





UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

November 14, 2022

MEMORANDA TO: Robert M. Taylor  
Deputy Director for New Reactors  
Office of Nuclear Reactor Regulation

FROM: Mohamed K. Shams, Director  Signed by Shams, Mohamed  
Division of Advanced Reactors and Non-Power on 11/04/22  
Production and Utilization Facilities  
Office of Nuclear Reactor Regulation

Brian W. Smith, Director  Signed by Smith, Brian  
Division of New and Renewed Licenses on 11/14/22  
Office of Nuclear Reactor Regulation

SUBJECT: RESPONSE TO THE NUSCALE DESIGN CERTIFICATION  
APPLICATION LESSONS LEARNED REPORT

This memorandum provides a response to the lessons learned from the U.S. Nuclear Regulatory Commission (NRC) Staff's Review of the NuScale Design Certification Application (Agencywide Documents Access Management System (ADAMS) Accession Number [ML22088A160](#)). The staff has undertaken significant improvements in its licensing processes and procedures over the past several years both in response to the lessons learned from the NuScale design certification review and as part of its overall advanced reactor readiness activities that were initiated in 2017. Through these activities, the staff has implemented enhancements focused on improving regulatory efficiency, clarity, and reliability for new reactor reviews including light-water small modular reactors and non-light water reactors. For example, the NRC has established an aggressive 21-month schedule for the Kairos Hermes construction permit and is executing this review on schedule and budget using these strategies. Using this experience and others, the NRC staff will continue to seek opportunities to optimize its advanced and new reactor review process.

The NuScale Lessons Learned Report identified four specific recommendations. This response outlines the staff's completed and ongoing actions that are responsive to these areas.

**Recommendation 1: Design Finalization at Application and Changes During Licensing**

The report recommended that applicants 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. The report recommended that staff conduct early assessment of the potential risk significance of these areas and discuss with the applicant any potential impacts on schedules or resources.

Staff Response:

The staff encourages early preapplication engagement with prospective applicants in accordance with the Advanced Reactor Policy Statement. There are significant benefits to robust preapplication engagement including enhanced regulatory predictability, reducing project risk, and accelerated review schedules. The NRC staff's draft white paper, "Pre-application Engagement to Optimize Application Reviews" (ML21145A106), provides information about steps that can be taken before submitting an application. This guidance, which will be formalized as part of the Advanced Reactor Content of Application Guidance (ARCAP) Interim Staff Guidance (ISG) to be issued in Fall 2022, encourages preapplication engagement on several topics including novel design features and testing plans. It also explains that if the applicant makes substantive changes to the application after submittal, those changes may impact the schedule and that if the applicant participates in preapplication activities then the design should not change significantly between preapplication and the time the application is submitted so that matters resolved in preapplication are not adversely impacted thereby impacting the review schedule. This preapplication guidance is being used to inform ongoing preapplication activities with new and advanced reactor developers. With regard to application reviews, the staff works proactively to identify any significant and challenging issues early in the review to minimize potential schedule impacts. In turn, it is incumbent upon the applicant to promptly submit information necessary to resolve these issues in order for the review to proceed as scheduled. The staff also strongly encourages applicants to provide regulatory engagement plans to define desired outcomes from preapplication reviews as discussed in the Regulatory Review Roadmap (ML17312B567).

Recently, the NRC staff conducted preapplication readiness assessment audits of preliminary safety analysis reports for the Kairos Hermes test reactor and Abilene Christian University's molten salt research reactor following formalized NRC staff guidance in the Office of Nuclear Reactor Regulation's Office Instruction LIC-116, "Preapplication Readiness Assessment" (ML20104B698). These audits fostered common understanding between the NRC staff and the applicants about design uncertainties and their potential impacts on review schedules. As a result of the NRC staff's feedback during the audits, the applicants updated their construction permit applications to minimize the likelihood that design changes or uncertainties would adversely impact NRC's review schedules and resource estimates. The staff is currently conducting a readiness assessment for the NuScale draft standard design approval application. NuScale has indicated that it will address the feedback received in its final application.

