

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

Introduction

This white paper describes an alternative approach for design certification application (DCA) submittals based upon a phased submittal of Tier 1/ITAAC and Tier 2 information. An option to utilize a phased DCA submittal process is being proposed in order to provide sufficient time for improvements to inspections, tests, analyses, and acceptance criteria (ITAAC) for SMRs to be developed, and to permit a Small Modular Reactor (SMR) Design Certification (DC) applicant sufficient time to implement these improvements. The conceptual bases underlying this alternative approach were discussed at an NRC public meeting on November 19, 2013 (ML13330B593), during which the industry agreed to provide a white paper describing a proposed phased DCA submittal process. This paper concludes that a phased DCA submittal approach would meet the regulatory requirements of 10 CFR Part 52 and could be permitted as an exercise of NRC discretion in performing the acceptance review. Furthermore, the phased DCA submittal alternative would not adversely impact the submittal schedule for SMR applications, nor would it adversely impact the NRC review schedule for such applications. The approach would enhance regulatory efficiency and effectiveness by allowing additional time for generic improvements to SMR ITAAC, including overall ITAAC standardization, to be developed and implemented. Furthermore, lessons learned from the review of new large light water reactor (LLWR) applications indicate that there are regulatory efficiency benefits to submitting the Tier 1 document at an appropriate time after the review of the Tier 2 standard design information has reached a more mature state.

This paper addresses the feasibility, appropriateness, and process by which such a phased DCA submittal is envisioned to support the NRC's design certification review process and schedule. Specifically, this paper discusses the following:

- Regulatory requirements for design certification
- Background on two-tiered approach to design certification
- Benefits of phased DCA submittal alternative
- Description of proposed phased DCA submittal alternative
- Proposed path forward for a phased DCA submittal alternative

Regulatory Requirements for Design Certification

NRC regulatory requirements governing the technical contents of a design certification application are located in 10 CFR 52.47. 10 CFR 52.47(a) requires that the DCA contain a final safety analysis report (FSAR). 10 CFR 52.47(b)(1) requires that the DCA contain the proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, a facility that incorporates the design certification has been constructed and will be operated in conformity with the design certification, the provisions of the Atomic Energy Act, and the NRC's rules and regulations.

Although not specified or defined in the regulations pertaining to DCAs, NRC practice (SRM-SECY-90-377) to date has established a two-tiered approach to design certification applications: a Tier 1 document that includes the ITAAC and other design material to be used during the rulemaking

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

certification process, and a Tier 2 document that includes design information at a level of detail similar to post-1985 FSARs.¹ NRC regulations in 10 CFR Part 2 (i.e., 10 CFR 2.811) include specific requirements for design certification applications but are silent on the timing for submitting information (e.g., information used for safety evaluations vs. information used for rulemaking activities). While the regulations do not explicitly address phased DCA submittal of the FSAR and ITAAC information, provisions exist for phased submittal for other types of applications, including construction permit and combined license applications, in 10 CFR 2.101.

Background on Two-Tiered Approach to Design Certification

Regulations for standard design approvals existed in various forms in 10 CFR Part 50² prior to promulgation of 10 CFR Part 52 and prior to the development of two concepts that are central to the Part 52 design certification process: ITAAC and the two-tiered approach. These concepts were discussed and approved in several separate policy papers of the early 1990s³. The process for standard design approvals (SDAs) originally included in 10 CFR Part 50 was used for plants such as SNUPPS, RESSAR, GESSAR, and CESSAR, and was essentially preserved in 10 CFR Part 52 as Subpart E. The option of certifying a standard design via rulemaking was provided by 10 CFR Part 52, Subpart B.

