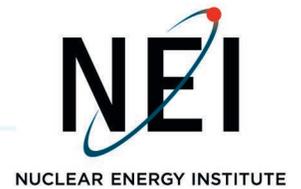


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June 9, 2021

Mr. Robert M. Taylor  
Deputy Director, Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**Subject:** NEI Input on Recent Application Experience for New Reactors

**Project Number: 689**

Dear Mr. Taylor:

The Nuclear Energy Institute (NEI)<sup>1</sup> and its members appreciate the Nuclear Regulatory Commission's (NRC) commitment to continuous improvement in the efficiency of licensing actions for new reactors. The NRC's efforts over the past decade to be more accountable, predictable, and efficient in its licensing actions have improved the timeliness of new reactor application reviews. Application review costs, however, have not seen similar improvements, and, as discussed below, remain excessively high. Therefore, in the spirit of continuous improvement, we respectfully submit that there is more work to be done to achieve reasonable and predictable NRC review schedules and costs. Likewise, the nuclear industry is pursuing actions of our own to enable more efficient new reactor reviews. Achieving more efficient NRC new reactor application reviews will impact the success of the advanced reactor demonstration projects funded by the Department of Energy (DOE), as well as the longer-term viability of new nuclear generation. Success on both fronts is essential to achieving the nation's carbon reduction, energy, economic, and national security goals, as reflected in the 2019 Nuclear Energy Innovation and Modernization Act (NEIMA) and direct communications from Congress to the Commission.<sup>2</sup>

This letter proposes additional opportunities the NRC could pursue to realize new reactor licensing efficiencies while maintaining rigorous, high-quality, and safety-focused reviews. These opportunities have been identified

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<sup>1</sup> The Nuclear Energy Institute (NEI) is responsible for establishing unified policy on behalf of its members relating to matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect and engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations involved in the nuclear energy industry.

<sup>2</sup> See, e.g., Nuclear Energy Innovation and Modernization Act (NEIMA), P.L. 115-439, 132 Stat. 5565 (14 Jan. 2019), available at [www.congress.gov/bill/115th-congress/senate-bill/512](http://www.congress.gov/bill/115th-congress/senate-bill/512); Letter from Senators Capito, Whitehouse, Barrasso, and Crapo to NRC Chairman Hansen dated May 25, 2021.

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based on the most recent application experience, including topical reports and 10 CFR Part 52 early site permit, standard design certification, and combined license applications, and they supplement letters from Oklo, Inc. and NuScale Power, LLC identifying lessons learned from their NRC application review experiences (see ML20357A001 and ML21050A431, respectively).

In our December 18, 2020 letter to the NRC (ML20353A393), we identified the need for the NRC regulatory framework to support timely and cost-effective reviews of new reactor applications, and several of the regulatory priorities cited in the letter are focused on achieving this goal. In response, the NRC in a January 21, 2021 public meeting described major actions that the agency has completed in roughly the last five years to improve the timeliness of reviews. These actions include: publishing generic licensing review schedules, developing a pre-application white paper, implementing strategies such as the use of core review teams and audits, developing guidance on the level of detail in applications, and completing recent application reviews on or ahead of schedule. As a result, the NRC's new reactor reviews are more than 12 months shorter than those conducted in the 2000s.

Reliably meeting the NRC review schedule targets is a significant accomplishment; however, we believe that there is an opportunity to achieve even shorter target review durations. Furthermore, the NRC's performance on review costs has not been positive. In fact, as discussed in our 2018 paper *Recommendations for Enhancing the Safety Focus of New Reactor Regulatory Reviews*, the NRC's inflation-adjusted review costs for recent applications are four times more expensive than NRC reviews performed more than a decade ago. This trend is of substantial concern to the industry. It is particularly troubling considering that NRC review costs increased even though the recent applications are for reactor designs with enhanced safety features and lower risk profiles.

Addressing the opportunities identified in this letter is intended to complement the industry's and NRC's on-going regulatory improvement efforts (e.g., TICAP/ARCAP and Part 53) and, if implemented, will lead to a more modern and efficient regulatory framework for new and advanced reactors. These additional recommendations are primarily based on recent application experiences, and could be incorporated into multiple other on-going activities. While the NRC works to institutionalize learnings for the longer term, the agency should leverage opportunities to address recent application experiences and make near-term improvements expeditiously. We recommend that the NRC implement the near-term improvements described below:

### **Near-Term Recommendations**

1. **Establish More Reasonable Review Duration and Cost Targets** – The first and most important recommendation is that the NRC establish reasonable generic targets for both the cost and duration of new reactor application reviews. The use of generic targets is fundamental to achieving review efficiencies (as demonstrated by the fact that the NRC has, more recently, reliably achieved their review duration targets). Conversely, the lack of a target will certainly lead to missed opportunities (as

demonstrated by the fact that, in the absence of a cost target, review costs have significantly increased). In our December letter, we provided an example of more reasonable targets: reviews in less than two years with costs less than \$10 million. While meeting these targets may depend in part on implementing longer-term improvements, such as Part 53, the NRC can and should establish more reasonable generic targets based on improvements that can be achieved in the near-term.

