL holders to implement the relaxation to apply the ASME BPV Code, Section XI, provisions rather than the Section III requirements for repair and replacement activities prior to the paragraph 52.103(g) finding. The regulatory guidance would be a stand-alone document using concepts drawn from existing guidance documents, and may involve NRC endorsement of codes or standards, with exceptions and clarifications as needed. The regulatory guidance would describe at least one acceptable way for facilities to implement the relaxation of the requirement to apply ASME BPV Code, Section III, prior to the paragraph 52.103(g) finding. The NRC would make any draft regulatory guidance available for public comment.

6.5.2 Policy Issues

Under Alternative 2 discussed above, the regulations would be amended to allow COL holders to generically apply the provisions in ASME BPV Code, Section XI, for repair and replacement activities prior to the paragraph 52.103(g) finding by the Commission. As described in paragraph 6.3.2.2 above, the staff would have to establish that the use of Section XI would allow the applicable ITAAC to be satisfied for the 52.103(g) finding. In such a case, it is unlikely that Alternative 2 would affect a current policy, create a conflict between policies, or create an unresolved policy issue. Therefore, no policy issue would need to be brought to the Commission.

6.6 **Impacts**

6.6.1 Alternative 1: No-Action

Under this alternative, the NRC would not amend its regulations and COL holders would continue to request prior authorization under paragraph 50.55a(z) to apply the ASME BPV Code, Section XI, provisions in lieu of the Section III requirements prior to the paragraph 52.103(g) finding. The NRC would not pursue any changes to the current process. The NRC would continue to assess the need to clarify the requirements in Section 50.55a as part of a periodic rulemaking update to Section 50.55a to incorporate the latest editions of the ASME BPV Code.

6.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

6.6.1.2 Impacts on Licensees

This alternative would have no incremental impacts on licensees because the current process would be maintained.

6.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC because the current process would be maintained.

6.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

6.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

6.6.2 Alternative 2: Rulemaking to Amend NRC Regulations to Allow Use of ASME BPV Code, Section XI, prior to 10 CFR 52.103(g) Finding

6.6.2.1 Impacts on Public Health, Safety, and Security

Under the rulemaking alternative, the NRC would need to evaluate the various possible instances where the ASME BPV Code, Section XI, provisions might be implemented rather than the Section III requirements, to provide reasonable assurance that there would be no impact on public health, safety, and security. Currently, differences between the generic use of Section XI of the ASME BPV Code in lieu of Section III of the ASME BPV Code are not understood by industry or the NRC.

6.6.2.2 Impacts on Licensees

Overall, the rulemaking alternative would result in cost savings to the applicable COL holders. Changes to the requirements would allow COL holders to apply ASME BPV Code, Section XI,

provisions for repair and replacement activities without submitting a request for an alternative under paragraph 50.55a(z) prior to the paragraph 52.103(g) finding. This would save licensee resources that would have been needed to prepare an alternative request under paragraph 50.55a(z), and to respond to requests for additional information during the NRC review of the alternative request. As noted above, the use of ASME BPV Code, Section XI, for repairs has been requested as a contingency, and the full extent of the need to use ASME BPV Code, Section XI, provisions for repairs is unknown. On a qualitative basis, the NRC considers that licensees will achieve cost savings from this rulemaking alternative. However, the NRC was not able to estimate the specific amount of these cost savings quantitatively.

6.6.2.3 Impacts on the NRC

Under the rulemaking alternative, there would be a significant one-time cost to the NRC, followed by a small savings because prior approval to use the provisions in ASME BPV Code, Section XI, would no longer be required. The NRC did not quantify the small reduction in burden.

The rulemaking costs would include the determination of whether relaxing the regulatory requirements to allow COL holders to use the ASME BPV Code, Section XI, provisions rather than the Section III requirements, prior to the paragraph 52.103(g) finding is appropriate and then the preparation of the proposed rule and accompanying guidance documents. For example, the rule change would require research to evaluate the interconnecting aspects of the current regulations in Parts 50 and 52 regarding implementation of ASME BPV Code, Section III, during plant construction, and the ITAAC requirements for Part 52 plants that specify compliance with ASME BPV Code, Section III. The costs would include NRC time to determine the feasibility of this relaxation; to prepare proposed rule language; to draft guidance documents, supporting analyses (e.g., a regulatory analysis and Office of Management and Budget paperwork burden analysis), and a *Federal Register* notice; and to conduct public outreach efforts during the rule and guidance development phases. After publishing the proposed rule, the NRC would incur costs associated with public comment resolution and preparation of the final rule, guidance documents, and supporting documentation for the rulemaking. This alternative results in rulemaking costs to the NRC of approximately (\$317,000) using a 7 percent NPV and (\$364,000) using a 3 percent NPV, as shown in Table K-9.

