Lessons Learned from the U.S. Nuclear Regulatory Commission Staff's Review of the NuScale Design Certification Application

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EXECUTIVE SUMMARY

In August 2020, the U.S. Nuclear Regulatory Commission (NRC) staff issued its final safety evaluation report[1] and concluded its safety and environmental reviews of a design certification application[2] (DCA) submitted by NuScale Power, LLC (NuScale), for a light-water-cooled small modular reactor with first-of-a-kind, gravity-driven, natural circulation for reactor core cooling. While the NRC staff completed its review of the NuScale DCA within the planned project schedule of 42 months, it recognized that there were best practices and key lessons learned for both the NRC and future applicants that can further enhance licensing reviews in accordance with the NRC's Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability. As such, the Office of Nuclear Reactor Regulation (NRR) established the NuScale Lessons Learned Team (LL Team) to assess the NRC's review, identify best practices and areas for improvement, and propose recommendations to NRR management for future new reactor design reviews.

The LL Team requested and received over 40 specific insights, best practices, and lessons learned for this report from key NRC staff and management who had actively participated in the day-to-day review of the NuScale DCA. This final report considers best practices, areas for improvement, and proposed recommendations identified by the LL Team. Sections 3 and 4 of this report summarize recommendations provided by NuScale and Nuclear Energy Institute as well as the NRC staff's response to those recommendations.

Overall, this report finds that the staff conducted the NuScale design certification review in accordance with the NRC's Principles of Good Regulation and that the independence and openness principles were clearly demonstrated. While the efficiency, clarity, and reliability principles were generally achieved, there are opportunities for continuous improvement through leveraging best practices and making changes in accordance with the lessons learned.

First, the report identifies a number of NuScale and NRC best practices that should be further enhanced and encouraged for future applicants. Section 1 discusses these best practices in more detail, but a few representative examples include the following:

- NuScale willingly engaged in preapplication activities to familiarize the NRC staff with the design based on its development to that point. These activities added to the staff's understanding of the main attributes of the design and allowed for the resolution of some key topic areas before the NuScale submittal.

- The NRC and NuScale developed a list of highly challenging issues (HCIs) that, by focusing on these topics, led to their more timely and efficient resolution.

- The NRC began efforts to streamline its safety evaluation report for the NuScale design, which yielded some benefits. A more concerted effort initiated at the beginning of the review would further concentrate efforts on the most safety-significant aspects of the design and create a sufficient safety basis for the staff's regulatory conclusions.

[1] "NuScale DC Final Safety Evaluation Report," dated August 28, 2020, Agencywide Documents Access and Management System (ADAMS) Accession No. ML20023A318

[2] "NuScale Power, LLC Submittal of the NuScale Standard Plant Design Certification Application," dated December 31, 2016, ADAMS Accession No. ML17013A229

The most significant review challenges and areas for improvement fell into the following four overarching categories:

(1) design finalization at application and changes during licensing
(2) application of a holistic, risk-informed review strategy
(3) enhancements of the request for additional information and audit processes
(4) establishment and management of review schedules and resource estimates

For each of these areas, the staff's report identifies and describes the lessons learned during the NuScale review, including actions that applicants and the NRC can take to improve future licensing reviews. These action items are intended to add to the efficiency, clarity, and reliability of reviews through enhanced stability in DCAs, more focused risk-informed reviews, better use of information-gathering tools, and greater adherence to project goals. The applicants and the NRC have a shared responsibility to work constructively on continuous improvements that can assist the agency in making timely and efficient licensing decisions.

In addition to these recommendations, the Nuclear Energy Institute and NuScale each submitted its own recommendations following completion of the NRC review of the NuScale DCA. This report references ongoing and planned NRR activities in response to these recommendations.

ACKNOWLEDGEMENTS

The U.S. Nuclear Regulatory Commission (NRC) Office of Nuclear Reactor Regulation would like to thank the NRC staff and management who provided input, insights, and constructive feedback to prepare this report.

The Office of Nuclear Reactor Regulation would also like to thank and commend the staff from the Office of Nuclear Regulatory Research, the Office of Nuclear Security and Incident Response, and the Office of the General Counsel for the tremendous teamwork in addressing complex, cross-cutting, and challenging issues related to the review of the NuScale Power, LLC (NuScale), design certification application (DCA). The NRC's Advisory Committee on Reactor Safeguards provided important feedback that improved the staff's review of the NuScale DCA.

The identification of review challenges and recommendations for improvements in this report does not diminish the significant efforts by the NRC staff to successfully complete the review of the NuScale DCA within the established schedule.

INTRODUCTION

Since the mid-1990s, the U.S. Nuclear Regulatory Commission (NRC) has certified seven new reactor designs and completed the review of eight combined license (COL) applications for 14 new reactor units under the review process outlined in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Following the issuance of COLs for Vogtle Electric Generating Plant, Units 3 and 4, and Virgil C. Summer Nuclear Station, Units 2 and 3, the NRC conducted a lessons learned effort and issued its report in April 2013.[3] The NRC routinely assesses its performance on these reviews and documents the results. The staff issued the most recent lessons learned report after it completed its review of the Clinch River early site permit application.[4]

Consistent with the focus on continuous improvement for both the NRC and its applicants, the agency initiated a lessons learned effort based on the review of the most recent new reactor design certification application (DCA); namely, the NuScale Power, LLC (NuScale), small modular reactor (SMR). This report documents the results of this review and will serve as a basis for continued improvements as the agency prepares to license new reactor technologies. Within the next 5 years, the NRC expects to receive applications for construction permits, COLs, standard design approvals, and DCAs for new reactors, based on first-of-a-kind (FOAK) and innovative technologies, including SMRs and nonlight-water reactors (non-LWRs). The NRC established the NuScale Lessons Learned Team (LL Team) to assess its licensing review. The LL Team recommends that both the NRC and applicants implement the best practices and lessons learned contained within this report.

In conducting its review, the NRC staff focused on its Principles of Good Regulation: independence, openness, efficiency, clarity, and reliability. Overall, the NRC staff conducted its NuScale DCA review in accordance with these principles, and the independence and openness principles were clearly demonstrated. While the efficiency, clarity, and reliability principles were generally achieved, there are opportunities for continuous improvement through leveraging best practices and making changes in accordance with the lessons learned.

The principles of reliability and clarity in the review of licensing applications are instrumental to the staff's efforts to reach a reasonable assurance determination that the new reactor design will be operated safely. Although the NRC conducted a reliable and clear review in determining whether NuScale had provided reasonable assurance that its SMR could be operated safely, the LL Team identified opportunities to improve these aspects of the NRC review for future new reactor DCAs.

This report assesses the efficiency of the NRC licensing review process by examining two factors: (1) the review duration and (2) the number of hours the staff spent to review the application. Both of these factors are heavily influenced by (1) the quality of the application and the value of preapplication activities to resolving issues early, (2) the degree to which the staff's assessment and resolution of technical issues was commensurate with their risk significance, and (3) the responsiveness of the applicant to the staff's questions and requests. An assessment of the data gathered for previous DCAs and COL applications, dating to the 1990s, shows that the staff's reviews, for the most part, had either exceeded their established duration

[3] "New Reactor Licensing Process Lessons Learned Review: 10 CFR Part 52," issued April 2013, Agencywide Documents Access and Management System (ADAMS) Accession No. ML13059A239

[4] "Best Practices and Lessons Learned from Review of the Clinch River Nuclear Site Early Site Permit Application," issued April 2021, ADAMS Accession No. ML19190A078

or the staff had expended a significant amount of resources on the review. In addition, the data showed that the staff had not routinely established or managed resource estimates for the previous reviews.