For a DCA, the Tier 2 document describes the standard plant design in accordance with 10 CFR 52.47(a). The Tier 1 information includes the ITAAC, as required by 10 CFR 52.47(b)(1), to demonstrate that the facility that incorporates the design certification has been constructed and will operate in conformity with the design certification (and its license, etc.). Tier 1 also includes the design information that is certified during the rulemaking process and subject to a more restrictive change control process to ensure standardization. Tier 1 design information is derived from the Tier 2 design information, and typically includes the descriptions of top level design requirements, equipment and component information and simplified figures, as necessary to support the design descriptions. By definition, there is no new design information in Tier 1 that is not already contained in Tier 2. The only information that may be new or not contained in the Tier 2 information is the verification methods developed for inclusion in the inspections, tests, and analyses portion of the ITAAC.

Early DCAs were submitted without a Tier 1 document, because the two-tiered approach had not yet been established via SRM-90-377. Tier 1 information including ITAAC for these early designs was submitted later, after the development of suitable guidance on the form and content of a design

¹ The definitions of Tier 1 and Tier 2 information are only provided in the appendices to 10 CFR Part 52 and are associated with specific certified designs. Although these definitions are similar, there are no specific definitions for Tier 1 and Tier 2 information provided in 10 CFR 52.1, Definitions, which apply universally to all Part 52 applicants or licensees.

² 10 CFR Part 50, Appendices N and O originally included the requirements for standardized design approvals, duplicate plant licenses, and replicate plant licenses. The requirements in these appendices have been modified, relocated, and redistributed over the years as a result of development of and later updating of 10 CFR Part 52.

³ These concepts were discussed in SECY-90-0377, SECY-91-178, SECY-91-210, etc.

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

certification rule. For more recent DCAs, the practice has been for Tier 1 and Tier 2 information to be submitted concurrently.

Applicants may still submit an application for a standard design approval in accordance with 10 CFR Part 52, Subpart E (i.e., without Tier 1 information and ITAAC), successfully pass the NRC acceptance review for docketing and obtain an SER documenting the NRC's safety review of the standard design. An applicant for SDA could convert its application to a DCA by supplementing its SDA with ITAAC required by 52.47(b)(1) and other required Tier 1 information. Similarly, a COL applicant referencing an SDA could provide the required ITAAC with its COL application.

Thus, there are both precedents for phased submittal of DCA information as well as existing processes that recognize that the NRC can complete its safety review for a standard design and review ITAAC later.

Benefits of Phased DCA Submittal Alternative

There are several ITAAC improvement efforts that are being proposed for SMR designs that offer mutual benefits to both applicants and the NRC in terms of regulatory efficiency and safety focus. Phased DCA submittal (Tier 2, then Tier 1) would permit sufficient time for these improvements to be developed and implemented prior to SMR DC applicant submittal of Tier 1 information, including ITAAC. Some of these ITAAC improvement efforts leverage the inherent benefits of the modular design and construction for SMRs, provide for ITAAC standardization, refine the Tier 1 format and content, and account for unique design features of SMRs. Without a near-term path for phased DCA submittals, improvements may be limited, or may not be feasible at all for near-term SMR DC applicants. Efforts to improve ITAAC for SMRs are consistent with this recommendation from the NRC Post-Combined License Part 52 Implementation Self-Assessment Working Group Report (ML13196A403):

“Additionally, for future design reviews such as those anticipated for Small Modular Reactors, the NRC staff should consider the use of standard terms or formats across designs to make ITAAC closure lessons more generally applicable.”

Experience from previous NRC reviews of DCAs shows that a sizable number of requests for additional information (RAIs) are generated by the NRC safety reviews, and often result in changes to the design described in Tier 2. Tier 1 and ITAAC information is not needed for NRC's safety review, and NRC review of this information typically follows the safety review. Applicant-originated design changes in addition to RAI-driven changes made during the NRC review often result in changes to the Tier 1 and ITAAC information. These changes have resulted in unanticipated revisions and re-reviews of Tier 1/ITAAC information, and have required additional expenditures of resources by the NRC and the applicants. There are tangible benefits to minimizing the frequency and magnitude of these re-reviews by allowing the review of Tier 2 to proceed without submitting Tier 1/ITAAC for a period of time until the NRC review of the design and changes to the design has reached a more mature and stable point.