In terms of risk informing the application review, the staff has developed guidance for risk-informed licensing approaches (see 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"). This guidance coupled with guidance to risk-inform the content of applications (See [Advanced Reactor Content of Applications Project](#)) serves to focus future applications on the most safety and risk significant aspects of the design, and in turn focus the staff's resources to enable effective and efficient risk-informed decision making. The staff's ongoing efforts to complete a rulemaking to develop a technology-inclusive, risk-informed and performance-based regulatory framework in accordance with the Nuclear Energy Innovation and Modernization Act (NEIMA) builds off of these guidance development efforts to increase the use of risk insights in decisionmaking.

**Recommendation 2: Application of a Holistic, Risk-Informed Review Strategy**

The report recommended that 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.

**Staff Response:**

As discussed in the report, for advanced reactor reviews, the NRC establishes core review teams with multidisciplined expertise during the preapplication engagement phase to identify any cross-cutting technical and regulatory issues, assess their risk significance, and ensures that the staff performs its review of a unique new reactor design in an integrated manner. The staff is implementing this approach for ongoing preapplication reviews and for the ongoing Kairos Hermes construction permit application enabling an efficient and timely review.

For the NuScale standard design approval (SDA) application review, the review team will be structured such that the interdisciplinary review team concepts will be addressed. The approach to performing the review will be documented in the charter for the NuScale SDA application review. In advance of the application being submitted, the staff plans to prepare risk insights associated with the new design through an assessment of NuScale's draft probabilistic risk assessment. These risk insights will be used to prioritize technical review areas and develop the schedules and allocation of resources for those review areas in accordance with their risk significance. A technical advisor will guide the technical review aspects of the application review and will continually assess and revise the risk insights, as necessary, throughout the review. The primary responsibilities of the technical advisor will be to ensure a holistic approach to the SDA application review, identify risk insights that can be used to guide the overall review, lead the resolution of highly challenging issues, support the implementation of audits, help streamline the request for additional information (RAI) process, and aid in the development and execution of schedules and allocations of resources for the review. Implementation of this approach, as well as core teams, will be evaluated and lessons learned developed and applied to inform the future structure and execution of such groups.

**Recommendation 3: Enhancements to the Requests for Additional Information and Audit Processes**

The report recommended that NRC 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.

**Staff Response:**

As discussed in the report, 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 (ML21141A238). The staff is implementing this guidance in current reviews. To date, for the

Kairos review, the staff and applicant have effectively communicated and resolved over 400 questions using audits and requests for confirmatory items resulting in a reduced need for formal RAIs. Further, the staff is leveraging the use of regulatory audits to the extent practicable in order to increase the efficiency of the review. Lastly, the use of interdisciplinary review teams and core review teams provides an additional means of focusing the staff's requests for information on the information needed to support reasonable assurance safety findings. The staff plans to collect additional data from the ongoing and near term reviews to identify and implement further enhancements.

#### **Recommendation 4: Establishment and Management of Review Schedule and Resource Estimates**

The report recommended that the staff continue transformative efforts in how it plans, schedules, and manages resources for reviews. 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 goals relative to the review schedule, whether as a result of applicant decisions (e.g., design changes) or NRC performance.

##### Staff Response:

In response to NuScale Lessons Learned and actions required by NEIMA, the staff has made enhancements to transform how it plans, schedules, and manages resources for reviews. Section 102(c) of the NEIMA required the NRC to develop performance metrics and milestone schedules for "requested activities of the Commission," including the review of new reactor licensing applications. NEIMA also establishes certain reporting requirements for the NRC in the event the NRC issues a final safety evaluation for a requested activity of the Commission later than the NRC established milestone schedule date. The NRC's generic milestone schedules were posted on the NRC's public website.

The staff has made enhancements to its project management software capabilities to better allocate resources to the most risk significant aspects of designs, track and manage resource expenditure, and increase accountability and transparency through the review process. Specifically, the Revised Reactor Program System has been improved over time to make the management of large licensing reviews easier for project managers, including the recent incorporation of aspects from the Enterprise Project Management system. The staff will also take advantage of other software packages, such as Microsoft Project Pro, to assist in managing large licensing reviews.