The rest of this report highlights the best practices and lessons learned during the course of the staff's review of the NuScale DCA and provides recommendations to improve the efficiency, reliability, and clarity of the NRC review of future new reactor designs. Further, the report highlights review practices that worked well during the NRC review of the NuScale DCA that should continue in future licensing reviews. Additionally, the report highlights the importance of focusing resources on risk-significant areas of the design. For the purpose of this report, the phrase "risk-significance" encompasses all aspects of risk-informed regulatory decision making, including the key principles of integrated decision making; namely regulatory compliance, defense-in-depth, safety margin, performance monitoring, and risk analysis (quantitative and/or qualitative, as appropriate).

Any report that reasonably assesses and identifies best practices and areas for improvement must be balanced in reflecting what all parties can do better. As such, this report discusses the areas where applicants and the NRC can improve and is not intended to disparage the efforts of either NuScale or the NRC staff to certify the novel NuScale design.

SECTION 1: BEST PRACTICES

The NRC successfully completed the NuScale review within established schedules while resolving a number of highly challenging issues (HCIs). Many best practices contributed to the successful review of the NuScale DCA. The LL Team recommends that the Office of Nuclear Reactor Regulation and applicants continue the following 12 practices in its future new reactor licensing reviews:

(1) NuScale voluntarily engaged in preapplication activities to familiarize the staff with the design based on its development to that point. These activities improved the NRC staff's understanding of the main attributes of the design and allowed for resolution of some key areas before DCA submittal.

(2) The NRC staff and NuScale developed and consulted a list of HCIs that led to increased attention to these topics. Specifically, this approach early in the review facilitated a more timely and efficient resolution of these issues.

(3) The NRC began efforts to streamline its safety evaluation report (SER) for the NuScale design, which yielded some benefits. A more concerted effort at the beginning of the review would further increase the focus on the most safety-significant aspects of the design and thus create a sufficient safety basis for the staff's regulatory conclusions.

(4) NuScale issued a regulatory gap analysis[5] letter during preapplication activities to identify unique areas of the design that deviate from traditional compliance approaches. This initiative provided early engagement in nontraditional areas of the design. The staff's white paper[6] encourages this type of preapplication exchange because it allows the staff to communicate early regulatory perspectives before receipt of an application.

(5) NuScale used topical reports for novel design features and approaches to allow the staff to generically review and approve such features. This increased NRC and NuScale attention on these review areas to facilitate more timely resolution.

(6) The NRC developed risk-informed approaches in a number of areas during the NuScale review that facilitated reaching safety determinations. The use of risk insights during the preapplication period and at the beginning of reviews helped the staff assess the risk significance of design attributes and thereby apply resources in a more efficient and reliable manner.

(7) The NRC and NuScale agreed on a more disciplined approach to issuing requests for additional information (RAIs) that considered the safety and regulatory bases for the questions. This approach resulted in a more effective and efficient use of the RAI process in comparison to prior reviews. This effort should be further expanded and coupled with other regulatory tools, such as audits, to further reduce the number of RAIs needed to reach safety determinations. Additionally, the electronic RAI system provided an efficient means to document, communicate, and track technical issues and yielded

[5] NP-RP-0612-023, Revision 0, "Gap Analysis Summary Report," dated July 31, 2012, ADAMS Accession No. ML12214A256

[6] "Pre-application Engagement to Optimize Advanced Reactors Application Reviews," issued May 2021, ADAMS Accession No. ML21145A106

real time data to support engagement between the NRC and NuScale on the status of key technical issues and overall project progress.

(8) Internally, the NRC increased its use of technology to facilitate more efficient development of safety evaluations and other correspondence. For example, the staff used SharePoint to enable the simultaneous editing of draft documents by the NRC's technical, legal, and project management staff and promote efficient and effective collaboration.

(9) The NRC and NuScale conducted NRC staff audits in areas involving FOAK design features, or review areas where the design was evolving, and used NuScale's electronic reading room as an efficient means to resolve highly technical issues. The NRC and NuScale gained valuable insights into the most efficient way to conduct audits over the course of the review. These insights should be captured and incorporated into audits for future applications.

(10) The NRC took a new approach to the review and concurrence on the advanced and final SERs. The NRC emphasized earlier management review of these reports to minimize the potential for substantive changes late in the process.

(11) The NRC staff coordinated with the Advisory Committee on Reactor Safeguards (ACRS) to support the committee's efforts to concentrate on the more risk-significant and novel design attributes. This resulted in fewer committee meetings on SER chapters that were less risk significant and enhanced focus on others. This approach is being used in other reviews as well.

(12) The NRC staff emphasized the need for continuity of the technical, project, and legal reviewers on the NuScale DCA to the maximum extent possible. This promotes a more reliable, clear, and efficient review. The NRC should explore ways to increase the stability of its review teams and collect data in future reviews to assess its performance in this area. The use of interdisciplinary review teams (discussed later) could yield improvements in this area, and the NRC should form these teams with reviewer stability considered whenever possible.

SECTION 2: NRC LESSONS LEARNED

While the NRC staff and NuScale had a number of significant accomplishments and best practices that supported timely completion of the review, they encountered challenges that adversely impacted the efficiency, reliability, and clarity of the review. Section 103 of the Nuclear Energy Innovation and Modernization Act recognized these types of challenges and requires the NRC to develop licensing strategies that (1) include the use of topical reports, standard design approvals, and other appropriate mechanisms as tools to introduce stages into the commercial advanced nuclear reactor licensing process, (2) evaluate options for improving the efficiency, timeliness, and cost-effectiveness of licensing reviews of commercial advanced nuclear reactors, including opportunities to minimize the delays that may result from any necessary amendment or supplement to an application, and (3) provide options for improving the predictability of the commercial advanced nuclear reactor licensing process, including the evaluation of opportunities to improve the process by which application review milestones are established and met. This section of the report highlights the most significant challenges that adversely affected the efficiency, clarity, and reliability of the NRC's reviews of the NuScale DCA and proposes approaches to improve the licensing process for future applications.

1. Design Finalization at Application and Changes During Licensing

When it submitted the application in December 2016, NuScale had not performed or completed important testing, analyses, or engineering evaluations to demonstrate the reliability of some safety-significant FOAK design features or structures, systems, and components. For example, when NuScale submitted its DCA to the NRC for review, it had not completed the required piping design, nor had it initiated certain required analyses associated with it. Instead, the applicant performed the required design calculations in parallel with the NRC staff's review of the DCA. As another example, NuScale did not include the inadvertent actuation block valve in the design description of the FOAK emergency core cooling system (ECCS) valve system discussed during initial preapplication meetings. Specifically, the testing and engineering evaluations of the inadvertent actuation block valve that were required for the staff review were not available when the applicant submitted its DCA. During the staff's safety review, NuScale's testing resulted in numerous changes in the design and additional analysis of the ECCS valve system that the applicant needed to address to demonstrate the performance of this FOAK design feature. This testing and the associated design changes resulted in substantial unanticipated resource and time expenditures for both NuScale and the NRC in the middle of the review.

