



September 6, 2019

Docket No. 9990278

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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](mailto:mmelton@nuscalepower.com).

Sincerely,

Zackary W. Rad  
Director, Regulatory Affairs  
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Enclosure: "Standard Design Approval: Regulatory Strategy Overview," PM-0919-66825, Revision 0

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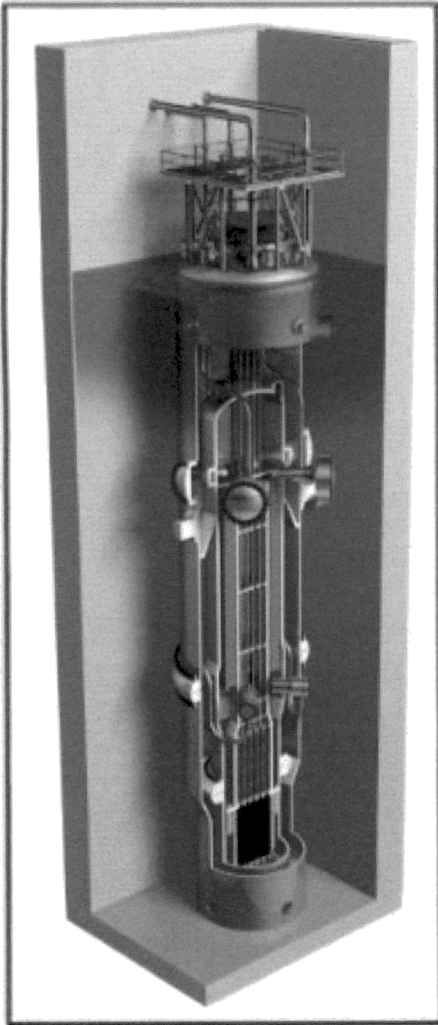


**Enclosure:**

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

NuScale Nonproprietary

# Standard Design Approval Regulatory Strategy Overview



**Zackary Rad**

Director, Regulatory Affairs

*September 25, 2019*

# Agenda

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- 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

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## 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

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- 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

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- 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

# Focus of Pre-Application Phase (continued)

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- 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

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- 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

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- 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

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- 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\*

# Proposed SDA Application Framework

| Application Part  | Combined License | Design Certification                   | SDAA – Required by Regulation          | SDAA – Needed to Support COL | Include as Part of SDAA Submittal          |
|---|------------------|--|--|------------------------------|--|
| Transmittal Letter  | ✓                | ✓                                      | ✓                                      | N/A                          | Yes  |
| Part 1: General and Financial Information                       | ✓                | ✓ (financial information not required) | ✓ (financial information not required) | N/A                          | Yes  |
| Part 2: Safety Analysis Report – Tier 1                         | N/A              | ✓                                      | No                                     | (see below)                  | (see below)                                |
| • Ch 1 - Introduction   | N/A              | ✓                                      | No                                     | No                           | No   |
| • Ch 2 - Unit Specific SSCs Design Descriptions and ITAAC       | N/A              | ✓                                      | No                                     | ITAAC Only                   | ITAAC Only (see Part 08)                   |
| • Ch 3 - Shared SSCs and Non-SSCs Design Descriptions and ITAAC | N/A              | ✓                                      | No                                     | ITAAC Only                   | ITAAC Only (see Part 08)                   |
| • Ch 4 – Interface Requirements                                 | N/A              | ✓                                      | No                                     | No                           | No   |
| • Ch 5 - Site Parameters  | N/A              | ✓                                      | No                                     | No                           | No (FSAR Ch 2)                             |
| Part 2: Safety Analysis Report – Tier 2                         | ✓                | ✓                                      | ✓                                      | ✓                            | Yes  |
| Part 3: Environmental Report                                    | ✓                | ✓                                      | No                                     | No                           | No   |
| Part 4: Technical Specifications                                | ✓                | ✓                                      | No                                     | ✓                            | Yes (could also be included in FSAR Ch 16) |