The NRC should consider utilizing the following principles in establishing more reasonable generic near-term review cost and schedule targets:

- a. **The NRC schedule targets should include the entire schedule for the NRC licensing action.** Currently, the NRC schedule targets focus only on the safety evaluation from the acceptance of the application (Docketing) to the issuance of the Final Safety Evaluation Report. These schedule targets do not include – but should include – the Environmental Review (which in some cases may be longer than the safety review), or the other stages of the licensing action, such as acceptance review and hearings (which in some cases have added 18 months to the schedule). Consequently, the NRC’s schedule target of 36 months for a non-light-water reactor (non-LWR) combined license application could be 48 months or more from the time of application submittal to NRC approval. NRC should ensure that the schedule targets do not depend upon moving review activities outside of the schedule (e.g., the pre-application period should not be a de facto extension of the overall review schedule).
- b. **The NRC should describe the basis for the schedule targets.** The NRC has not provided any explicit basis for the durations of the current schedule targets. As an example, the NRC generic milestone schedule for a non-LWR combined license application that does not reference a design certification is 30 months, whereas the generic milestone schedule for a similar LWR application is 36 months. No basis is provided for this discrepancy in review schedules. If the NRC’s basis is related to the safety and risk profile of the design, then it is noted that some light-water small modular reactors (SMRs) could have safety and risk profiles that are similar to non-LWRs. Furthermore, the NRC should consider the simplicity of the design in establishing the targets, since the NRC should be able to complete a micro-reactor review faster than a more complex design.
- c. **Reasonable schedule targets should be aggressive, consider the carbon free energy needs of the country, and reflect the direction provided by Congress to improve efficiency within the agency’s processes.** In any circumstance, the commercial viability of an advanced reactor project hinges, in part, on the availability of an efficient licensing process. Additionally, applicant licensing schedules may be driven by specific federal mandates or goals. For example, the DOE, at the direction of Congress, has established requirements for the Advanced Reactor Demonstration Project (ARDP) to begin operations by 2027, which will require that either the 10 CFR Part 50 or Part 52 review be completed in a timely manner, e.g., the NRC would need to complete the safety reviews in 24 months, 12 months sooner than the current NRC target of 36 months. To the NRC staff’s credit, it has acknowledged that review targets should be understood to be based on a representative application, and that the

actual review schedule for a particular application could be shorter or longer than the target based upon factors such as the simplicity/complexity of the design, the safety/risk profile and margin to the safety limits, and the scope of potential policy and technical issues related to novel features of the design. See recommendation 2.d in the next section for the importance of clear and timely schedule communication on a particular application.

- d. **Similar to the schedule targets, the NRC cost targets should have a basis, be aggressive, and consider commercial and governmental objectives.** The increasing NRC review costs for new reactor applications are not sustainable and are on a trajectory toward \$100 million for each new design. The NRC needs to perform a root cause analysis to determine why the inflation-adjusted review costs continue to increase, even though recent applications are for designs with enhanced safety and lower risks. While we believe NRC could achieve a generic review cost target of \$10 million, as a threshold matter, the NRC generic cost target should be well below \$50 million (roughly the costs for the AP-1000) for designs that are simple and have high levels of safety. In establishing cost targets, the NRC should consider either stating these targets in inflation-adjusted terms, or in terms of person-hours.
  - e. **Each applicant should be provided cost and review schedule estimates when their application is accepted.** In at least one case, the NRC has delayed providing a schedule as staff learn more about an applicant's licensing approach. This puts NRC staff and applicants in limbo as it is unclear how long it will take to gather enough information to issue a schedule, especially if the outcomes and metrics for each portion of the review are unclear or not in place. Thus, the NRC should always provide a schedule upon application acceptance, even if the NRC needs to make it provisional with metrics for completion and in anticipation of being updated once the review begins in earnest. This is particularly important in the near-term as various applicants will not be leveraging a single approach to the presentation of their safety case. Although the NRC has been able to complete some reviews on time or even ahead of schedule, in other cases, the NRC has set aggressive review schedules, but missed key milestones. While an aggressive schedule is appreciated as a signal of the NRC's intent to perform more timely and efficient reviews, NRC should also recognize that smooth execution of those schedules is equally important. To the extent that "pinch points" in the schedule (e.g., Advisory Committee on Reactor Safeguards review) can be anticipated and mitigated, the NRC staff should work with applicants to avoid associated delays and successfully meet target schedules.
2. **Improving Efficiency in the Review Process** – In April 2018, NEI sent the NRC a paper titled *Recommendations for Enhancing the Safety Focus of New Reactor Regulatory Reviews* (ML18116A053). While the agency has made some progress in considering this input, more can be done to leverage these learnings for greater efficiency in licensing reviews of new reactors. Our 2018 recommendations were, in part, intended to increase NRC management engagement in decision-making. While we have seen positive communication of expectations for new reactor reviews from NRC management to staff in the intervening years, there remains ample opportunity to