The NRC identified and tracked 29 HCIs during its review of the NuScale DCA. The HCIs represented complex issues, some of which were associated with the completeness of the design or the availability of supporting information to enable the staff to reach a safety finding. In addition, NuScale made substantial design changes throughout the review, either unilaterally to complete the design or to address the staff's questions and concerns. Consequently, the staff expended a significant number of additional hours to audit and review NuScale's new information (e.g., redesigning, reanalysis, downstream effects, and new test data), as well as to perform its own confirmatory analyses. Notable examples of such design changes include (1) testing and redesigning the FOAK ECCS valve system, including the potential for inadvertent actuation block valve failure, (2) containment response under certain accident scenarios, (3) potential for a recriticality event due to ECCS actuation as a result of boron redistribution, (4) potential for steam generator density wave oscillation instability, (5) potential for containment leakage from the combustible gas monitoring system, and (6) reactor trip setpoints and

associated reanalysis of several events described in DCA Chapter 15 with respect to transient and accident analyses.

In light of the challenges associated with the information available at the time of the NuScale DCA submittal and similar obstacles affecting the efficiency and effectiveness of other reviews, the NRC drafted a white paper to encourage robust preapplication engagement. In accordance with the Advanced Reactor Policy Statement published in Volume 73 of the *Federal Register* (FR), page 60612 (73 FR 60612), the NRC encourages early interactions with prospective advanced reactor applicants, and such licensing interaction and guidance early in the design process will contribute towards minimizing complexity and adding clarity and reliability to the licensing and regulation of advanced reactors.

As discussed in the preapplication engagement white paper, if the applicant makes substantive changes to the application after submittal, those changes may impact the schedule. Further, if the applicant participates in preapplication activities, it should minimize, to the extent possible, design changes between preapplication activities and the time the application is submitted so that matters resolved during preapplication interactions are not adversely affected. At the time of submittal, the applicant should list any design changes that may impact decisions made during the preapplication process and any remaining ongoing design, testing, and analysis efforts. Finally, the applicant should acknowledge that significant design changes in the midst of the staff review may alter the review schedule and resources.

The NRC staff acknowledges that some design attributes may evolve during the review and that some additional data may be developed as well. To support an efficient and reliable review, applicants must identify, early in the review, any potential information gaps or design changes being considered and provide detailed plans for when the necessary data and information will become available. These aspects can have a significant impact on the overall schedule for the review and contribute to an inefficient use of NRC and applicant resources due to rework and rereview. The NRC should similarly assess early whether the areas potentially impacted would adversely affect the schedule or resources needed and communicate its assessment to the applicant.

Applicant Action: At the beginning of the licensing review, applicants should identify, in their submittals, all design aspects that are still undergoing finalization, testing, or analysis or that are otherwise subject to change, especially if these deviate from discussions between the applicant and the NRC during preapplication meetings. Similarly, the applicant should promptly communicate any design changes identified during the review, and also the applicant's timeline for providing the new information to the staff and include their impact on those technical areas already under staff review. This list will allow early engagement with the NRC staff to adjust the emphasis and allocation of resources to minimize rework or delays in the schedule.

NRC Action: The NRC staff should carefully evaluate the list provided by the applicant to ensure schedules and resources are appropriately allocated. In addition, the staff should conduct early assessment of the potential risk significance of these areas and discuss with the applicant any potential impacts on schedules or resources. For design changes that are not risk significant, the NRC should seek to understand the change while minimizing the allocation of additional resources or schedule delays that are not necessary to reach a reasonable assurance determination.

2. Application of a Holistic, Risk-Informed Review Strategy

While the NRC made substantial progress in conducting a risk-informed review of the NuScale application, opportunities remain to further enhance its ability to apply risk-informed principles during the review of new and advanced reactors. During the NuScale review, the NRC staff and NuScale spent considerable effort aligning on the risk information provided in the application. This occurred in parallel with the ongoing safety review in other areas of the application. This reduced the ability to incorporate insights from the risk information into other portions of the review. In addition, because the NRC conducted the review in a matrixed manner (i.e., work was distributed to divisions and branches to conduct their focused review) and not in an integrated holistic manner, risk insights were less effectively incorporated into specific review areas. Reviewers were not always aware of the risk significance of their review in the context of the overall design. This contributed to increased focus and effort in some areas that may not have been commensurate with their risk significance.

New and advanced reactor designs will employ novel and integrated passive and inherent features to demonstrate safety. Correspondingly, the NRC must adapt its review strategy to ensure integrated safety and environmental reviews from the beginning. For example, the NuScale SMR design is the first reactor design that does not require Class 1E power or offsite power sources for safety. Thus, for such a novel design, the staff's traditional review approach to the DCA chapter on electric power would not be effective until the completion of several other DCA chapters, such as those associated with engineered safety features, instrumentation and controls, transient and accident analysis, and severe accidents. This example illustrates that, when the NRC receives new and different designs for review, the staff should initiate and conduct its review in an integrated manner. The NRC must ensure that it conducts its review of these novel features in a holistic, risk-informed manner that acknowledges their relative contribution to the safety case for the design. This includes reducing the scope and depth of review of novel features when risk-informed insights demonstrate such as approach is warranted. Similarly, applicants should be aware that, in accordance with 10 CFR 50.43(e), the performance of each safety feature must be demonstrated, and it must be shown that the interdependent effects among the design's safety features are acceptable. The applicant should describe how its application will accomplish this demonstration.

The NRC has already initiated efforts to enhance its review strategy to be more risk informed and focused. For new and advanced reactor reviews, the NRC should establish an interdisciplinary review team at the preapplication engagement phase to identify any cross-cutting technical and regulatory issues, assess their risk significance, and ensure that the staff performs its review of a unique new reactor design in an integrated manner. This focused team should be smaller and more flexible than the matrixed team used in the NuScale and prior new reactor application reviews. The team should include NRC subject matter technical experts from review areas related to the novel and risk-significant features in the design. A lead project manager will support and coordinate the team's activities and interactions with other technical reviewers and the applicant. Examples of the team's role and contributions to the efficiency, clarity, and reliability of the staff review include (1) assessing the novelty of the entire design during the preapplication phase and identifying the applicability of NRC regulations and technical review interdependencies, (2) recommending whether to request supplemental information from the applicant before accepting and docketing the application, (3) conducting briefings for management early in the review process on potential review challenges, (4) recommending approaches to achieving an integrated risk-informed review, (5) providing risk-informed input for establishing the NRC's review schedule and resource estimates, and

(6) maintaining cognizance of any design modifications after the application is docketed and providing recommendations for adjusting the staff's review strategy and schedule accordingly.

Applicant Action: At the beginning of a licensing review, and potentially during preapplication, the applicant should prepare and present to the NRC staff its approach to performing its risk assessment and the key conclusions. This should include sufficient detail and completeness for the NRC staff to reach early conclusions on the relative risk significance of various aspects of the design. It is recognized that the design risk assessment may evolve throughout the NRC staff's review because of issues identified by the staff or self-initiated by the applicant. In these cases, the applicant should promptly inform the staff of any new risk insights or vary the importance of previous insights.

NRC Action: The NRC should establish an interdisciplinary review team to prioritize this early engagement and dedicate resources to timely decisionmaking on the applicant's risk insights. The NRC should appropriately document the outcomes from this assessment and incorporate the findings into its development of schedules and allocation of resources for the review. Additionally, the NRC should use this information to conduct an integrated and holistic review of the design.

3. Enhancements to the Requests for Additional Information and Audit Processes

While the NRC staff and NuScale saw improvements in the use of RAIs and audits, continuous improvement is necessary to enhance clarity and reliability, as these tools will continue to be a critical component to ensure the docketing of key safety and technical information necessary to support the staff's reasonable assurance findings.