Table K-9 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	469	\$131	(\$61,453)	(\$53,675)	(\$57,925)
2022	Develop Proposed Rule	1	469	\$131	(\$61,453)	(\$50,164)	(\$56,238)
2022	Develop Reg Guide for Proposed Rule	1	408	\$131	(\$80,221)	(\$65,484)	(\$73,414)
2023	Develop/Issue Final Rule	1	469	\$131	(\$61,453)	(\$46,882)	(\$54,600)
2024	Develop/Issue Final Rule	1	469	\$131	(\$61,453)	(\$43,815)	(\$53,010)
2024	Develop/Issue Reg Guide for Final Rule	1	408	\$131	(\$80,221)	(\$57,197)	(\$69,199)
Total:					(\$406,254)	(\$317,218)	(\$364,387)

By relaxing the regulations, the NRC would eliminate the need to review alternative requests from the small number of applicable COL holders to apply the ASME BPV Code, Section XI, provisions for repair and replacement activities rather than the Section III requirements, prior to the paragraph 52.103(g) finding.

6.6.2.4 Additional Considerations

The alternative would have no incremental impacts on State, local, or Tribal governments.

6.6.2.5 Summary of Benefits and Costs

Alternative 2 would result in net costs to the NRC of approximately (\$317,000) using a 7 percent NPV, due to rulemaking.

6.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would allow COL holders to apply the ASME BPV Code, Section XI provisions, rather than the Section III requirements, for repair and replacement activities prior to the paragraph 52.103(g) finding without the need to submit an alternative request. Combined license holders would not be required to comply with this relaxation. Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

6.8 Stakeholder Feedback

6.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. At that meeting, NEI made a presentation about its suggestions for this rulemaking. In its recommendations, the NEI included the proposal to relax the regulations to allow COL holders to apply the ASME BPV Code, Section XI, provisions rather than the Section III requirements prior to the paragraph 52.103(g) finding. NEI asserted that early additional use of Section III can put unnecessary transients on plant systems to satisfy the post-repair testing requirements in Section III, and could restrict the licensee from transitioning to other relevant ASME BPV Code provisions (e.g., Section XI) on a per system basis.

6.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

6.9 Staff Recommendation

The NRC staff recommends maintaining the status quo of Alternative 1, "No-Action," by using Section III requirements. COL holders may continue to use the ASME BPV Code, Section XI, provisions as long as they do not conflict with the Section III requirements (essentially meeting Section III through reconciliation), or submit a request to apply the ASME BPV Code, Section XI, provisions prior to the paragraph 52.103(g) finding as an alternative to meeting the requirements in Section 50.55a. This recommendation is based on the small number of potential COL holders that might implement this regulatory relaxation, which does not support the expense of rulemaking at this time. In addition, performing repair and replacement activities

in accordance with Section XI would complicate maintenance of the ITAAC completion because neither the industry nor the NRC has assessed all of the differences between Section XI of the ASME BPV Code and Section III of the ASME Code regarding repairs. Therefore, there is no technical basis for supporting a rulemaking to allow the use of Section XI. The NRC will evaluate the NRC regulations to determine whether a clarification of the implementation of ASME BPV Code, Section III, is needed.

7.0 NOTIFICATION TO THE DIRECTOR OF THE OFFICE OF NUCLEAR REACTOR REGULATION OF SIGNIFICANT IMPLICATION FOR PUBLIC HEALTH AND SAFETY OR COMMON DEFENSE AND SECURITY

The NRC's regulations require applicants and licensees under Part 52, including holders of SDAs and applicants for standard DCs, to inform the Regional Administrator of information that has a significant implication for public health and safety or common defense and security.

The NRC is considering whether to require notification of this information to the Director of the Office of Nuclear Reactor Regulation because the Regional Administrator's function does not include oversight of applicants for and holders of SDAs and applicants for DCs.

7.1 Existing Regulatory Framework

Paragraph 52.6(b) requires that each license applicant or licensee under Part 52, each applicant for or holder of a Part 52 SDA, and each applicant for a Part 52 DC following Commission adoption of a final DC regulation, notify the Commission of information having a significant implication for public health and safety or common defense and security. This notification must be made to the Administrator of the appropriate Regional Office within 2 working days of identifying the information. As described in paragraph 1.43(a), the Office of Nuclear Reactor Regulation is responsible for developing, issuing, and implementing regulations, policies, programs, and procedures for all aspects of licensing, inspection, and safeguarding of manufacturing, production, or utilization facilities.

7.2 Regulatory Issues

The current regulations require applicants and holders of SDAs and applicants for a DC to inform the Regional Administrator of information that has a significant implication for public health and safety or common defense and security. However, the Regional Administrator is not involved in the issuance of either SDAs or DCs, nor is the Regional Administrator responsible for the receipt or review of applications for Part 52 permits, certifications, or licenses. Therefore, there may be a delay in assessing and acting upon the information because the cognizant and responsible organization for these applications and approvals has not been notified.

7.3 Discussion of Alternatives

7.3.1 Alternative 1: No-Action

7.3.1.1 Description of Alternative 1

This alternative would maintain the current notification to the Regional Administrator of information that has a significant implication for public health and safety or common defense and security from applicants for and holders of SDAs and applicants for DCs.

