REGULATORY ANALYSIS

DRAFT REGULATORY GUIDE DG-1321

GUIDANCE FOR CHANGES DURING CONSTRUCTION FOR NEW NUCLEAR POWER PLANTS LICENSED UNDER 10 CFR PART 52

The NRC is considering the development of this new RG to provide clarity and consistency on the timing of proposed changes to or departures from the design of SSCs of a facility, as described in the FSAR, as updated, being constructed under a COL covered by 10 CFR 52.98(b) and (c). Specifically, this RG addresses the timing of such proposed changes to or departures from the design, as described in the FSAR, as updated, before the Commission has made a finding under 10 CFR 52.103(g), and the timing of submission of such changes to the NRC for regulatory review. This guidance includes the timing of the beginning of construction of SSCs in accordance with proposed departures from the facility design described in the referenced certified design. Changes or departures from the design described in the FSAR, as updated, include both those within the scope of the standard certified design (and described in the "plant-specific design control document (DCD)" as defined in Section VIII of 10 CFR Part 52, Appendices A, B, C, D, E, and F) and those outside the scope of the standard certified design. To the extent feasible, this guidance harmonizes the treatment of changes to or departures from the design of a facility under construction pursuant to a COL as described in the FSAR, as updated, with the treatment of changes to the design of a facility operating under 10 CFR Part 50.

1. Statement of the Problem

Based on the discussions below, the NRC is considering issuing a new Regulatory Guide DG-1321 to clarify and describe a process that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for implementation of changes to the design of structures, systems, and components (SSCs) of a facility being constructed under a combined license (COL) covered by Title 10 of the Code of Federal Regulations (CFR), Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants", Sections 52.98(b) and (c), "Finality of Combined Licenses; Information Requests." Section 52.98(b) covers COLs that do not reference a certified standard design or a manufacturing license, but does cover a COL that references a standard design approval (SDA), and section 52.98(c) covers COLs that reference a certified standard design. Specifically, this RG addresses the timing of a proposed change to the design of facility SSCs during construction, as the facility design is described in the final safety analysis report (FSAR), as updated, and for which a license amendment is required by an applicable change process of 10 CFR Parts 50 or 52. Such a clarification would implement a risk-informed, performance-based approach to licensing.

The construction of the first facilities licensed under 10 CFR Part 52, the construction and operating experience of the 10 CFR Part 50 nuclear power facilities, and other initiatives related to control of the licensing basis for those facilities have yielded lessons regarding the control of design changes during facility construction. To the extent feasible, this guidance will harmonize the treatment of changes to the design of a facility under construction pursuant to a COL with the treatment of changes to the design of a facility operating under Part 50 in view of the differences between the regulatory status of those facilities.

In the 1997 design certification rulemaking for the U.S. Advanced Boiling Water Reactor (ABWR), the Commission stated that it modeled 10 CFR Part 52 Appendix A, "Design Certification Rule for the U.S. Advanced Boiling Water Reactor," Section VIII.B.5, on 10 CFR 50.59. Both provisions then allowed a licensee to make changes to its facility as described in the FSAR (including Tier 2 of the plant-specific DCD) "without prior NRC approval" provided specified criteria are met. If a proposed departure from Tier 2 required an amendment, however, then the licensee would be required to obtain NRC approval through the appropriate process set forth in the appendix before implementing the proposed departure. The text of these regulations was similar to 10 CFR 50.59 until the NRC amended 10 CFR 50.59 in 1999. The NRC intended the 1999 amendments to 10 CFR 50.59 to clarify the applicable requirements for a licensee to determine whether a license amendment was required or not. As relevant here, the 1999 version of the rule deleted the phrase "without prior NRC approval" from the former 10 CFR 50.59(a), and replaced it with "without obtaining a license amendment pursuant to 10 CFR 50.90" in the new 10 CFR 50.59(c)(1), but it did not modify the provisions of Section VIII in the appendices to 10 CFR Part 52. The staff notes that a proposed change to inspections, tests, analyses, and acceptance criteria (ITAAC) requires an amendment pursuant to 10 CFR 52.98(f) and also requires an exemption under Section VIII.A and 10 CFR 52.63(b). The exemption must meet the standards set forth in 10 CFR 52.7.

One comment on the 10 CFR 50.59 rulemaking in 1999 concerned the requirement to obtain a license amendment before implementing a change that involves a change to a technical specification (TS) or meets one of the criteria in 10 CFR 50.59(c)(2). In response to the comment, the Commission, in the Statements of Consideration for the 1999 10 CFR 50.59 final rule, discussed the timing of "implementation" of a change to the facility vis-à-vis the issuance of an amendment authorizing the proposed change. The Statements of Consideration indicated that a holder of an operating license (OL) may install and test a change requiring an amendment under 10 CFR 50.59(c)(2) before the amendment is granted, provided that such installation and testing of the change did not violate a TS or otherwise meet one of the 10 CFR 50.59(c)(2) criteria for prior approval. The Commission indicated that it did not consider the design change "implemented" until the licensee used the re-designed 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.