In 2008, the NRC's Office of New Reactors (NRO) issued office instruction NRO-REG-101, "Development, Review and Approval Process for Requests for Additional Information," to provide guidance to NRO staff on implementing the RAI process[7]. In 2019, after the merger of NRO and NRR, the staff issued office instruction LIC-115, Rev. 0, "Processing Request for Additional Information,"[8] to consolidate NRO-REG-101 and the RAI process guidance contained in NRR office instruction LIC-101, "License Amendment Review Procedures." During the course of the NuScale review, the staff initiated an effort to enhance the RAI process through greater focus on the regulatory requirements, safety significance, and clarity of RAIs. The staff documented this improvement in revision 1 to LIC-115, dated August 5, 2021.[9] Unfortunately, the staff completed that initiative after the early phases of the NuScale review when the majority of RAIs were issued. As such, some early RAIs did not benefit from the enhancements. As discussed previously, additional opportunities are available to focus the staff's review only on RAIs necessary to support the reasonable assurance finding. For example, while the NRC and NuScale used audits well in many cases, these sometimes were the result of RAIs being issued when it may have been more beneficial to conduct the audit first and then assess the need for RAIs. As such, the staff relied more heavily than may otherwise be necessary on the RAI process to obtain information on areas of the design.

The NRC and NuScale leveraged audits with varying degrees of success during the review, when it became apparent that the audits helped the staff understand key design attributes and focus on the information the applicant needed to supply on the docket to support safety findings.

[7] http://www.nrc.gov/docs/ML0806/ML080600394.pdf
[8] https://www.nrc.gov/docs/ML1924/ML19242B237.pdf
[9] ADAMS Accession No. ML21141A238

However, the NRC did not implement a reasonably consistent approach for the establishment and conduct of audits. While some variability may be warranted by the nature of the audit topic, the NRC should use consistent approaches, such as focused durations; clear and tangible objectives; routine schedules for progress reports; and phased approaches that prevent moving on to subsequent portions of audits before both the applicant and the NRC agree that precursor activities have been satisfactorily completed.

To conduct a timely and resource-focused safety review, RAI development must be complemented effectively by an applicant's responsiveness to RAIs. During the development of the NuScale review schedule, the NRC proposed a 30-day RAI response period.[10] NuScale evaluated the NRC staff proposal and requested a 60-day RAI response time to provide high-quality responses to the staff RAIs.[11] Data from the electronic RAI system show that NuScale was able to provide RAI responses within the 60-day goal approximately 70 percent of the time to support the review of DCA and 80 percent of the time to support the review of topical reports associated with the DCA. In many cases, the delayed responses were associated with HCIs that were posing challenges to the review schedule. The delayed responses contributed to inefficiencies in the review and preparation of the safety evaluation chapter inputs. For example, delays in some RAI responses prevented the NRC from declaring the Phase 2 milestone (draft safety evaluation with open items) fully met for key chapters such as those related to reactor performance under accident conditions. Overall, this contributed to project schedule and resource risks.

The NRC staff and future applicants should agree to key performance expectations on both sides for the issuance of and response to RAIs and the conduct of audits. Real-time data should then be collected during the review and routinely assessed by both entities to identify opportunities for improvements. When substantial delays occur during a review with either issuing or responding to an RAI that could adversely impact the ability of either party to perform their functions efficiently, it should be elevated, and changes to the allocated review resources, schedules, or both should be discussed.

Applicant Action: Applicants should review NRC RAIs and audit plans to assess whether the key attributes described above are included. Applicants should promptly raise any concerns and request clarification calls as necessary. Additionally, applicants should meet commitments for RAI responses and communicate any anticipated delays early. Applicants should acknowledge the impact of delays on the review schedule and resources.

NRC Action: The NRC should devote additional attention to ensuring that RAIs and audits conform to NRC guidance and assessing whether there are more effective means to gather the information, thereby maximizing the efficiency of the use of these tools to gather only the information necessary to reach a reasonable assurance determination. The NRC staff should assess at the beginning of each review whether enhanced management review and oversight of RAIs is warranted. For example, the NRC staff may determine that division-level management should either review all RAIs, for a specific project, or implement a more focused approach where RAIs are reviewed for selected topics within a project (e.g., critical path issues, high project risk issues) to ensure adherence to these principles. Likewise, NRC staff may determine

[10] NuScale presentation, "Design Certification Pre-Application Submittal Licensing Topic Resolution," Revision 0, dated April 21, 2015, ADAMS Accession No. ML15111A203

[11] NRC Letter to NuScale, "Review Schedule for the NuScale Power, LLC, Standard Design Certification of a Small Modular Reactor," dated May 22, 2017, ADAMS Accession No. ML17103A380

that NRC senior management should periodically sample RAIs to assess conformance with guidance and engage with applicants when they raise significant concerns about RAIs.

4. Establishment and Management of Review Schedule and Resource Estimates

The NRC's mission is focused on providing reasonable assurance of adequate protection of public health and safety, promoting the common defense and security, and protecting the environment. The NRC will expend the necessary time and resources to ensure that this mission is accomplished. However, the NRC staff acknowledges it must be disciplined in how it conducts its reviews, which includes establishing reasonable schedules and resource estimates for its activities and then tasking management to meet them.

At the beginning of the NuScale review, the NRC staff established a 42-month review schedule but did not provide NuScale with a resource estimate for the review.[12] Additionally, as the NRC developed its internal resource estimates, it is not evident that the agency could clearly tie the resource allocations to the risk or safety significance of those design aspects of the review. Furthermore, the NRC's system for tracking project completion did not integrate the status of the project closely with the resources being expended, especially in discrete technical disciplines. As such, the NRC lacked an effective real-time mechanism to link expenditures with risk significance and project completion. This circumstance led to exceeding internal estimates without proper early identification and engagement.

The NRC staff recognized this challenge during the review. As an interim corrective action, the staff developed detailed resource estimates for the completion of the final phases of the review. Leveraging the best information available from the project management software, NRC management and staff manually assessed resource expenditures biweekly over these remaining phases. To support effective cost management, as areas of the review were completed, the NRC staff closed the associated charge codes to avoid inadvertent costs to NuScale. Despite late design changes incorporated by NuScale, the NRC was able to complete its review within the established schedule and resource estimates it had developed.

This significant NRC challenge reflects the need for better scheduling and cost accounting methodologies in executing its safety mission. This will enhance the efficiency, clarity, and reliability of the review for the NRC and future applicants. Over the last year, as part of its transformation activities, the NRC has improved its ability to develop more challenging schedules and resource estimates without compromising safety. This includes better software for project management and resource expenditures based on data analytics and enhanced reporting capabilities for real-time tracking and monitoring by the staff and management. The staff has developed internal dashboards that provide the status of HCIs, track performance against schedules and resource estimates, and allow detailed assessments of areas of potential challenges. For recent projects, such as the Shine Medical Technologies, LLC,[13] application and Kairos Hermes[14] construction permit, the NRC issued detailed schedules and resource estimates to the applicants and is managing those projects in accordance with such plans. This

[12] NRC Letter to NuScale, "Review Schedule for the NuScale Power LLC Standard Design Certification of a Small Modular Reactor," dated May 22, 2017, ADAMS Accession No. ML17103A380

[13] "Shine Medical Technologies, LLC—Operating License Application Technical Review Schedule," dated April 30, 2020, ADAMS Accession No. ML20114E315

[14] "Kairos Power, LLC—Hermes Test Reactor Construction Permit Application Review Schedule and Resource Estimate," dated December 15, 2021, ADAMS Accession No. ML21343A214

includes piloting a new external dashboard[15] for the Kairos application that will increase transparency and openness in the conduct of the review.