Description of Proposed Phased DCA Submittal Process

This proposal for a phased DCA submittal alternative addresses the topics of the acceptance review, docketing and noticing, timing for Tier 1 document submittal, public participation, and whether the

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

process complies with the NRC regulations and policy, or whether a phased DCA submittal process would require rulemaking or an exemption.

After the NRC receives a DCA, it performs an acceptance review of the application for docketing. NRC guidance for performing an acceptance review of a DCA, set forth in NRC Office Instruction NRO-REG-100, instructs the NRC staff to perform a completeness review to ensure that the application contains the information required by regulations in order for the staff to begin its detailed technical review. The guidance also affords the NRC some flexibility and discretion in performing its acceptance review to ensure the application meets the two-part objective: completeness and technical sufficiency. A phased submittal of a DCA, where the initial submittal is a complete and technically sufficient Tier 2 document, would meet the criteria for technical sufficiency, because Tier 2 will contain sufficient technical information in scope and depth for the staff to perform its detailed technical review within a predictable timeframe. The DCA submittal of Tier 2 information would be accompanied by a commitment to provide the Tier 1 and ITAAC information at a mutually agreeable timeframe following Tier 2, which would be timely to support the overall DCA review schedule. Thus, a phased DCA submittal process would also meet the completeness criteria, because the applicant will have submitted all of the information required by the applicable regulations in Part 52, such that the staff can begin its detailed technical review. This would allow the staff to docket the application and perform its detailed technical review. The basis supporting this alternative approach is the fact that the design information necessary for the NRC staff to perform its detailed technical review is contained or incorporated by reference in the Tier 2 document.

The ITAAC included in the Tier 1 document are only reviewed by the NRC staff in order to ensure that they are sufficient to confirm that the plant is constructed and will operate in conformity with the certified design. Notably, ITAAC are not required for the NRC to make a reasonable assurance finding with regard to resolution of safety issues associated with the design. The underlying purpose of the NRC's regulations will be met even if the ITAAC and Tier 1 information are submitted later, provided that it is submitted at an appropriate time to support the NRC's ongoing DCA review schedule.

Based on the above, an acceptance review of the Tier 2 document would be sufficient for DCA docketing and an additional acceptance review would not be needed when the ITAAC and Tier 1 document are subsequently submitted. This approach is also consistent with submittal of additional technical reports or other information necessary for the NRC staff to conduct its review prior to or following docketing of the DCA.

In addition, NRC guidance in NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," including Design Specific Review Standards (DSRS), recognizes that "the review of ITAAC cannot be completed until after the rest of the . . . application has been reviewed against acceptance criteria contained in this ... section." The phased DCA submittal alternative is consistent with the NRC review guidance in the SRPs and DSRSs that instructs the NRC staff to complete their review of the Tier 2 information prior to completing review of the associated Tier 1 information and ITAAC. It is our understanding that the review approach discussed in the NRC's guidance allows the NRC staff to become familiar with and understand the proposed design prior to reviewing the ITAAC. This approach is also consistent with Commission policy in SRM-SECY-90-377, which states:

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

“With regard to ITAAC, the Commission has previously amplified on the provisions of Part 52 by stating that “ITAAC are to provide reasonable assurance that a plant which references the design is built and will operate in accordance with the design certification, and thus are not to be used to reach a final conclusion on any safety question associated with the design.” ITAAC should not be used to impose additional design requirements. ITAAC are to be sufficient to confirm that a plant is built and will operate in conformance with the design certification.”