The Commission did not amend 10 CFR Part 52 in 1999 to conform to the 1999 amendments to 10 CFR 50.59 because the Commission anticipated other future rule changes for 10 CFR Part 52 based on an ongoing lessons-learned review. The Commission indicated it would consider proposed changes to 10 CFR Part 52, including the "implementation" of changes subject to amendments, in an integrated fashion. The Commission did modify the Section VIII.B.5 '50.59-like change process" in the 2006 AP1000 design certification rule (10 CFR Part 52, Appendix D, "Design Certification Rule for the AP1000 Design") to replace the term "unreviewed safety question" with more specific criteria and define a new term, "change to a method of evaluation," consistent with the corresponding changes in the 1999 10 CFR 50.59 rule. In 2007, the Commission amended 10 CFR Part 52, including amendments to Section VIII.B.5 in each design certification appendix to incorporate the same changes included in the AP1000 design certification rule. However, the 2007 10 CFR Part 52 comprehensive amendment left Section VIII.B.5.a in each 10 CFR Part 52 appendix certifying a standard design unchanged. Specifically, section VIII.B.5.a of each such 10 CFR Part 52 appendix includes the phrase "without prior NRC approval," which differs from the new text added to 10 CFR 50.59(c)(1) and (2) in 1999 quoted above with respect to implementation. This unchanged text in Section VIII.B.5.a of each 10 CFR Part 52 appendix certifying a standard design is consistent with the Commission's position stated in the 1997 ABWR design certification rulemaking cited above.

As explained above and in the final Statements of Consideration for the 1999 rule amending 10 CFR 50.59, for operating plant licenses issued under 10 CFR Part 50, "implementation" of a change to the design of an SSC described in the FSAR begins when the licensee uses the SSC in facility operations. Installation and testing of the SSC, as changed, is not considered "implementation" unless the installation or testing itself would violate a TS or would require an amendment under the criteria of 10 CFR 50.59(c)(2). The NRC staff has determined that licensees may construct or implement changes to an SSC in a plant that is under construction under 10 CFR Part 52 before the NRC has made a final determination on a license amendment and any associated exemption from certification information that applies to the SSC, similar to the installation and testing of a change to an SSC in an operating plant under Part 50. For an operating plant under 10 CFR Part 50, the NRC must approve an amendment before the licensee may declare the SSC operable or place the SSC in use in the facility. For plants under construction under 10 CFR Part 52, the determination comparable to placing the SSC in use in facility operations ("operability" for SSCs controlled by TS) for a 10 CFR Part 50 facility occurs when the licensee notifies the NRC that the prescribed inspections, tests, and analyses for that SSC have been performed and that the prescribed acceptance criteria have been met.

Similar to operating plants where a system is not operable while it is out of service for maintenance and testing, there are no immediate nuclear safety consequences for a new plant to be outside of its licensing basis if the plant construction has not been completed and fuel has not been loaded. Given the lack of safety consequences, the NRC is considering allowing licensees to construct SSCs in accordance with design changes for which the licensee has sought or will seek an amendment from the NRC. Under this proposed guidance, such construction will be subject to certain conditions that the licensee must satisfy before it submits the ITAAC notification letter for the SSC to the NRC under 10 CFR 52.99(c)(1) or 10 CFR 52.99(c)(2). This would be consistent with current practice for operating plants, under which licensees may install and test modifications (e.g., during an outage) in parallel with NRC review of required license amendment requests. Once a 10 CFR Part 52 licensee constructing a facility declares an ITAAC complete by submitting an ITAAC closure notice, the design of the SSCs required to meet that ITAAC must be consistent with the design described in the FSAR, as updated, and the plant-specific DCD. Licensee configuration management programs ensure that changes are properly controlled. The configuration management programs, along with inspections and the ITAAC process itself, provide assurance that the plant is constructed in accordance with the license.

Through the NRC's Construction Inspection Program (CIP), the NRC staff uses inspections of construction activities to independently verify that the licensee successfully carries out construction activities and identifies and corrects deficiencies that may have an impact on the ITAAC or other construction activities. The staff implements the CIP through Inspection Manual Chapter 2503, "Construction Inspection Program: Inspections of Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) Related Work." The results of the CIP are an essential part of the basis for the staff's determination, in accordance with 10 CFR 52.103(g), that the acceptance criteria have been met. CIP activities can continue while a licensee is constructing SSCs whose design departs from the FSAR, as updated. Instead of acting on

findings that the constructed plant does not match the design described in the FSAR, however, the NRC staff will incorporate the findings into pending license amendments and any associated exemptions, changes to or departures from SSCs that will be subject to requests for new amendments and association exemptions, and changes to or departures from SSC designs made without NRC approval in accordance with the change process in Section VIII of the appendices to 10 CFR Part 52 or 10 CFR 50.59.