build these expectations into the structure of new reactor reviews and translate individual learnings into process improvements and practice (rather than wait for the conclusion of additional rulemakings and guidance development).

To that end, the NRC should consider utilizing the following principles in improving the efficiency of the review process in the near term:

- a. **The NRC should increase consistency in the use of risk insights to inform the NRC's review (more review of risk significant areas and less review in areas that are not risk significant).** Recent applicants have seen inconsistent benefits from the use of risk-information. A near-term opportunity that would benefit both the NRC staff and applicants is to define, or identify criteria for determining, what is "credible." A common understanding and consistent application of this key concept will facilitate more efficient reviews of proposed designs with very low risk baselines. Recent applicants have experienced NRC reviews that unnecessarily spent substantial review resources on issues with very low safety significance (e.g., orders of magnitude below Commission safety goals). Similarly, in some cases, the NRC's use of relative risk caused it to identify aspects of the design as significant, even though in absolute terms the risk was insignificant.<sup>3</sup> Accordingly, the applications that used a probabilistic risk assessment (PRA) have not resulted in the more efficient NRC reviews that would have been expected. To address this, NRC and applicants should have clear alignment on the role and potential graded use of the PRA by applicants through successive phases of regulatory review. Another opportunity that would benefit NRC staff and applicants is to provide structured process support with respect to the Commission's direction in SRM-SECY-19-0036 that risk-informed principles be applied by NRC staff when strict, prescriptive application of deterministic criteria is unnecessary to provide for reasonable assurance of adequate protection. In recent years, the NRC has consistently touted the advantages of risk-informed decision-making. Turning this expectation into reality in the near term by providing process direction for new application reviews will enable more consistent use of risk-information by NRC staff and applicants.<sup>4</sup>
- b. **The NRC should take immediate steps to realign on the appropriate level of detail and content of applications.** Specifically, the NRC should 1) focus on the information that is necessary and sufficient to meet the regulations, and 2) rely on downstream requirements and programs. The NRC has pursued efforts over the past several years related to "right-sizing" the amount of information in the application. While plans to use design specific review standards and a safety-focused review for the NuScale design certification did not result in review efficiencies, they have informed the NRC's current efforts (primarily focused on the use of a Core Team Approach and the advanced reactor content of application

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<sup>3</sup> For examples, see "Lessons-Learned from the Design Certification Review of the NuScale Power, LLC Small Modular Reactor" (ML21050A431), February 19, 2021, at 3.2 and 3.3

<sup>4</sup> Id. at 3.2

project, or ARCAP) and the development of guidance on the level of detail in applications. However, these efforts should be supplemented with other near-term actions (i.e., beyond developing future guidance). Recent applicants have sought to use the insights underlying these NRC efforts by including in their applications only that information which is necessary to demonstrate how a regulation is satisfied and by grading the discussion of structures, systems, and components (SSCs) based on the safety significance of those SSCs. Nevertheless, staff reviewers have requested substantial additional information that is neither relevant to the applicant's safety case nor necessary to verify compliance with NRC regulations. Thus, there has been mixed application by the NRC staff of the NRC's own lessons learned. It is too early to know if the Core Team Approach alone will drive incorporation of these learnings. A likely contributing factor is, with available guidance correctly focused on safety-significant SSCs, there is little to rely on for a common understanding of reasonable descriptions and review for SSCs of lower safety significance. The Core Team Approach presents an opportunity to articulate this common understanding, first for individual applications, and then to adopt the philosophy generically for additional near-term applications. In any case, consistent NRC staff application of regulations, guidance, and precedent should support renewed focus on including only necessary and sufficient information in applications. When an applicant proposes a design for which a traditional design basis event (e.g., Loss of Coolant Accident) is so unlikely that it is not a credible event, the NRC should not require the applicant to still analyze the event as a hypothetical or stylized event as part of the design basis. The application should be reviewed on its merit and NRC should resist overreach that would inappropriately limit the options of subsequent applicants, e.g., a combined license that references a design certification. NuScale's experience and recommendation to rely on downstream requirements and programs to supplement design detail and test data as part of NRC safety findings is also relevant here.<sup>5</sup> NRC's reluctance to rely on downstream requirements and programs will drive the inclusion of detail in earlier-stage applications that is unnecessary to make the NRC's required safety findings on those applications, and which is redundant to information already required of applicants at an appropriate later stage.