# Proposed SDA Application Framework

| Application Part   | Combined License   | Design Certification                                   | SDAA – Required by Regulation | SDAA – Needed to Support COL | Include as Part of SDAA Submittal                      |
|--|--------------------|--|-------------------------------|------------------------------|--|
| Part 5: Emergency Plans  | ✓                  | Optional (Not in NuScale DCA)                          | No                            | No                           | No   |
| Part 6: Security Plans   | ✓                  | Optional (Not in NuScale DCA)                          | No                            | No                           | No   |
| Part 7: Exemptions, Departures, and Variances                                    | Yes, if Applicable | Yes, if Applicable                                     | Yes, if Applicable            | N/A                          | Yes - Exemptions                                       |
| Part 8: License Conditions; Inspections, Tests, Analyses and Acceptance Criteria | ✓                  | ✓ (ITAAC only)<br>NuScale DCA references Part 2 Tier 1 | No                            | Yes (only ITAAC)             | Yes (only ITAAC)<br>Could include as a separate report |
| Part 9: Withheld Information   | ✓                  | ✓<br>NuScale DCA provides list of tables and figures   | ✓                             | N/A                          | Yes  |
| Part 10: Quality Assurance Program Description                                   | ✓                  | ✓<br>NuScale DCA references separate topical report    | ✓                             | ✓                            | Yes  |
| Part 11: Supplemental Information (e.g., Limited Work Authorization)             | Yes, if Applicable | Yes, if applicable<br>None for NuScale DCA             | No                            | No                           | No   |
|  |                    |  |                               |                              |  |
|  |                    |  |                               |                              |  |

# Updates to SDA Application Content

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- 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

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- 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

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- 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

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- 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

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## 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<sup>th</sup> Quarter 2021
- Complete acceptance review..... 1<sup>st</sup> Quarter 2022
- Final Safety Evaluation Report..... 1<sup>st</sup> Quarter 2024
  - Requesting twenty-four month review schedule
  - Recommend 4 phase review

# Draft NuScale Regulatory Engagement Plan

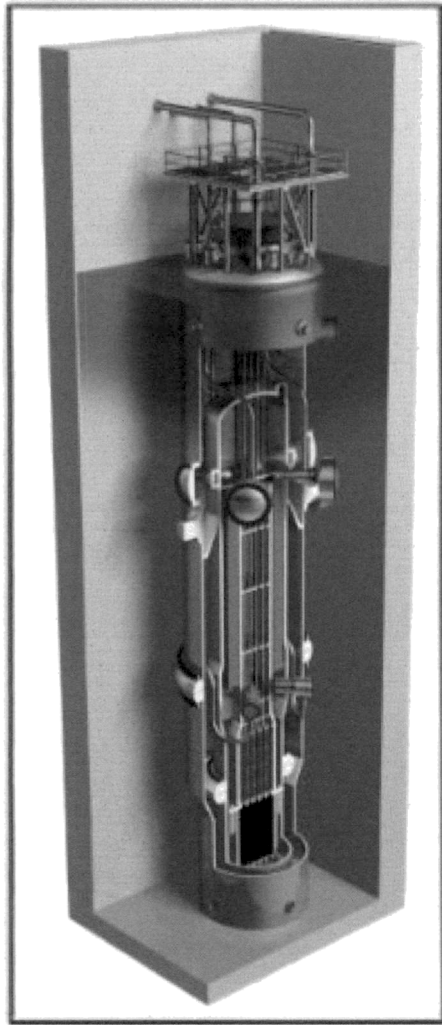
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- Based on NEI 18-06, “Guidelines for Development of a Regulatory Engagement Plan”
- Identifies the planned regulatory approach
  - Application framework, etc.
- Defines interactions and roles and responsibilities to facilitate effective communication
- 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

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- 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

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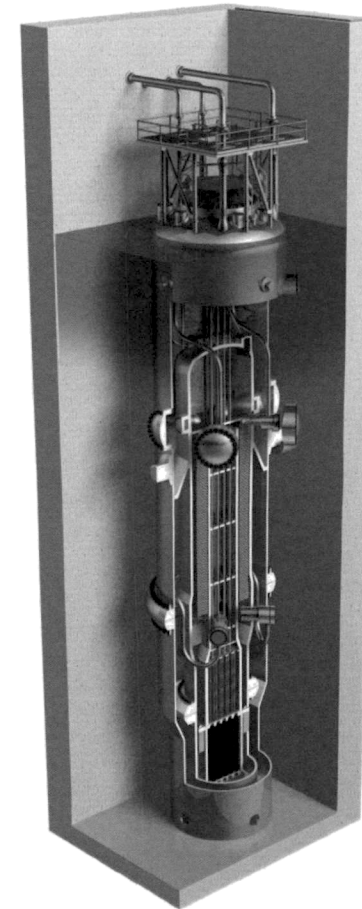
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