NRC Action: The NRC must continue its efforts to achieve its safety mission through transformative efforts in how it plans, schedules, and manages resources for its projects. This includes leveraging enhanced software capabilities and project management tools to provide real-time assessments of performance relative to the initial estimated resources to complete the review, including staff hours and contractor support. Additionally, the NRC must be transparent with its applicants on its performance, including identifying early any challenges to meeting its performance goals relative to the review schedule, whether as a result of applicant decisions (e.g., design changes) or NRC performance.

[15] https://www.nrc.gov/reactors/non-power/hermes-kairos/dashboard.html

SECTION 3: STAFF'S RESPONSE TO THE NUSCALE RECOMMENDATIONS

In a letter to the NRC Executive Director for Operations dated February 19, 2021 (ADAMS Accession No. ML21050A431), NuScale proposed five recommendations to implement before the staff reviews NuScale's application for a standard design approval, which the company expects to submit in 2022. In the NRC's response dated April 15, 2021 (ADAMS Accession No. ML21102A307), the staff acknowledged receipt of NuScale's letter and replied that the staff would provide its assessment of NuScale's five recommendations as part of its own lessons learned activity.

This section of the report provides the NRC staff's response to NuScale's recommendations.

NuScale Recommendation #1

> Establish an appeal process to resolve disagreements between applicants and the NRC staff with respect to preliminary interpretations of requirements and guidance. The consequence of the absence of such a process is that regulatory burden has steadily increased from one applicant to the next without consideration of whether new staff positions have merit from a safety perspective.

NRC Staff Response

Consistent with NRC's Principles of Good Regulation, the staff strives for clarity and reliability in its application of the regulations. Similarly, if safety and technical disagreements occur, in accordance with the agency's openness and efficiency values, multiple processes are already available to applicants to address NuScale's concerns about the resolution of disagreements. For example, applicants may (1) demonstrate compliance with regulatory requirements through means other than those described in NRC guidance documents, (2) request meetings with senior NRC management to discuss their technical concerns, or (3) escalate their concerns to the Executive Director for Operations or the Commission. While the NuScale letter identifies some good practices, the staff has determined that establishing a new and separate appeal process is unnecessary to adhere to the Principles of Good Regulation and that adjudicating differences between the staff and applicants through a formal appeal process would likely require significant additional resources and time for both the applicant and the NRC. As such, the staff does not believe that a new, separate appeal process would enhance the efficiency of the staff's review of a new reactor licensing application. As discussed in Section 1, "Best Practices," the NRC staff recommends applicants and the staff to develop and leverage a list of HCIs to focus the applicant and staff resources to facilitate a more timely and efficient resolution of the HCIs. For instance, during the review of NuScale DCA, some of the HCIs, such as the IAB valve single failure criterion were resolved by engaging the senior leadership in the agency.

NuScale Recommendation #2

> Implement risk-informed decisionmaking consistent with the Commission's direction in Staff Requirements Memorandum SRM-SECY-19--0036 to "apply risk--informed principles when strict, prescriptive application of deterministic criteria…is unnecessary to provide for reasonable assurance of adequate protection." NuScale did not observe application of the SRM in the DCA review outside the specific decision rendered by that SRM. The consequence of this

limited application increased review durations and costs even where risk insights demonstrated adequate protection.

NRC Staff Response

This recommendation aligns well with the staff's lessons learned that reviews need to be conducted using a holistic, risk-informed review strategy. While the staff implemented multiple approaches to performing the NuScale review in a risk-informed manner, such as the evaluation of multi-module interactions or a module-drop event during refueling, the staff's lessons learned and NuScale's recommendation reflect opportunities for continuous improvement for both applicants and the NRC. The staff continues to refine its review approach for safety and regulatory decisionmaking processes and issued Office Instruction LIC-206, Revision 1, "Risk-informed Decision Making in Licensing Reviews," in June 2020. Additionally, the staff is developing a technology-inclusive, risk-informed, and performance-based regulatory framework through the 10 CFR Part 53 rulemaking and associated efforts, which the NRC staff response to NuScale Recommendation #3 discusses in more detail. These efforts, coupled with the actions described in the NRC's lessons learned on this topic, are intended to enhance the focus of safety reviews on the most risk-significant aspects of the design. Furthermore, as part of NRC's transformational efforts to become a modern and risk-informed regulator, the NRC staff published NUREG/KM-0016, "Guidance for Integrating Risk Insights into NRC Decisions,"[16] in March 2021. This publication provides detailed guidance on using the Be riskSMART framework and contains example case studies from across a series of disciplines.

NuScale Recommendation #3

Define credible. Numerous NRC requirements incorporate the concept of credible. The consequence of a lack of a definition is unpredictability in the review as interpretations vary among the staff, resulting in increased review durations and costs even for events of incredibly low frequencies and often with insignificant radiological consequences. In a complementary effort, NRC should endorse IAEA standard SSR-2/1 as an acceptable method for evaluating the adequacy of defense in depth.

NRC Staff Response

The NRC staff recognizes that the term "credible" is used in slightly different contexts in various NRC regulations and guidance documents, but it is not defined. However, the staff is taking several actions to ensure that the expectations are clear and predicable for defining accident sequences, including appropriate controls to prevent and mitigate potential accident consequences and taking probabilistic considerations into account as appropriate. In most cases, the term "credible" is used to ensure that requirements are not imposed to protect against nonphysical or obviously very unlikely events or phenomena. The definition of the term and possible demarcations of what may or may not be deemed credible can differ based on how a specific design and licensing methodology incorporate the concept. As such, developing generic definitions of credible may not present the most technology-inclusive approach and could unintentionally limit the ability of applicants to propose reasonable alternative methods for determining what is credible for their designs.

The current regulations under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR Part 52 provide a regulatory framework that, if met, ensures

[16] https://www.nrc.gov/reading-rm/doc-collections/nuregs/knowledge/km0016/index.html

that there is adequate protection of public health and safety, and the environment, including appropriate defense in depth. NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition" (SRP), includes guidance for LWRs that represent a sufficiently broad spectrum of transients and accidents or initiating events.

As required by the Nuclear Energy Innovation and Modernization Act, the NRC is developing a technology-inclusive, risk-informed, and performance-based regulatory framework (10 CFR Part 53 rulemaking) for any new reactor applicant. As part of this rulemaking activity, the NRC staff is developing flexible options for selecting licensing-basis events. The Nuclear Energy Institute (NEI) describes one approach for licensing-basis event selection in NEI 18-04, Revision 1, "Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development," issued August 2019,[17] which the NRC endorsed in Regulatory Guide 1.233, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light Water Reactors," issued June 2020.[18] This approach uses probabilistic risk assessment (PRA) in an enhanced role for the selection of licensing-basis events. By following this approach, an applicant can establish the event sequences for which its proposed design must include prevention and mitigation measures. While the embedded methodology considers frequency, engineering judgment remains an important part of the process. The methodology does not address what is "credible" but instead includes a determination of what sequences are specifically considered in the design and programmatic controls and those that contribute to the "residual risk" associated with a facility. Without using insights from a full-scope PRA in a holistic fashion, it is more difficult and can be even more subjective to define what constitutes "credible" for a given plant.

