September 6, 2019

U.S. Nuclear Regulatory Commission
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SUBJECT: NuScale Power, LLC Submittal of Presentation Materials Entitled “Standard Design Approval: Regulatory Strategy Overview,” PM-0919-66825, Revision 0

The purpose of this submittal is to provide presentation materials to the NRC for use during the Standard Design Approval (SDA) pre-application meeting on September 25, 2019.

The enclosure to this letter is the nonproprietary version of the presentation entitled “Standard Design Approval: Regulatory Strategy Overview.”

This letter makes no regulatory commitments and no revisions to any existing regulatory commitments.

If you have any questions, please contact Michael Melton at 240-833-3007 or at mmelton@nuscalepower.com.

Sincerely,

Zackary W. Rad
Director, Regulatory Affairs
NuScale Power, LLC

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Enclosure: “Standard Design Approval: Regulatory Strategy Overview,” PM-0919-66825, Revision 0
Enclosure:

"Standard Design Approval: Regulatory Strategy Overview," PM-0919-66825, Revision 0
Standard Design Approval
Regulatory Strategy Overview

Zackary Rad
Director, Regulatory Affairs

September 25, 2019
Agenda

• Introduction and opening remarks
• Safety message
• Background and engagement objectives
• Focus of pre-application phase
• Planned approach to pre-application topics
• Overview of key pre-application/review topics
  - Proposed standard design approval (SDA) application framework
  - Updates to SDA application content
  - Format of SDA application content
  - Pre-application audits and assessments
  - Additional planned pre-application topics
• Overview of proposed schedule
• Draft NuScale Regulatory Engagement Plan
• Summary
Safety Message

Decision Making

• Consistent process: Individuals use a consistent, systematic approach to make decisions. Risk insights are incorporated as appropriate.
  – The organization establishes a well-defined decision-making process, with variations allowed for the complexity of the issue being decided.
  – Individuals demonstrate an understanding of the decision-making process and use it consistently.

Office Safety

• Serious injuries and deaths aren’t limited to industrial environments – gravity is universal and persistent
• From OSHA fatality reports – 22 reported fatalities in 2019 from slips, trips, and falls down stairs
  – 5 from slips (same level falls)
  – 8 from trips (same level falls)
  – 9 from falling down stairs
Background and Engagement Objectives

• Background
  – NuScale is planning to use the SDA review process under 10 CFR 52 Subpart E to obtain NRC approval for changes that arise from the design update projects
  – The design update projects include power uprate (NPM-200), cost optimization, and other changes identified during design finalization
  – Consistent with part 52.133, the SDA will be referenced by future applicants in a combined license application (COLA)

• Engagement Objectives
  – Introduction to pre-application focus areas
  – Overview of select pre-application topics
  – Overview of planned schedule and future interactions
Focus of Pre-Application Phase

• Align on application scope/content and key aspects of review
  – Application scope and format (FSAR, TS, ITAAC, etc.)
    • Inclusion of select “deferred” scope (e.g., COL Items, CDI)
    • Indication and categorization of content updates
  – Protocol for and treatment of risk-informed and optimized content
    • Level of detail consistent with significance
    • COL items focused on NuScale design-specific items vs. exhaustive
    • Determination and treatment of “non-significant” changes/departures*
  – Protocol for and implementation of risk-informed (safety-focused) review
    • Better defined standard for determining “reasonable assurance” and “credible” events
      » Scope and depth of review consistent with significance

*potential gap in existing regulations
Focus of Pre-Application Phase (continued)

• Alignment on application scope/content and key aspects of review (continued)
  - Administrative and process requirements for review implementation
    • Requirements for treatment of supporting information (e.g., incorporated by reference (IBR), referenced, etc.)
    • Improved rigor in conduct of audits (planning, schedule, scope management)
    • Process for achieving alignment on review topics (e.g., escalation)
  - Scope/Budget management
  - Tools to ensure effective and consistent implementation (e.g., REP, review plan)

• Familiarization with key design/analysis updates
  - Facilitate more effective review through early introduction
    • Design described in SDA application will be similar to that provided in the NuScale design certification application (DCA)
    • Significant first-of-a-kind (FOAK) topics have been resolved as part of the DCA review
  - Identify any potential challenges in advance
Approach to Pre-Application Topics

- Pre-application engagements for review-related topics will generally include
  - Proposed approach, methodology, criteria etc.
  - Example results developed through pilot application
  - Iterative engagements to incorporate input and achieve alignment
  - Final approach captured in writing to facilitate consistent implementation

- Technical topics will focus on those anticipated to improve review effectiveness
  - Key design/analysis updates
  - Topics maturing early in application development
  - SDA application “change packages” may be provided via eRR prior to application submittal when practical
Overview of Select Pre-Application Topics

- Proposed SDA application framework
  - Potential regulatory "gaps"
- Updates to application content
  - Categories of updated content
- Format of SDA application content
- Pre-application readiness assessment
Proposed SDA Application Framework