In addition, the NRC staff believes that a facility under construction pursuant to a COL in some respects has regulatory status similar to a facility for which an operating license (OL) under 10 CFR Part 50 has been issued and differs in regulatory status from a facility being constructed under a construction permit (CP) issued under 10 CFR Part 50. For a facility under construction pursuant to a CP issued under 10 CFR Part 50, the NRC has reviewed only a preliminary safety analysis report (PSAR), which does not present final design information, and which is not controlled under 10 CFR 50.59, even after issuance of a CP. Accordingly, the CP holder retains flexibility to modify the design of the facility while it is under construction, but, in connection with the OL application, will be required by 10 CFR 50.34(b) to submit an FSAR to describe the final design, including pertinent information developed since submission of the PSAR. The CP, however, does not confer the regulatory stability associated with a COL.

Upon issuance of an OL, a Part 50 licensee is situated similarly to a holder of a COL under Part 52 to the extent the NRC has found that the design as described in the FSAR satisfies NRC regulatory requirements and the information in the facility FSAR is now subject to regulatory control (10 CFR 50.59 for an FSAR associated with an OL, and section 50.59 or both section 50.59 and Section VIII of a design certification appendix to Part 52 for an FSAR associated with a COL). For an OL, the licensee may make, install and test a change to the facility that requires an amendment under section 50.59 before the NRC makes a final determination on the LAR, provided that such installation and testing of the change does not violate a TS or otherwise meet one of the 10 CFR 50.59(c)(2) criteria for prior approval, as indicated in the SOC for the 1999 rulemaking amending 10 CFR 50.59.

In October 23, 2018, the Nuclear Energy Institute (NEI) submitted a letter (ADAMS Accession No. ML18305B421.) requesting that the NRC consider clarifying the requirements for the timing of changes during construction of a facility pursuant to a COL. While the NRC recognizes that additional flexibility during construction may also come at the cost of reduced regulatory stability, the NRC staff has determined that additional flexibility for changes during construction pursuant to a COL is justified. Accordingly, this RG clarifies the timing of when a licensee may begin construction of facility SSCs pursuant to a COL in accordance with a change to or departure from the design of the facility as described in the plant-specific DCD and FSAR, as updated.

2. Objective

The objective of 10 CFR 52.98(b) and 10 CFR 52.98(c) is to ensure that a COL licensee applies the change processes that applies to its license. Section 52.98(c) requires COL holders to (1) evaluate proposed changes to their facilities for their effects on the licensing basis of the facility, as described in the FSAR, and (2) submit a license amendment to obtain NRC approval for changes that meet specified criteria as having a potential impact upon the basis for issuance of the COL. Section 10 CFR 52.98(b) covers COLs that do not reference a standard design or a manufacturing license, but does cover a COL that references a standard design approval (SDA). Specifically, the proposed RG addresses the timing of a proposed change to the design of facility SSCs during construction, as the facility design is described in the final safety analysis

report (FSAR), as updated, and for which a license amendment is required by an applicable change process of 10 CFR Parts 50 or 52.

The objective of this regulatory action is to update NRC guidance and allow a licensee flexibility in constructing a facility pursuant to a COL while also maintaining compliance with the 10 CFR 52.98(b) and 10 CFR 52.98(c) requirements for licenses issued under 10 CFR Part 52 for which a license amendment is required by an applicable change process of 10 CFR Parts 50 or 52.

3. Alternative Approaches

To address the issues identified above in Section 1, Statement of the Problem, the NRC staff considered the following alternative approaches:

- 1. Do not issue a new Regulatory Guide.
- 2. Issue the new Regulatory Guide as DG-1321 to clarify the timing of changes and departures to a facility during construction under a COL.
- 3. Revise 10 CFR Part 52 to provide clarity and consistency on the timing of proposed changes to a facility being constructed under a COL.

Alternative 1: Do Not Issue a new Regulatory Guide

Under this alternative, the NRC would not issue additional guidance, and the current guidance would be retained. If NRC does not take action, there would not be any changes in costs or benefit to the licensees or NRC. This alternative is considered as the "no-action" alternative and provides a baseline condition from which any other alternatives will be assessed. However, the "no-action" alternative would not address the issues identified above and the NRC would continue to review each application on a case-by-case basis, thus providing no additional relief to the licensee during construction under 10 CFR Part 52 beyond what is currently provided.