7.3.1.2 Assessment of Alternative 1

The “no-action” alternative would continue the potential delay in assessing and acting upon the information that may have a significant implication for public health and safety or common defense and security because the notification is required to be provided to an organization that is not responsible for these approvals and applications.

7.3.2 Alternative 2: Rulemaking to Require the Applicant or Licensee to Notify the Director of the Office of Nuclear Reactor Regulation

7.3.2.1 Description of Alternative 2

Under this alternative, the NRC would pursue rulemaking to revise the regulations in paragraph 52.6(b) to require the applicable applicants or licensees to notify the Director of the Office of Nuclear Reactor Regulation of information that has a significant implication for public health and safety or common defense and security for those Part 52 applications or approvals that are not the responsibility of a Regional Administrator. Alternative 2 would also revise paragraph 52.6(b) to require notification of the Director of the Office of the Nuclear Reactor Regulation within 2 working days of identifying the information.

7.3.2.2 Assessment of Alternative 2

Alternative 2 would ensure that the Director of the Office of Nuclear Reactor Regulation would be promptly notified of information that has a significant implication for public health and safety or common defense and security for those Part 52 applications or approvals (SDAs and DCs) that are not the responsibility of a Regional Administrator.

7.4 Regulatory Scope

The NRC is considering updating the regulations in paragraph 52.6(b).

7.5 NRC Guidance, Policy, and Implementation Issues

7.5.1 NRC Guidance

There is currently no regulatory guidance that addresses this regulation, and the NRC would not plan to develop new regulatory guidance as part of the actions for resolving this issue.

7.5.2 *Policy Issues*

Under the rulemaking alternatives discussed above, no policy issues would need to be brought to the Commission.

7.6 **Impacts**

7.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would not pursue any changes to the current regulatory framework.

7.6.1.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

7.6.1.2 *Impacts on Licensees*

Because this alternative would not change the current process, the receipt of the application by the responsible and cognizant organization for certain Part 52 approvals of an application may be delayed.

7.6.1.3 *Impacts on the NRC*

This alternative would have no incremental impacts on the NRC.

7.6.1.4 *Additional Considerations*

This alternative would have no incremental impacts on State, local, or Tribal governments.

7.6.1.5 *Summary of Benefits and Costs*

Alternative 1 would not result in any changes to the current regulatory framework; therefore, there would be no associated costs or benefits.

7.6.2 *Alternative 2: Rulemaking to Require the Applicant or Licensee to Notify the Director of the Office of Nuclear Reactor Regulation*

7.6.2.1 *Impacts on Public Health, Safety, and Security*

Because this alternative would require notifying the responsible and cognizant organization for certain Part 52 approvals, it is expected that there would be more timely responsiveness to the information provided. There would be no significant increase or reduction in public health, safety, and security.

7.6.2.2 *Impacts on Licensees*

Relevant applicants and licensees would incur no impact on resources to notify the responsible and cognizant organization of the information that has a significant implication for public health and safety or common defense and security. Under this alternative, the applicant or licensee

would still be required to notify the NRC; the individual notified would be the only change. The cost of the applicant's or licensee's actions would be unchanged.

7.6.2.3 Impacts on the NRC

By changing the notification requirements, the responsible and cognizant NRC individual would be able to assess and act upon information that has a significant implication for public health and safety or common defense and security in a timelier manner than under the current regulatory framework. However, the cost of the NRC's actions would be unchanged. The NRC would incur rulemaking costs of approximately (\$65,000) using a 7 percent NPV and (\$74,000) using a 3 percent NPV, as shown in Table K-10.

Table K-10 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2021	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$17,892)	(\$19,308)
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
2024	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$14,605)	(\$17,670)
Total:					(\$81,937)	(\$64,846)	(\$73,925)

7.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

7.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net cost to the NRC of (\$65,000) using a 7 percent NPV, due to rulemaking costs.

7.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would change the NRC recipient that an applicable applicant or licensee would notify. This would be a change to a reporting requirement. Reporting requirements such as this one do not meet the definition of "backfitting" and, therefore, are outside the scope of the backfitting and issue finality regulations.

7.8 Stakeholder Feedback

7.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

7.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices of the Advisory Committee on Reactor Safeguards (ACRS). No members of the ACRS provided feedback on this topic during or following the public meeting.

7.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Require the Applicant or Licensee to Notify the Director of the Office of Nuclear Reactor Regulation,” to require that certain applicants and licensees under Part 52 notify the Director of the Office of Nuclear Reactor Regulation of information that has a significant implication for public health and safety or common defense and security.

8.0 DISCONTINUE USE OF PRIORITY RANKING MODEL FOR GENERIC ISSUES AND ALLOW A RISK-INFORMED APPROACH

Paragraphs 52.47(a)(21) and 52.79(a)(20) require that the information submitted for a DC and for a COL include technical resolutions of the applicable unresolved safety issues (USIs) and medium- and high-priority generic safety issues (GSIs) that are identified in NUREG-0933, “Resolution of Generic Safety Issues” (NRC 2019-TN6337). This requirement is also included in paragraphs 52.137(a)(21) and 52.157(f)(28) for SDA and ML applications.