• Application pursuant to 10 CFR 52, Subpart E
• Final Safety Analysis Report (FSAR) for the “entire facility” (10 CFR 52.135) including associated changes to Topical and Technical Reports
• Include application parts not specifically required by 10 CFR 52 Subpart E
  – Consistent with the applicable portions of the NuScale DCA and RG 1.206*
    • Technical Specifications
    • ITAAC
    • Exemptions
  – Support efficient incorporation of SDA by COL applicants
  – Improve review effectiveness by providing comprehensive application
• Provisions clarifying post approval change process for COL applicants*

*potential gap in existing regulations
## Proposed SDA Application Framework

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<thead>
<tr>
<th>Application Part</th>
<th>Combined License</th>
<th>Design Certification</th>
<th>SDAA – Required by Regulation</th>
<th>SDAA – Needed to Support COL</th>
<th>Include as Part of SDAA Submittal</th>
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<tr>
<td>Transmittal Letter</td>
<td>✓</td>
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<td>✓ (financial information not required)</td>
<td>✓ (financial information not required)</td>
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<td>(see below)</td>
<td>(see below)</td>
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<td>• Ch 1 - Introduction</td>
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<td>ITAAC Only (see Part 08)</td>
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<td>No (FSAR Ch 2)</td>
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<td>✓</td>
<td>Yes (could also be included in FSAR Ch 16)</td>
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<th>Include as Part of SDAA Submittal</th>
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<td>✓ (ITAAC only) NuScale DCA references Part 2 Tier 1</td>
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<td>Yes (only ITAAC)</td>
<td>Yes (only ITAAC) Could include as a separate report</td>
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<td>✓</td>
<td>NuScale DCA provides list of tables and figures</td>
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Updates to SDA Application Content

- Updates to content (from DCA) will generally fall into the following categories:
  - Targeted design/analysis updates
    - Increase thermal power output
    - Improve commercial viability
    - Improve constructability
  - Address "deferred" items
    - Select COL items from DCA
      - Generic BOP design items
      - Operational items
    - Select conceptual design items
  - Enhancement of application content
    - Risk-informed content - removing excessive detail where applicable
    - Improved consistency and rigor in identifying requirements for downstream applicants (i.e., COL items)
  - Address any updated regulations/guidance
Format of SDA Application Content

• Content will be formatted to facilitate more effective review
  – Color-coded text directly in the application to indicate changes from the DCA and denote significance, e.g.,
    • Black - no change
    • Brown – change screened as not-significant
    • Blue – changes that screen as potentially significant
  
• In principle, only those items color-coded "blue" will require further review
  
• Version showing deletions (strikeouts) may be placed in the eRR to help facilitate effective review
  
• Final black/white version submitted in support of the NRC staff’s final SER issuance
Pre-Application Audits and Assessments

• Pre-application audits should be focused for the SDA application
  – Design and methodologies FOAK topics will be consistent with those addressed in DCA review

• SDA application change packages may be provided prior to application submittal when practical
  – Focus on significant, mature updates to design, analyses, and programs

• Prior experience with the DCA indicates that there are opportunities to improve effectiveness of readiness review
Additional Planned Pre-Application Topics

- Risk-informed (safety-focused) review process
- Enhancement of application content
  - Risk-informed (safety-focused) content
  - COL items, CDI, etc.
- Application review schedule
  - Opportunities to improve overall review schedule
  - Detailed schedule development
- Description of design changes from DCA to SDA
  - Early engagement on key topics
  - Application/design overview prior to submittal
- Administrative and process requirements/expectations for review implementation
  - Requirements for treatment of supporting information (e.g., IBR, referenced, etc.)
  - Improved rigor in conduct of audits (planning, schedule, scope management)
  - Process for achieving alignment on review topics (e.g., escalation)
- Scope/Budget management
Overview of Proposed Schedule

Pre-application

• Anticipate pre-application meetings at least every 2-3 months
  – Near term objective to collaborate on detailed schedule

Application

• Submittal of SDA application .......... 4\textsuperscript{th} Quarter 2021
• Complete acceptance review......... 1\textsuperscript{st} Quarter 2022
• Final Safety Evaluation Report...... 1\textsuperscript{st} Quarter 2024
  – Requesting twenty-four month review schedule
  – Recommend 4 phase review
Draft NuScale Regulatory Engagement Plan

- Based on NEI 18-06, “Guidelines for Development of a Regulatory Engagement Plan”
- Identifies the planned regulatory approach
  - Application framework, etc.
- Defines interactions and roles and responsibilities to facilitate effective communication
- Focus, consistent with pre-application phase, is to gain alignment on key elements of the review and reduce regulatory uncertainty
  - Will establish fundamental framework and facilitate the development of review plan/instructions that will ensure consistent implementation
Summary

• Pre-application phase will focus on ensuring effective, safety-focused review
  – Focus review on significant differences from DCA design
    • Design described in SDA application will be similar with that provided in DCA
    • Significant FOAK topics have been resolved as part of the DCA review
  – Safety focused application format and content
  – Facilitating consistent implementation of key review protocols

• Documenting the resolution of application and review topics is key to ensuring consistency during review
  – Regulatory engagement plan will help establish framework
  – NRC review plan/instructions will ensure consistent implementation
Comments, Questions & Review of Actions