The staff has also made enhancements to ensure transparency in its scheduling. For example, the NRC staff created internal and external (public) dashboards for the review of the Kairos Hermes construction permit and the NuScale SDA application. These dashboards provide key information on project status, review milestones, due dates, main technical issues, expenses, resources used, and percent of tasks completed. The dashboards automatically gather information from existing NRC data systems in near real-time, such as workflow management and time and labor reporting software and present it in a concise and user-friendly format in one, easy to access place. The dashboards contain the information necessary to track the health and status of the project while standardizing the information collection and assessment such that it can then be easily replicated as needed for upcoming reviews of other new and advanced reactor applications. With these

enhancements, project managers have more tools available to closely monitor a projects resource expenditures in a frequent and timely manner, communicate clearly with applicants, and address abnormalities as needed.

The staff has also implemented enhanced project controls to ensure more accountability during reviews. As discussed previously, resources will be allocated in reviews in accordance with the anticipated risk significance of design aspects at the beginning of reviews. As the review progresses, project managers and technical reviewers will use the enhanced tools to assess project status and ensure timely completion of interim milestones. If unanticipated circumstances arise, such as design changes or identification of new risk significant aspects, project managers and technical staff will assess the impacts on project schedule and resource expenditures and make recommendations to management for appropriate adjustments. Before adjustments are made, NRC staff will engage with the applicant to communicate proposed changes and request feedback. Any significant changes to schedules or resource estimates will be formally communicated to the applicant and updated in NRC project management tools.

The impact of the dashboards and project controls has enhanced communication with internal and external stakeholders that increases clarity and openness on new and advanced reactor licensing reviews while reducing the burden on the NRC project staff to manually collect and organize the information. NRC staff has received positive feedback from stakeholders on these tools. The NRC staff also implemented a generic process for documenting and communicating changes to schedules and hours estimates and the bases for the changes to account for various factors, including design changes, changes to the scope of reviews requested by applicants, and delays in receiving information from applicants.

Based on the actions outlined above, the staff has concluded that the identified actions in the NuScale Lessons Learned Report have been implemented and processes have been established to enhance the efficiency and effectiveness of regulatory reviews. The staff continues to gain experience in these areas through preapplication reviews of multiple new and advanced reactor designs; through the construction permit application reviews of the Kairos Hermes Test Reactor and the Abilene Christian University Molten Salt Research Reactor; and the Readiness Assessment for the NuScale SDA application. As additional experience is gained from these and other reviews, the staff will continue to make enhancements to its licensing processes, as appropriate, and continue to identify and institutionalize best practices.

With this response, the staff considers the actions in the NuScale Lessons Learned Report to be closed.

SUBJECT: RESPONSE TO THE NUSCALE DESIGN CERTIFICATION APPLICATION  
LESSONS LEARNED REPORT DATE: NOVEMBER 14, 2022

**DISTRIBUTION:**

PUBLIC

RidsAcrsMailCenter Resource

RidsOgcMailCenter Resource

RidsNrrDnrlMail Resource

RidsNrrOd Resource

RidsNrrDanu Resource

AKock, NRR

RTaylor, NRR

MKing, NRR

SMoore, ACRS

BSmith, NRR

BThomson, NRR

MShams, NRR

CCarusone, NRR

JBowen, NRR

CMiller, NRR

RFelts, NRR

ABuford, NRR

EBenner, NRR

MSampson, NRR

MFranovich, NRR

MKhanna, NRR

JDonoghue, NRR

MRoss-Lee, NRR

BPham, NRR

JHeisserer, NRR

GSuber, NRR

ACubbage, NRR

MDudek, NRR

SLynch, NRR

GBowman, NSIR

KBrock, NSIR

CWolf, OCA

SBurnell, OPA

**ADAMS Accession No.: ML22294A144**

**NRR-106**

OFFICE	NRR/DANU/UARP	NRR/DNRL	NRR/DANU
NAME	ACubbage	BSmith	MShams
DATE	10/26/2022	11/14/2022	11/4/2022

**OFFICIAL RECORD COPY**