The NRC is considering rulemaking to update this requirement because the NRC has discontinued use of a priority ranking model for GSIs. In its place, the NRC has implemented a screening process using the risk criteria in RG 1.174, Revision 3, “An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis” (NRC 2018-TN6335).

8.1 Existing Regulatory Framework

Paragraph 52.47(a)(21) requires an applicant for a DC to include in its application the technical resolution of the technically relevant USIs and medium- and high-priority GSIs that are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application. Similarly, paragraph 52.79(a)(20) requires the same information in the FSAR for COL applicants. Paragraph 52.137(a)(21) requires the same information from an applicant for a standard design, and paragraph 52.157(f)(28) requires the same information from an applicant for a manufacturing license.

Appendix B of NUREG-0933 contains a list of the GSIs that are applicable to operating and future reactor plants, including issues that have been resolved with requirements and issues that are in progress for resolution. The priority designations for all issues are consistent with those listed in Table II of the Introduction to NUREG-0933.

Management Directive (MD) Handbook 6.4, “Generic Issues Program” (2015 Revision; TN6360), Section II.B, “Applicability to New Reactor Applications,” states that in accordance with paragraphs 52.47(a)(21) and 52.79(a)(20), applications for DCs must consider USIs and medium- and high-priority GSIs identified in the NUREG-0933. In 1999, MD 6.4 (NRC 1999-TN6361) was updated to no longer prioritize GSIs as high, medium, low, or drop, and started to use risk to identify significant GSIs. Upon completion of the risk screening and assessment

process, an issue would be identified as a bona fide Generic Issue (GI) or be rejected from the program. Hence, for the purposes of paragraphs 52.47(a)(21) and 52.79(a)(20), as well as paragraph 52.137 (a)(21) and 52.157(f)(28), any GI that passes the screening and assessment process is considered equivalent to a high-priority GI.

The screening and assessment processes use risk to screen out issues that would not have a significant impact on facilities. The criteria are based on the same technical basis that is used for determining whether the risk associated with a specific facility design change is acceptable. The NRC uses risk criteria illustrated in Figure 4 of RG 1.174, Revision 3. Licensees use these criteria to determine whether a proposed facility change has too high of a risk to be implemented. Similarly, the NRC uses these same criteria to determine whether an issue is significant enough to continue in the GI process. Therefore, if an issue has a significant risk impact on facilities, then it is identified as a GI in the GI Program and added to NUREG-0933 for applicants to consider in their license applications.

8.2 Regulatory Issues

The regulations in paragraphs 52.47(a)(21) and 52.79(a)(20), as well as 10 CFR 52.137 (a)(21) and 52.157(f)(28), identify a priority ranking model for GSIs that the NRC revised with an alternative risk-informed assessment approach for GSIs that were processed under the guidelines approved for MD 6.4 in 1999 and described in NUREG-0933. Because the regulations were not changed to reflect the new assessment approach, not only does an applicant have to address applicable USIs and medium- and high-priority GSIs, but the applicant also must address all issues that were determined to be legitimate GSIs after the process was changed in 1999.

8.3 Discussion of Alternatives

8.3.1 *Alternative 1: No-Action*

8.3.1.1 *Description of Alternative 1*

This alternative would maintain the current requirement of DC and COL applicants to provide information about the technical resolution of the applicable USIs and medium- and high-priority GSIs that are identified in the version of NUREG-0933 current on the date up to 6 months before the docket date of the application.

8.3.1.2 *Assessment of Alternative 1*

The “no-action” alternative is no longer appropriate because the NRC has discontinued the use of a priority ranking model for addressing GSIs in lieu of a risk-informed approach. Therefore, this alternative would not address current procedures described in MD 6.4 that classify safety issues that are determined to be legitimate GSIs by the GI process without using the high and medium designation. This clarity is needed to avoid omissions by DC, COL, SDA, and ML applicants. In addition, the current inefficient review of all older GI prioritized as medium and high would continue.

8.3.2 *Alternative 2: Rulemaking to Allow a Risk-Informed Approach*

8.3.2.1 *Description of Alternative 2*

Under this alternative, the NRC would revise the current regulations in paragraphs 52.47(a)(21) and 52.79(a)(20), as well as paragraphs 52.137 (a)(21) and 52.157(f)(28), to identify risk-significant GSIs required to be addressed by DC, COL, SDA, and ML applicants after the process was changed by MD 6.4 in 1999. This process would be captured in future updates to NUREG-0933 and RG 1.206.

8.3.2.2 *Assessment of Alternative 2*

Alternative 2 would allow applicants to screen GSIs based on risk. More specifically, applicants would continue to not need to address pre-1999 GSIs identified as low risk but would be able to apply a risk-based process for considering those pre-1999 GSIs identified as medium and high risk. This change would reflect the NRC's replacement of the priority ranking in the regulations with a risk-informed screening model of GSIs after 1999. It would allow applicants to address the resolution of GSIs consistent with the agency's risk-informed process described in NUREG-0933 and would ensure that the scope of GSIs addressed by DC, COL, SDA, and ML applicants is complete.