The timing of submittal of the Tier 1 information, including ITAAC, should be established such that the overall NRC review schedule and duration is not adversely impacted. The NRC review process for a DCA has typically included the following phases:

- Phase 1 – Preliminary Safety Evaluation Report (SER) and Request for Additional Information (RAI) preparation
- Phase 2 – SER with open items (OIs) (an open item is an RAI that is not yet resolved)
- Phase 3 – Advisory Committee of Reactor Safeguards (ACRS) review of SER with OIs and meetings
- Phase 4 – Advanced SER with no OIs
- Phase 5 – ACRS review of Advanced SER with no OIs and meetings
- Phase 6 – Final Safety Evaluation Report (FSER) completed

Ideally, submittal of the Tier 1 information for the DCA should occur when the bulk of RAI resolutions have been reflected in the Tier 2 design information, such that the Tier 1 information can be based on this more mature and stabilized information. To support the overall DCA review schedule, the Tier 1 information for the DCA should be submitted prior to completion of Phase 2 of the NRC’s review.

Industry proposes that submittals of the Tier 1 document be provided with the first consolidated revision of the Tier 2 document, to incorporate RAI responses and other changes submitted to the NRC. This Tier 1 information would be based on the more stabilized Tier 2 design, and would facilitate a more focused and efficient review. We envision that applicants would establish the phased submittal date for the Tier 1 document during the acceptance review period in connection with the NRC development of its overall DCA review schedule. Other alternatives, such as a phased submittal of the Tier 1 document scheduled at a fixed time following docketing of the Tier 2 design information (e.g., 9, 12, 15 months, etc.), were also considered. Whichever approach is chosen, it should achieve the objective to assure that Tier 1 is reviewed based on mature and stable Tier 2 design information, without adverse impact on the overall DCA review schedule. While the phased DCA submittal alternative provides for submittal of the Tier 1 and Tier 2 documents at separate times, the information necessary for the NRC to perform an adequate review, support meetings with the ACRS, and develop a final safety evaluation report will be available when needed.

The rulemaking process follows the design approval process outlined above and is addressed in 10 CFR 52.51. The phased submittal alternative for SMR DCAs supports the administrative review process described in 10 CFR 52.51 and does not adversely affect the ability of the NRC to issue a notice of rulemaking or provide the opportunity for public comment on proposed rulemaking for design certification. Other opportunities for public participation during the NRC’s review of a DCA are also provided at public ACRS meetings. These administrative processes and public participation opportunities

Proposed SMR Design Certification Application Submittal Process to Improve Regulatory Efficiency

are intact and will remain so without restriction for any SMR DC applicant that chooses to adopt the phased DCA submittal alternative.

As outlined herein, it is the industry's view that a phased DCA submittal can be implemented within the current regulations and an exemption to the regulations in 10 CFR 52.47(b)(1) is not necessary. Phased DCA submittal is consistent with and supports the review process for design information and ITAAC information described in existing NRC staff review guidance documents (i.e., SRPs and DSRs). The NRC has flexibility in its acceptance review process to exercise discretion regarding DCA completeness (i.e., Tier 1 submitted later). The regulations in 10 CFR Part 2 associated with processing a DCA are silent on a phased submittal alternative (or submittal in parts). The underlying purpose of regulations for NRC design certification is to ensure resolution of all safety issues associated with standard designs and to ensure that ITAAC are sufficient to confirm that the plant is constructed and will operate in conformity with the certified design. This purpose is achieved by issuance of an FSER and design certification rulemaking (DCR), which are the culmination of the aforementioned NRC review phases. The underlying purpose of the regulations is not affected by phased submittal of the Tier 1 information because the information necessary for the NRC to conduct and complete its review is available when needed to support the FSER and DCR.

Proposed Path Forward for a Phased DCAs Submittal Alternative

Formal NRC policy changes or guidance documents do not appear to be necessary to implement the phased DCA submittal alternative. Additionally, implementation of the proposal in this paper does not appear to require any changes to the regulations in 10 CFR Part 52. It is anticipated that NRC staff could provide any necessary instructions for implementation of the phased DCA submittal alternative via internal memorandums, specific DCA review handbooks, or other internal office instructions.

Subject to NRC acceptance of a phased DCA submittal alternative, DC applicants should notify the NRC of their intention to follow this alternative approach as part of pre-application interactions with the NRC. Industry envisions that applicants would follow up with formal correspondence to this effect.