c. **The NRC should implement a clearly defined appeal process, as described by NuScale, for discrete issues encountered during new reactor application reviews.**<sup>6</sup>

Related recommendations are identified in our April 2018 paper, *Recommendations for Enhancing the Safety Focus of New Reactor Regulatory Reviews*.<sup>7</sup> An appeal process will enable more timely resolution of key policy and technical issues that arise during the review (e.g., issues that applicants believe they have already adequately addressed, or otherwise are not required by the regulations to address). The lack of such an appeal process has led

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<sup>5</sup> Id. Recommendation 4

<sup>6</sup> Id. at 3.1.2

<sup>7</sup> "Recommendations for Enhancing the Safety Focus of New Reactor Regulatory Reviews" (ML18116A053), April 25, 2018, Recommendations 6.3 and 6.4.

- to numerous staff-applicant impasses that have required excessive time and resource expenditures to resolve.
- d. **Open communication and alignment on project scope and plan should benefit all parties.** The NRC staff and new reactor applicants need to communicate frequently on the expectations for every aspect of an application review. The shared responsibility for project management cannot be overstated. In particular, alignment on key issues, prioritization, and plans for the review should be clearly communicated and documented in a timely manner. Beyond the use of tools such as Regulatory Engagement Plans, both NRC staff and applicants need to have a common understanding of goals and metrics throughout pre-application activities and the application review. This is particularly salient if the resources invested in pre-application activities are to add significant value for all parties in the subsequent application review.
  - e. **Reinforce audit best practices.** Applicants have seen successful audits, but not all are efficient. Applicants and NRC staff should have a shared understanding of how audit questions, answers, and resolutions will be documented. Whether they occur as part of an audit Q&A or during the audit itself, useful applicant-staff exchanges that result in mutual understanding on key topics should be documented so that they are captured for reference with the Advisory Committee on Reactor Safeguards (ACRS). Additionally, a routine, e.g., monthly, report to update the scope of the audit has been vital to the most beneficial audits for NRC staff and applicants. This will ensure common expectations for what NRC staff are reviewing and what types of information they are seeking through the audit. Adequate preparation by NRC staff to understand basic design information or technical concepts prior to the audit has been shown to maximize the benefit for both NRC staff and applicants, creating an efficient audit that is focused on topics for detailed review.
3. **Clarify the Role of the ACRS** – As NuScale characterizes in its recent lessons learned letter, the role of the ACRS should be clarified to enable more effective and efficient reviews.<sup>8</sup> The ACRS is established to independently review and report on those portions of the application which concern safety. As such, the ACRS expertise is most valuable when applied to reviewing specific matters that are novel or may have a significant impact on the determination of reasonable assurance of adequate protection of the public health and safety. The ACRS's value here is manifested in their ability to challenge assumptions made by the applicant and staff, and to raise considerations that may have been overlooked. However, the ACRS's independent review of the NRC Staff's work need not essentially duplicate the staff's review scope and depth, nor should the ACRS intervene in the staff's day to day performance of their review. As the Commission has noted, advisory committees such as the ACRS "are structured to provide a forum where experts representing many technical perspectives can provide independent advice that is factored into an agency's decision-making

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<sup>8</sup> "Lessons-Learned from the Design Certification Review of the NuScale Power, LLC Small Modular Reactor" (ML21050A431), February 19, 2021, at 3.5

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process.”<sup>9</sup> If the ACRS would like to review the adequacy of existing regulations, it should not do so as part of a review of an applicant’s submittal. This type of assessment should not be charged to applicants.

As was noted above, Oklo, Inc. and NuScale Power, LLC have recently sent letters to the NRC identifying lessons learned with their application experiences. NEI emphasizes the importance of addressing these lessons learned so that the full benefit of their resolution may be realized by NRC staff and applicants, generically. In this letter, NEI has taken a comprehensive look at generic implications of recent application experiences, while also avoiding the need to repeat supporting details already communicated directly via these recent applicant letters. If you have questions concerning our input, please contact me, or Kati Austgen at [kra@nei.org](mailto:kra@nei.org).

Sincerely,



Marcus Nichol

c: Ms. Andrea D. Veil, NRR, NRC  
Ms. Anna H. Bradford, NRR/DNRL, NRC  
Mr. Mohamed K. Shams, NRR/DANU, NRC  
NRC Document Control

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<sup>9</sup> *NextEra Energy Seabrook, LLC* (Seabrook Station, Unit 1), CLI-19-7, 90 NRC 1, 13 n.74 (2019).