8.4 **Regulatory Scope**

Under Alternative 2, the NRC would amend paragraphs 52.47(a)(21), 52.79(a)(20), 52.137(a)(21), and 52.157(f)(28).

8.5 **NRC Guidance, Policy, and Implementation Issues**

8.5.1 *NRC Guidance*

Under Alternative 2, the NRC does not anticipate the need to develop new regulatory guidance because NUREG-0933 and RG 1.206 would be periodically updated. The NRC issued revision 3 of RG 1.174 in January 2018, which provides one acceptable approach for implementing risk-informed applications. There would be no need to revise MD 6.4.

8.5.2 *Policy Issues*

Under Alternative 2, no policy issues would need to be brought to the Commission.

8.6 **Impacts**

This section analyzes the two alternatives discussed above to update the regulations reflecting the approach for screening GSIs using the risk-informed criteria in RG 1.174.

8.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would not pursue any changes to the current process.

8.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

8.6.1.2 Impacts on Applicants and Licensees

This alternative would maintain the current impact on applicants because the current regulations require information based on an outdated and inefficient process. Moreover, interactions between the applicant and the NRC would continue to be necessary to explain the current process and needed information. There would be no impacts on licensees.

8.6.1.3 Impacts on the NRC

This alternative would maintain the current impact on the NRC because the regulations require submission of information inconsistent with its current review model, as described in Section 8.3.1. The NRC would therefore have to expend some resources to define what information is needed from an applicant in this area.

8.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

8.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

8.6.2 Alternative 2: Rulemaking to Allow a Risk-Informed Approach

Under this alternative, the NRC would conduct rulemaking to allow DC and COL applicants to submit the technical resolution of GSIs using a risk-informed approach without the need for additional NRC guidance on what information is needed.

8.6.2.1 Impacts on Public Health, Safety, and Security

There would be no increase or reduction in public health, safety, and security because the applicant would still be required to address the risk-significant USIs and the GSIs described in NUREG-0933.

8.6.2.2 Impacts on Applicants and Licensees

The NRC expects that DC, COL, SDA and ML applicants would need to commit fewer resources to develop applications using the risk-informed approach described in NUREG-0933, due to increased clarity in the regulations. The decrease in needed resources results from the regulations more closely matching the description of the information that is needed for NRC review, which the staff did not quantify. Alternative 2 would align the regulations with existing guidance, as discussed above, resulting in increased clarity and regulatory certainty. As a result, the NRC estimates that the incremental impacts on licensees would be negligible.

8.6.2.3 Impacts on the NRC

By allowing applicants to use a risk-informed approach, the process would follow the current GI Program. This change would eliminate the need for NRC to provide additional guidance to applicants that explains what information is needed. The NRC would incur rulemaking costs of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table K-11.

Table K-11 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

8.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

8.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in net costs to the NRC of (\$32,000) using a 7 percent NPV, due to rulemaking.

8.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this appendix section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of any approval issued under Part 52. Alternative 1 would maintain the status quo of requiring new reactor applicants to provide information resolving USIs and GSIs, thereby imposing no change in requirements or NRC staff positions. Alternative 2 would align the description of the information required by DC, COL, SDA, and ML applicants concerning GSIs with the current process described in NUREG-0933. This change would not affect the issue finality of these applicants.

8.8 Stakeholder Feedback

8.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

8.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

8.9 Staff Recommendation

The NRC staff recommends Alternative 2, “Rulemaking to Allow a Risk-Informed Approach,” to remove the reference to the outdated ranking model for GSIs from the application requirements for DC, COL, SDA, and ML applicants. Applicants could then implement a risk-informed approach to address GSIs that is consistent with the updated NRC review model described in the current revision of NUREG-0933, without the need for NRC and new reactor applicants to interact to clarify the current process.

9.0 10 CFR 52.97(A)(2) ITAAC COMPLETION AT COL ISSUANCE

The regulation in paragraph 52.97(a)(2) states that the Commission may find, at the time it issues a COL, that certain acceptance criteria in one or more of the ITAAC in a referenced ESP or standard DC have been met. The NRC is considering whether to revise the language in paragraph 52.97(a)(2) from “have been met” to “are met.” This contemplated change is consistent with requirements in the AEA and paragraph 52.103(g) that the acceptance criteria in the COL “are met.”

9.1 Existing Regulatory Framework

Section 185.b of the AEA requires the Commission to make a finding that the acceptance criteria in a COL “are met” prior to a licensee commencing operation of its facility. Similarly, the regulation in paragraph 52.103(g) requires, in part, that before the licensee operates the facility, the Commission makes a finding that the acceptance criteria in the COL “are met.”