In response to stakeholder feedback on the 10 CFR Part 53 rulemaking and to afford applicants additional flexibility in defining and evaluating licensing-basis events without using PRA in an enhanced role, the staff is developing two additional approaches. One of these approaches uses PRA in a traditional role that is intended to better align NRC requirements with International Atomic Energy Agency (IAEA) Specific Safety Requirements No. SSR 2/1, "Safety of Nuclear Power Plants: Design," issued 2012.[19] This traditional approach includes defining design rules and allowing the use of stylized events to establish a design basis for the associated structures, systems, and components. While not meant to include physically impossible events or phenomena, the traditional approach introduces intentional conservatisms, to account for uncertainties or limitations in testing and analysis data, in the "credible" accidents that the applicant is required to analyze and address in the design. The other option under development would provide an alternative approach to selecting licensing-basis events by establishing a maximum credible or hypothetical accident. All three approaches would provide acceptable means of identifying the spectrum of credible events to support the safety case. The staff continues to encourage prospective new reactor license applicants to engage the NRC staff as early as practicable to discuss topics such as licensing-basis event selection and what approach they propose to identify credible accident scenarios for their design.

NuScale Recommendation #4

> Rely on downstream requirements and programs to supplement design detail and test data as part of NRC safety findings. Downstream programs include programs required by regulation; e.g., Appendix B quality assurance, the ASME

[17] ADAMS Accession No. ML19241A336
[18] ADAMS Accession No. ML20091L698
[19] https://www.iaea.org/publications/8771/safety-of-nuclear-power-plants-design

Code, and ITAAC [inspections, tests, analyses, and acceptance criteria]. The consequence of not relying on these required programs is increased cost and time to develop applications and obtain approval, without improving the safety of the constructed facility. In the case of the NuScale DCA, application development and review costs exceeded half a billion dollars.

NRC Staff Response

The staff must reach a safety finding on compliance with applicable NRC regulatory requirements at the design certification stage. Nevertheless, the NuScale recommendation has merit in that a holistic approach to safety requires not just considering safety in the reactor design within a silo but also how safety will be maintained during the construction and operation of a nuclear power plant. As discussed above, the NRC's establishment of an interdisciplinary review team will include direction to assure safety holistically, giving appropriate credit to programs that are implemented following the design phase (referred to here as "downstream" programs). The staff also notes that, in some areas of the NuScale DCA review, it relied on "downstream" programs. For example, the Design Specific Review Standard sections for the NuScale review referenced various "downstream" programs, such as the quality assurance program under 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"; the environmental qualification program under 10 CFR 50.49, "Environmental qualification of electrical equipment important to safety for nuclear power plants"; code design, inservice inspection, and inservice testing programs under 10 CFR 50.55a, "Codes and standards"; maintenance rule requirements under 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants"; and programs under 10 CFR 50.36, "Technical specifications." Nevertheless, opportunities do exist to consider "downstream" programs more substantially in a holistic review. For example, NRC staff efforts are underway to develop performance-based guidance that would increase reliance on operational programs rather than design features in nuclear reactors. With regard to potential regulatory changes, the staff recommends that NuScale provide its comments to the NRC (1) as part of the staff's ongoing rulemaking efforts to align the licensing processes under 10 CFR Part 50 and 10 CFR Part 52 and (2) as part of the 10 CFR Part 53 rulemaking.

NuScale Recommendation #5

Clarify the role of the ACRS. The ACRS's approach during the NuScale DCA review worked because the NuScale SMR was the only advanced reactor design under review. However, it was unnecessarily broad and burdensome, and the same approach may not work if there are multiple advanced reactor designs under review, as expected in the near future. The consequence of not clarifying the role of the ACRS is that the ACRS, due to resource constraints, may delay the approval and deployment of nuclear power plants with advanced safety features.

NRC Staff Response

The ACRS is an independent body from the staff and is established by the Atomic Energy Act of 1954, as amended (AEA). The ACRS, in accordance with its statutory responsibilities under the AEA, reviews and advises the Commission with regard to the licensing and operation of production and utilization facilities and related safety issues, the adequacy of proposed reactor safety standards, technical and policy issues related to the licensing of evolutionary and passive plant designs, and other matters referred to the ACRS by the Commission.

As part of its continuing effort to become more effective and assist the agency in its transformation initiatives, the ACRS completed a self-assessment of its review of the NRC staff's SER for the NuScale DCA. The ACRS published the results of its self-assessment in a letter report.[20]

The staff notes that the ACRS demonstrated agility in agreeing to adjust its review approach such that it was briefed only on risk-significant topics rather than on each SER chapter. This new and innovative concept was successfully implemented and represented a significant change from past ACRS practice. Nevertheless, opportunities exist to further enhance the efficiency of this process.

The applicant, the NRC staff, and the ACRS should meet early in the review to align on the approach for ACRS engagement. The parties should discuss how to streamline the number of ACRS interactions and meetings during the review and how to focus those on the most risk-significant aspects of the design. The staff should continue to encourage applicants to have early interactions with the ACRS to inform them of the overall design and its key safety principles. These early interactions should facilitate more efficient engagements as the ACRS prepares its recommendations to the Commission in accordance with its statutory responsibilities. Overall, the staff expects these concerted efforts will result in a more efficient ACRS review.

[20] "Observations and Lessons-Learned from ACRS Licensing Reviews Relevant to Future Advanced Reactor Applications," dated October 2, 2020, ADAMS Accession No. ML20267A655

SECTION 4: STAFF'S RESPONSE TO THE NEI RECOMMENDATIONS

In a letter to the NRC, the NEI included a set of recommendations[21] for the staff to consider in order to improve the efficiency of its new reactor licensing reviews. This section provides the NRC staff's response to these recommendations.

NEI Recommendation #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.

NRC Staff Response

As directed by the Nuclear Energy Innovation and Modernization Act of 2019, the NRC staff established generic milestone schedules for licensing reviews,[22] including the review of an application for a non-LWR. When it established these schedules, the staff noted that it will work with each licensee or applicant to establish a specific schedule for each request, which may be shorter or longer than the generic milestone schedule, based on the specific needs of the licensee or applicant and the NRC staff's resources. Cost estimates for LWR reviews are available on the NRC Web site[23] and may be informative for general planning and budgeting purposes. However, costs for reviews of future non-LWR applications will vary depending on many considerations, such as the overall complexity of the design, novel design features, the quality of the submitted application, and the level of preapplication engagement with the NRC.

While the NEI's recommendation focused on generic schedules, the NRC staff acknowledges in its lessons learned recommendations that enhanced effort is needed in establishing project-specific schedules and resource estimates and then manage to them. This report provides recommendations on how applicants and the NRC can facilitate more efficient, clear, and reliable reviews to achieve those goals.

Furthermore, the NRC's preapplication white paper cited above describes the benefits of robust preapplication engagement with the NRC staff. It proposes a set of preapplication activities that, if used appropriately, will enable the staff to offer a more predictable, efficient review of a non-LWR license application with a potentially shorter schedule. As reactor technologies mature and the NRC staff and industry gain more experience with non-LWR licensing and collect more data on the associated level of effort, the staff may adjust the generic schedules

[21] "NEI Input on Recent Application Experience for New Reactors," dated June 9, 2021, ADAMS Accession No. ML21160A246

[22] https://www.nrc.gov/about-nrc/generic-schedules.html

[23] https://www.nrc.gov/reactors/new-reactors/new-licensing-files/nro-fee-transformation-data.pdf

and cost estimates. In the meantime, the NRC is working to develop a review process for advanced reactors with the goal of making the reviews more efficient and safety focused. The NRC staff anticipates that the new process will require less review time and fewer resources, assuming that the incoming applications are complete and address the NRC feedback provided during preapplication interactions.