<u>Alternative 2: Issue a new Regulatory Guide as DG-1321 to clarify the timing of changes and departures to a facility during construction under a COL</u>

Under this alternative, the NRC would issue a new Regulatory Guide as DG-1321. This guidance would clearly define the point at which a licensee constructing a facility pursuant to a COL could begin constructing SSCs in accordance with proposed changes and departures from the facility described in the FSAR, as updated, and would incorporate the latest information from experience with reviews of these changes and departures. This guidance would also address issues for a combined license holder that references a certified design regarding when a licensee may begin construction or modification of SSCs. This guidance would harmonize the treatment of changes to a facility under construction pursuant to a COL with the treatment of changes to a facility operating under 10 CFR Part 50, to the extent feasible. By issuing the new RG, the NRC would ensure that the guidance available in this area is current and accurately reflects the staff's positions.

The impact to the NRC would be the costs associated with preparing and issuing the regulatory guide revision. The impact to the public would be the voluntary costs associated with

reviewing and providing comments to NRC during the public comment period. The value to NRC staff and its 10 CFR Part 52 licensees would be the benefits associated with enhanced efficiency and effectiveness in using a common guidance document as the technical basis for license applications and other interactions between the NRC and its regulated entities. While the NRC recognizes that additional flexibility during construction may also come at the cost of reduced regulatory stability, the NRC staff has determined that additional flexibility for changes during construction pursuant to a COL can be justified

Alternative 3: Revise 10 CFR Part 52 to provide clarity and consistency on the timing of proposed changes to a facility being constructed under a COL

In this alternative, the NRC would pursue rulemaking to address the timing of proposed changes to a facility during construction, as the facility is described in the FSAR, as updated, before the Commission has made a finding under 10 CFR 52.103(g). Specifically, this action would clarify that a COL holder may begin construction of structures, systems, and components (SSCs) that include changes to or departures from the facility described in the referenced certified design, prior to NRC's issuance of a license amendment affecting those SSCs. The rule would also reorganize the information in Part 52 so that the description of the process that applicants and licensees would use to make changes to Tier 2 FSAR information as well as requests for exemption and would appear in the regulations only a single time in Part 52, either Subpart B or C, or in 10 CFR 50.59. The descriptions of requirements currently appearing in Section VIII.B.5 of each Part 52 appendix would be replaced by language referencing either Subpart B or C or 50.59. This would harmonize the treatment of changes to the design of a facility under construction pursuant to a COL with the treatment of changes to the design of a facility operating under 10 CFR Part 50, to the extent feasible.

This alternative would provide clarity to the regulations by making it clearer which and how requirements apply. Appropriate information regarding the revised regulation would appear in the statement of considerations and could provide additional clarity by describing various scenarios and how a license amendment and an exemption, if any, is required in each case. No additional information beyond the discussion in the statement of considerations is necessary for this alternative because the alternative does not include any changed or added requirements or conditions.

Initially, the NRC would have incremental costs to undertake the rulemaking process for this portion of the Parts 50 and 52 alignment and lessons learned rulemaking. These costs include the preparation of the proposed rule and accompanying guidance documents. The costs would include NRC staff time 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 and supporting documentation for the rulemaking. In the context of a comprehensive rulemaking to update Parts 50 and 52, the issues in the new RG would be a minor component of the rulemaking effort because it is a clarification of rather than a change to existing requirements.

Adding clarifying language to the regulations would not result in additional requirements necessitating NRC actions, such as backfit evaluations. However, removing ambiguity from the regulatory language would potentially result in a more efficient regulatory process, thereby reducing the time needed to respond to necessary requests and questions from industry and

ultimately saving NRC staff time and resources. However, a comprehensive rulemaking could be expected to take 3-5 years for completion compared to the anticipated time of 1 year to publish this new RG. In addition, the new RG will provide immediate relief to facilities being constructed under 10 CFR Part 52.

The staff notes that efforts have already begun to propose policy and regulatory updates in new reactor licensing review. In January 2015, the staff issued SECY-15-0002 (ADAMS Accession No. ML13281A382) in order to propose that the Commission direct a coordinated rulemaking effort to address both the alignment of 10 CFR Parts 50 and 52, and the lessons learned from recent 10 CFR Part 52 licensing efforts. In September of 2015, the Commission approved the staff's recommendations and issued SRM-SECY-15-0002 (ADAMS Accession No. ML15266S023). The staff reported in SECY-19-0084 (ADAMS Accession No.19161A194) that public meetings have been held and the regulatory basis and draft regulatory analysis for these efforts are both anticipated to be released for public comment in calendar year 2020.

Conclusion

Based on this regulatory analysis, the NRC staff concludes that issuance of a new regulatory guide is warranted. The action will provide clarity and consistency on the timing of proposed changes to a facility being constructed under a COL in a timely manner.