The regulation in paragraph 52.97(a)(2) allows for a Commission finding that “certain acceptance criteria in one or more of the [ITAAC] in a referenced early site permit or standard design certification have been met” at the time the COL is granted. This section also notes that such a finding will preclude any required finding under paragraph 52.103(g), which sets out requirements for operation under a COL, with respect to that ITAAC.

9.2 Regulatory Issues

The “have been met” language in paragraph 52.97(a)(2) does not align with the “are met” language of Section 185.b of the AEA and paragraph 52.103(g). The finding made pursuant to paragraph 52.103(g) is that the acceptance criteria “are met” at the time of the finding. The words “have been met” can mean that the ITAAC were met at some earlier time but may not have been maintained, so they are no longer met at the time of the paragraph 52.97(a)(2) finding. This language could call into question whether ITAAC have been maintained when the paragraph 52.97(a)(2) finding is made.

9.3 Discussion of Alternatives

9.3.1 Alternative 1: No-Action

9.3.1.1 Description of Alternative 1

Under this alternative, the NRC would take no action and the current wording of paragraph 52.97(a)(2) would be retained.

9.3.1.2 Assessment of Alternative 1

This alternative would leave the language in paragraph 52.97(a)(2) inconsistent with that in the AEA and paragraph 52.103(g) and not eliminate the ambiguity about the ITAAC being met at the time of COL approval versus having been met at some prior time and possibly not being maintained.

9.3.2 4.2 Alternative 2: Rulemaking

9.3.2.1 Description of Alternative 2

Under this alternative, the NRC would change the language in paragraph 52.97(a)(2) from “have been met” to “are met.”

9.3.2.2 Assessment of Alternative 2

Alternative 2 would align the criteria for the Commission’s ITAAC finding made at the time of COL issuance under paragraph 52.97(a)(2) with the criteria for the Commission’s ITAAC finding made pursuant to paragraph 52.103(g) and Section 185.b of the AEA. This change would also clarify that the finding under paragraph 52.97(a)(2) is that the applicable acceptance criteria “are met” at the time of the finding.

9.4 Regulatory Scope

Alternative 2 would modify the language in paragraph 52.97(a)(2) from “have been met” to “are met.”

9.5 NRC Guidance, Policy, and Implementation Issues

9.5.1 NRC Guidance

The recommended change would not affect regulatory guidance.

9.5.2 Policy Issues

The recommended rulemaking would not affect a current policy, create a conflict between policies, or create an unresolved policy issue.

9.6 Impacts

9.6.1 Alternative 1: No-Action

9.6.1.1 Impacts on Public Health, Safety, and Security

This alternative would have no impacts on public health, safety, or security.

9.6.1.2 Impacts on Applicants and Licensees

This alternative would retain language in paragraph 52.97(a)(2) that is inconsistent with that in the AEA and paragraph 52.103(g) and leaves the potential misconception that the ITAAC need not be met at the time of the Commission’s finding.

9.6.1.3 Impacts on the NRC

This alternative leaves in place regulatory uncertainty in the licensing process.

9.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

9.6.1.5 Summary of Benefits and Costs

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

9.6.2 Alternative 2: Rulemaking

9.6.2.1 Impacts on Public Health, Safety, and Security

The recommended rulemaking would have no impacts on public health, safety, or security.

9.6.2.2 Impacts on Applicants and Licensees

This alternative would create no significant impacts on an applicant or licensee, because the primary purpose of the change is to provide clarity and regulatory alignment.

9.6.2.3 Impacts on the NRC

This change would provide clarity and certainty to the licensing process. The NRC would incur rulemaking costs of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table K-12.

Table K-12 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

9.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

9.6.2.5 Summary of Costs and Benefits

Net costs would be due to the incremental cost of rulemaking, approximately (\$32,000) using a 7 percent NPV.

9.7 Backfitting and Issue Finality

Neither alternative would constitute backfitting or affect the finality of any approval issued under Part 52. Alternative 1 would result in no change in existing requirements or NRC staff positions.

Alternative 2 would involve clarifying and aligning current requirements and would not create new or revised requirements or staff positions.

9.8 Stakeholder Feedback

9.8.1 Feedback from the Public Meeting for Comment

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

9.8.2 Feedback from the Advisory Committee on Reactor Safeguards

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

9.9 Staff Recommendation

The staff recommends Alternative 2, “Rulemaking,” by modifying the language in paragraph 52.97(a)(2), to align the criteria for the Commission’s ITAAC finding made at the time of COL issuance with the Commission’s ITAAC finding made pursuant to paragraph 52.103(g) and with the language used in the Section 185.b of the AEA.

10.0 REPORTING REQUIREMENTS AT COMPLETION OF POWER ASCENSION TESTING – START OF ASSESSMENT OF ANNUAL FEES

On June 19, 2020, the NRC published the final Fee Rule in the *Federal Register* (“Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020” [85 FR 37250; TN6389]), which, among other things, modified the timing of the start of assessment of annual fees for holders of an OL issued under Part 50” and holders of COLs issued under Part 52. Specifically, the final rule amended paragraph 171.15(a) so that the assessment of annual fees for holders of an OL for a power reactor licensed under Part 50 and a COL under Part 52 now commences upon notification by the licensee or COL holder to the NRC of successful completion of power ascension testing, rather than when a licensee is issued an OL under Part 50 or after the Commission makes a finding under paragraph 52.103(g), respectively.