NEI Recommendation 1.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).

NRC Staff Response

The generic milestone schedules for non-LWR license reviews assume that applications are reasonably complete and do not have major gaps in the required information. For this reason, the schedule duration begins when the NRC staff accepts the application for review and ends with issuance of the final SER, as indicated in footnote 1 to the table of the generic milestone schedules posted on the NRC public Web site. Since the environmental review is intended to inform the decisionmaker's review, these schedules implicitly include completing the final environmental impact statement concurrent with or before the final SER.

With regard to acceptance reviews, the NRC intentionally engages with applicants at the beginning of a review to discuss this duration. This duration is informed by the quality of the application, the extent of any voluntary preapplication discussions conducted with the applicant, and the complexity of the design. The staff strives to establish aggressive acceptance review schedules whenever possible, as demonstrated by the preapplication white paper process, which proposes situations in which the NRC will waive the acceptance review.

Finally, the mandatory hearing process is the Commission's means for evaluating the staff's work and conducting appropriate deliberations to determine whether to grant a license. The NRC staff will always work with the Commission to conduct that process as efficiently as possible but will not establish schedules that constrain the Commission's ability to execute its statutory authority. The NRC staff should engage with the applicant at the appropriate time during the licensing process, once the Commission issues its hearing schedule, to ensure that both parties understand the schedule and opportunities to execute it in the most efficient manner.

NEI Recommendation 1.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.

NRC Staff Response

The NRC staff based the schedule targets for non-LWR licensing reviews on the assumption that non-LWR designs would vary in complexity, and some could be completed on shorter schedules than reviews of applications for LWRs. Specifically, the NRC's generic schedules for reviews of operating licenses and COLs estimate 36 months for non-LWRs and 42 months for LWRs. The preamble to the table of generic schedules states, "The NRC staff will work with each licensee or applicant to establish a specific schedule for each request, which may be shorter or longer than the generic milestone schedule based on the specific needs of the licensee or applicant and the staff's resources." As mentioned above, the NRC staff and industry are in the early stages of non-LWR licensing and may use data to refine these generic schedules in the future.

NEI Recommendation 1.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 [U.S. Department of Energy], 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 NEI Recommendation 2.d in the next section for the importance of clear and timely schedule communication on a particular application.

NRC Staff Response

The NRC's mission is focused on providing reasonable assurance of adequate protection of public health and safety, promoting the common defense and security, and protecting the environment. In fulfilling its mission, the NRC staff is actively engaging with ARDP participants and selectees in preapplication activities to support potentially accelerated review schedules as

the prospective applicants work to complete their applications. Planning for these reviews, and the reviews of other non-LWR license applications, follows the more aggressive generic schedules established for non-LWRs, with due consideration of each applicant's design and its requested review schedule. As a recent example, the NRC established an aggressive 21-month schedule for the Kairos Hermes construction permit.[24] This schedule reflects the high quality of the application and the value of the applicant's preapplication activities. The NRC will similarly look to leverage these initiatives and the lessons learned in this report to continue to set aggressive schedules in support of safely licensing new and advanced reactor designs.

NEI Recommendation 1.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.

NRC Staff Response

As previously mentioned, the NRC staff and industry are in the early stages of non-LWR licensing, and data on the costs of non-LWR licensing reviews are limited at this time. The NRC is striving to enhance its processes to provide more timely and efficient safety decisions and cost estimates for both SMRs and non-LWR designs, but costs may vary among reviews based on the complexity and maturity of different designs as well as the quality of the submitted application. At the beginning of each new application process, the NRC is providing both a schedule letter and a resource estimate for the safety and environmental portions of the review. Recent examples, including the Shine medical isotope review and the Kairos Hermes construction permit application, reflect the staff's commitment to conducting these reviews in a more timely and cost-effective manner without compromising safety. The NRC has developed new data-driven analytical capabilities to track and monitor costs and routinely engages with applicants on how the review is tracking relative to the estimates provided. As part of its efforts to conduct more efficient reviews, the NRC is using an interdisciplinary team approach that focuses the number of technical reviewers assigned to the review commensurate with the risk significance of design attributes, thereby reducing costs. The staff remains committed to its current practice of assessing the status of each project every 2 weeks to provide current costs and projections to both the staff and the applicants. As noted in the response to NEI Recommendation #2, the staff is also developing guidance to address the content of advanced reactor applications (for applications under 10 CFR Parts 50, 52, or 53 using the Licensing Modernization Process (LMP)) under the Technology Inclusive Content of Application Project (TICAP) and Advanced Reactor Content of Application Project (ARCAP) initiatives to focus its effort and resources on the most risk-significant areas.

[24] "Acceptance for Docketing of the Hermes Non-Power Test Reactor Construction Permit Application, Submitted by Kairos Power. LLC," dated November 29, 2021, ADAMS Accession No. ML21319A354

NEI Recommendation 1.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.

NRC Staff Response

The NRC staff's practice is to develop a review schedule and cost estimates tailored to each application, including estimates of NRC staff hours and contractor costs needed to complete the review. This recommendation aligns well with the staff's lessons learned on establishing review schedules and resource estimates and managing to them. For each review, the NRC will inform the applicant of the estimated costs and schedules for the safety and environmental portions of the review once sufficient information is available from the applicant and the NRC staff has formally accepted the application for docketing. The NRC staff provides this information to the applicant before beginning the indepth review of the application and expending substantial resources. If the NRC staff determines that significant changes to the schedules or costs are warranted, it will discuss the changes and the reasons for the changes and document them on the docket. The NRC staff has internal controls that govern these types of changes and collects relevant data to inform initial estimates and identify potential efficiency gains for future reviews. As the NRC staff and industry gain additional experience with non-LWR licensing, the NRC staff will continue to enhance the collection, analysis, and sharing of data to support timely and efficient licensing reviews.

NEI Recommendation #2:

NEI Recommendation 2.a:

> Improving Efficiency in the Review Process. 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).

NRC Staff Response

This recommendation aligns well with the staff's lessons learned on the application of a holistic, risk-informed review strategy for new and advance reactors. The staff intends to implement the actions described in this report to address this comment.

In addition, as required by the Nuclear Energy Innovation and Modernization Act, the NRC staff is developing a technology-inclusive, risk-informed, and performance-based regulatory framework, centered on the rulemaking efforts to develop 10 CFR Part 53 and the development of guidance needed to support this new regulatory framework. The new framework will support future applications and reviews for new advanced LWRs and non-LWRs. A key part of this framework is guidance described in the industry-developed LMP document NEI 18-04, Revision 1, endorsed by the NRC in Regulatory Guide 1.233. This methodology provides a structured process to apply risk-informed principles in making findings of reasonable assurance of adequate protection. It also includes a systematic, risk-informed process for licensing-basis event selection, which establishes a spectrum of anticipated operational occurrences, design-basis events, and beyond-design-basis events.

The staff is also engaging industry and stakeholders in applying a risk-informed approach to developing guidance to address the content of advanced reactor applications (for applications under 10 CFR Parts 50, 52, or 53 using the LMP process) under TICAP and ARCAP initiatives. All of these efforts will help further risk-inform the staff's reviews by focusing its effort and resources on the most risk-significant areas. Additionally, implementing an integrated review with an interdisciplinary review team, which includes risk analysts with the other team members, also serves to risk inform the staff's reviews.