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” (TN6338), does not contain any notification or reporting requirements. Also, Parts 50 and 52 do not contain any provisions requiring licensees to notify the NRC of the completion of power ascension testing. Only current Part 52 COLs contain a standard license condition that requires written notification be submitted to the NRC upon successful completion of power ascension testing. The NRC is considering whether to amend its regulations to require all future Part 50 power reactor licensees and Part 52 COL holders to notify the NRC of the completion of power ascension testing.

10.1 Existing Regulatory Framework

Under paragraph 171.15(a), the NRC begins to assess annual fees for a Part 50 power reactor licensee or a Part 52 COL holder beginning on the date when the licensee or COL holder provides notification to the NRC that the power ascension testing has been completed. No regulation requires a Part 50 power reactor licensee or Part 52 COL holder to notify the NRC of the completion of the licensee's power ascension testing. The NRC's practice has been to add a license condition to each new COL to require the licensee to notify the NRC of the licensee's completion of power ascension testing. This license condition is one of a series of conditions requiring the licensee to inform the NRC of when the licensee reaches certain milestones so the NRC can begin related inspection activities.

10.2 Regulatory Issues

The final fiscal year (FY) 2020 annual fee rule requires Part 52 COL holders and new Part 50 power reactor licensees to start being assessed annual fees upon providing a notification of successful completion of power ascension testing to the NRC. The NRC needs to ensure that the licensee promptly submits a notification of successful completion of power ascension testing so the NRC can begin assessing Part 171 fees. The NRC's regulations do not require Part 50 power reactor licensees or Part 52 COL holders to notify the NRC of the completion of power ascension testing. Continuing to issue license conditions to require each new license to notify the NRC of completion of power ascension testing would prolong a case-by-case approach rather than addressing it generically.

10.3 Discussion of Alternatives

10.3.1 Alternative 1: No-Action

10.3.1.1 Description of Alternative 1

This alternative would maintain the current regulatory framework in which the NRC includes a license condition in each new Part 52 COL to require the licensee to notify the NRC upon successful completion of power ascension testing, so the NRC knows when to begin assessing annual fees. The NRC would also have to include a license condition for future Part 50 licensees to notify the NRC upon completion of power ascension testing.

10.3.1.2 Assessment of Alternative 1

Under Alternative 1, the NRC would continue to rely on license conditions in each power reactor license as the means for requiring licensees to inform the NRC to begin assessing annual fees. This case-by-case approach is less efficient than addressing the issue generically.

10.3.2 Alternative 2: Rulemaking

10.3.2.1 Description of Alternative 2

Under Alternative 2, the NRC would pursue rulemaking to revise Part 50 to add a requirement in Section 50.71, "Maintenance of records, making of reports," for a future Part 50 power reactor licensee or Part 52 COL holder to provide a prompt written notification to the NRC of the successful completion of power ascension testing.

10.3.2.2 Assessment of Alternative 2

This alternative would ensure that the NRC receives prompt written notification from licensees, which would enable the NRC to begin assessing Part 171 annual fees. This notification could also be used by the NRC to initiate its related inspection activities currently initiated through the notification required by license condition. By including a generic requirement in the regulations applicable to all Part 50 power reactor licensees and Part 52 COL holders, the NRC would not need to depend on the inclusion of license conditions to determine when the milestone that triggers the start of assessing Part 171 annual fees has been achieved.

10.4 Regulatory Scope

Under Alternative 2, Section 50.71 would be amended to add a requirement for future Part 50 power reactor licensees and Part 52 COL holders to provide a timely written notification to the NRC upon successful completion of power ascension testing.

10.5 NRC Guidance, Policy, and Implementation Issues

10.5.1 *NRC Guidance*

There is no existing NRC guidance pertaining to this matter.

If Alternative 1 is adopted, no regulatory guidance would need to be developed.

If Alternative 2 is adopted, no regulatory guidance would need to be developed. This alternative would only provide the necessary reporting requirement for future Part 50 power reactor licensees and Part 52 COL holders to notify the NRC of the completion of power ascension testing.

10.5.2 *Policy Issues*

There are no policy issues because there would be no changes to the requirements for issuance of future Part 50 power reactor OLs or Part 52 COLs.

10.5.3 *Implementation Issues*

There are no implementation issues because current Part 52 COLs already include a standard license condition that requires them to notify the NRC upon successful completion of power ascension testing. If Alternative 2 is adopted, the requirement would apply only to future Part 50 power reactor licensees and Part 52 COL holders.