With regard to the role and potential graded use of the PRA by applicants through successive phases of regulatory review, the staff is considering this feedback in its development of the 10 CFR Part 53 proposed rule and has formed a working group to evaluate possible approaches. The staff is also currently developing a trial-use regulatory guide to endorse American Society of Mechanical Engineers (ASME)/American Nuclear Society (ANS) RAS-1.4-2021, "Probabilistic Risk Assessment Standard for Advanced Non-Light Water Reactor Nuclear Power Plants," and NEI 20-09, "Performance of PRA Peer Reviews Using the ASME/ANS Advanced Non-LWR PRA Standard," for demonstrating the acceptability of PRA results used to support advanced non-LWR licensing.

NEI Recommendation 2.b:

> The NRC should take immediate steps to realign on the appropriate level of detail and content of applications.

NRC Staff Response

With regard to future applications for advanced LWRs and non-LWRs, the staff is making extensive efforts to develop application and review guidance within the ARCAP and TICAP initiatives. The TICAP guidance is based on the use of the risk-informed, performance-based LMP process. The staff is also modernizing its SRP through the SRPMod effort. The purpose of this initiative is to improve the quality of NRC reviews by modernizing SRP sections to focus the staff's review on aspects important to safety and to consistently use risk insights with engineering judgment. The staff is engaging extensively with industry and stakeholders to develop this ARCAP and TICAP guidance and to determine the appropriate level of detail for advanced reactor applications (under 10 CFR Parts 50, 52, or 53 using the LMP process),

keeping in mind technology-inclusive considerations. The goal of this approach is to address the information that is necessary and sufficient to meet the regulatory requirements and focus the staff's review resources on the most risk-significant aspects. The staff is developing performance-based approaches where appropriate, which allow for more reliance on operational programs to provide reasonable assurance of adequate protection and less on the review of design features. For example, draft ARCAP Chapters 9 and 10 provide performance-based guidance that focuses on meeting existing regulations for the control of routine effluents and occupational dose and radiation protection.

Additionally, the NRC is currently conducting rulemaking to align the licensing processes in 10 CFR Part 50 and 10 CFR Part 52. The Commission also confirmed that its Severe Accident Policy Statement and other Commission direction identified in SECY-15-0002, "Proposed Updates of Licensing Policies, Rules, and Guidance for Future New Reactor Applications," dated January 8, 2015, apply to new 10 CFR Part 50 power reactor applications in a manner consistent with applications submitted under 10 CFR Part 52.

Because several decades have passed since the NRC reviewed a construction permit application for a light-water power reactor, the staff developed and published draft staff interim guidance, "Safety Review of Light-Water Power-Reactor Construction Permit Applications," dated December 3, 2021,[25] to facilitate the safety review of LWR construction permit applications. The staff will continue to assess experience with the use of this guidance and the interdisciplinary team approach to align the necessary level of detail in applications with information needed to make its findings of reasonable assurance of adequate protection.

NEI Recommendation 2.c:

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

NRC Staff Response

Consistent with the NRC's Principles of Good Regulation, the staff strives for clarity and reliability in its application of the regulations. Similarly, if safety and technical disagreements occur, in accordance with the agency's openness and efficiency values, multiple processes are already available to applicants to address NuScale's concerns about the resolution of disagreements. For example, applicants may (1) demonstrate compliance with regulatory requirements through means other than those described in NRC guidance documents, (2) request meetings with senior NRC management to discuss their technical concerns, or (3) escalate their concerns to the Executive Director for Operations or the Commission. For example, during the NuScale review, when potential disagreements on HCIs between NuScale and the staff occurred, these issues were routinely elevated to the Director of the former Office of New Reactors for consideration and timely decisionmaking. NuScale routinely availed itself of the opportunity to elevate issues in this manner. While the NuScale letter identifies some good practices, the staff has determined that establishing a new and separate appeal process is unnecessary to adhere to the Principles of Good Regulation, and that adjudicating differences between the staff and applicants through a formal appeal process would likely require significant additional resources and time. As such, the staff does not believe that a new, separate appeal process would enhance the efficiency of the staff's review of a new reactor licensing application.

[25] ADAMS Accession No. ML21165A157

NEI Recommendation 2.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 preapplication activities and the application review. This is particularly salient if the resources invested in preapplication activities are to add significant value for all parties in the subsequent application review.

NRC Staff Response

The NRC staff agrees that open and transparent communication is essential to efficient project management and reviews of new reactor licensing applications. In addition to setting expectations and priorities through preapplication and regulatory engagement plans, the NRC staff encourages regular, frequent communication throughout preapplication activities and application reviews. Public meetings, periodic status reports, and docketed correspondence with applicants and prospective applicants help to achieve a common understanding of review goals and metrics, address emergent issues, and keep the plans up to date in a timely manner.

The NRC staff values openness and transparency in conducting licensing reviews and other NRC business. Recent enhancements to the NRC public Web site include additional information about ongoing non-LWR licensing reviews and preapplication engagement with potential applicants and vendors. The NRC staff is also developing new communication tools, such as dashboards, on the NRC public Web site in an effort to provide near real-time information on individual non-LWR licensing reviews.

NEI Recommendation 2.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 [question and answer] 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 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.

NRC Staff Response

This recommendation aligns well with the NRC staff's lessons learned on enhancing the RAI and audit processes. The NRC staff agrees that a common understanding of the process, scope, basic design and technical information, and expected documentation is necessary for

efficient audits that support reviews of new reactor licensing applications. The NRC staff is committed to addressing these aspects in an audit plan provided to the applicant before the staff begins that audit and also recognizes that changes to the plan may be warranted as an audit progresses. During the course of the NuScale review, the staff and NuScale made real-time adjustments to how audits were conducted to establish clear goals and milestones that focused the effort and duration of these reviews. The NRC intends to carry these best practices forward and implement the identified lessons learned in future reviews.

NEI Recommendation #3:

Clarify the Role of the ACRS

NRC Staff Response

The ACRS is an independent body from the staff and is established by the AEA. In accordance with its statutory responsibilities, the ACRS reviews and advises the Commission with regard to the licensing and operation of production and utilization facilities and related safety issues, the adequacy of proposed reactor safety standards, technical and policy issues related to the licensing of evolutionary and passive plant designs, and other matters referred to the ACRS by the Commission.

As part of its continuing effort to become more effective and assist the agency in its transformation initiatives, the ACRS completed a self-assessment of its review of the NRC staff's SER for the NuScale DCA (See Footnote 18.)

The staff notes that the ACRS demonstrated agility in agreeing to adjust its review approach such that it was briefed only on risk-significant topics rather than on each SER chapter. This new and innovative concept was successfully implemented and represented a significant change from past ACRS practice. Nevertheless, opportunities exist to further enhance the efficiency of this process.

The applicant, the NRC staff, and the ACRS should meet early in the review to align on the approach for ACRS's engagement. The parties should discuss how to streamline the number of ACRS interactions and meetings during the review and how to focus those on the most risk-significant aspects of the design. The staff will encourage applicants to have early interactions with the ACRS to inform it of the overall design and its key safety principles. These early interactions should facilitate more efficient engagements as the ACRS prepares its recommendations to the Commission in accordance with its statutory responsibilities. Overall, the staff expects these concerted efforts will result in a more efficient ACRS review.