10.6 Impacts

10.6.1 *Alternative 1: No-Action*

Under this alternative, the NRC would have to rely on the inclusion of license conditions in each future license, to ensure that Part 50 power reactor licensees and Part 52 COL holders provide prompt written notification to the NRC upon successful completion of power ascension testing. The NRC would not pursue any changes to the regulations.

10.6.1.1 Impacts on Public Health, Safety, and Security

Because this alternative would not change the current process, there would be no increase or reduction in public health, safety, and security.

10.6.1.2 Impacts on Applicants and Licensees

This alternative would have no incremental impacts on applicants or licensees.

10.6.1.3 Impacts on the NRC

This alternative would have no incremental impacts on the NRC.

10.6.1.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

10.6.1.5 Summary of Costs and Benefits

Alternative 1 would not result in any changes in the current regulatory framework; therefore, there would be no associated costs or benefits.

10.6.2 Alternative 2: Rulemaking

Under this alternative, the NRC would pursue rulemaking to revise Part 50 to add a requirement in Section 50.71 for all future Part 50 power reactor licensees and Part 52 COL holders to provide a prompt written notification to the NRC of the successful completion of power ascension testing.

10.6.2.1 Impacts on Public Health, Safety, and Security

Because this alternative would involve only the addition of a written notification requirement for future Part 50 power reactor licensees and Part 52 COL holders, there would be no impacts on public health, safety, and security.

10.6.2.2 Impacts on Applicants and Licensees

This alternative would result in establishing clear requirements for future applicants for Part 50 OLs and Part 52 COLs in the regulations regarding the written notification of the completion of power ascension testing. This alternative would not have an impact on currently operating Part 50 power reactor licensees and current Part 52 COL holders. The NRC expects that there would be no increase in regulatory burden associated with providing a one-time written notification by future Part 50 power reactor licensees and Part 52 holders because the NRC would otherwise require the licensees to provide the same written notification via a license condition.

The improved clarity of regulatory requirements afforded by the rulemaking would provide more regulatory certainty and improve efficiency. This could result in resource savings for the applicant because the NRC would not have to develop license conditions to require notification of completion of power ascension testing. The NRC did not estimate these benefits and burden reductions quantitatively.

10.6.2.3 Impacts on the NRC

The NRC would benefit from reduced administrative costs associated with preparing the license by eliminating the need to include a license condition in future Part 50 power reactor OLs and Part 52 COLs that would require licensees to provide a written notification of completion of power ascension testing. Furthermore, adding a requirement in Section 50.71 would increase the clarity of NRC’s regulations by more closely matching the new wording in Part 171 regarding the start of assessment of annual fees for future Part 50 power reactor licensees and Part 52 COL holders. However, the NRC would incur rulemaking costs with this alternative of approximately (\$32,000) using a 7 percent NPV and (\$37,000) using a 3 percent NPV, as shown in Table K-13.

Table K-13 NRC Rulemaking Costs, Alternative 2

Year	Activity	Number of Actions	Hours	Weighted Hourly rate	Cost		
					Undiscounted	7% NPV	3% NPV
2022	Develop Proposed Rule	1	156	\$131	(\$20,484)	(\$16,721)	(\$18,746)
2023	Develop/Issue Final Rule	1	156	\$131	(\$20,484)	(\$15,627)	(\$18,200)
Total:					(\$40,969)	(\$32,349)	(\$36,946)

10.6.2.4 Additional Considerations

This alternative would have no incremental impacts on State, local, or Tribal governments.

10.6.2.5 Summary of Costs and Benefits

Alternative 2 would result in costs to the NRC due to rulemaking of approximately (\$32,000) using a 7 percent NPV.

10.7 Backfitting and Issue Finality

Neither of the alternatives presented by the NRC staff in this section, if implemented, would constitute backfitting under Section 50.109 or affect the issue finality of an approval issued under Part 52. Alternative 1 would maintain the status quo because no changes would be made to Section 50.71, so there would be no change in requirements or NRC staff positions. Alternative 2 would add a written notification requirement to Section 50.71 to align with the final FY 2020 annual fee rule change in Part 171. The new regulatory provision in Section 50.71 would not impose any substantive changes in requirements or NRC staff positions, and this notification requirement would not meet the definition of “backfitting.” Therefore, a rulemaking under Alternative 2 would not constitute backfitting or affect issue finality.

10.8 Stakeholder Feedback

10.8.1 *Feedback from the Public Meeting for Comment*

The NRC held a Category 3 public meeting on January 15, 2019, to discuss updating regulations for future new reactor licensing applications and to solicit comments on the rulemaking. There were no comments or suggestions related to this matter.

10.8.2 *Feedback from the Advisory Committee on Reactor Safeguards*

On September 20, 2019, the NRC staff met with individual members of the ACRS Subcommittee on Regulatory Policies and Practices. No members of the ACRS provided feedback on this topic during or following the public meeting.

10.9 Staff Recommendation

The NRC staff recommends Alternative 2, "Rulemaking," to add a requirement in Section 50.71 for future Part 50 power reactor licensees and Part 52 COL holders to notify the NRC of the successful completion of power ascension testing.